Article:

Joda, T, Ferrari, M and Brägger, U (2017) Monolithic implant-supported lithium disilicate (LS2) crowns in a complete digital workflow: A prospective clinical trial with a 2-year follow-up. Clinical Implant Dentistry and Related Research, 19 (3). pp. 505-511. ISSN 1523-0899

https://doi.org/10.1111/cid.12472

Monolithic implant-supported lithium disilicate (LS2) crowns in a complete digital workflow: A prospective clinical trial with 3-year follow-up

Tim JODA, Marco FERRARI, Urs BRAGGER

PD Dr. med. dent. Tim Joda, DMD, MSc
Head, Section for Digital Reconstructive Technology + Implant Dentistry [DiRecT + ID],
Assistant Professor & Research Associate, Department of Reconstructive Dentistry & Gerodontology,
School of Dental Medicine, University of Bern, Switzerland
Author's contribution:
concept/design of the study, data collection, statistics and analysis/interpretation, drafting article, critical revision, and final approval of the article, funding

Prof. Dr. med. dent. Marco Ferrari, MD, DDS, PhD
Chair, Department of Prosthodontics & Dental Materials
School of Dental Medicine, University of Siena, Italy
Author's contribution:
data interpretation, critical revision, and final approval of the article

Prof. Dr. med. dent. Urs Bragger, DMD
Chair, Department of Reconstructive Dentistry & Gerodontology,
School of Dental Medicine, University of Bern, Switzerland
Author's contribution:
concept/design of the study, statistics and analysis/interpretation, critical revision, and final approval of the article

Running Title:
Implant-supported monolithic LS2 crowns

Conflict of Interest:
The authors declare no conflict of interest.

Correspondence Address:
PD Dr. med. dent. Tim Joda, DMD, MSc
Head, Section for Digital Reconstructive Technology + Implant Dentistry [DiRecT + ID];
Assistant Professor & Research Associate, Department of Reconstructive Dentistry & Gerodontology;
School of Dental Medicine, University of Bern
Freiburgstr. 7 │ 3010 Bern │ Switzerland
Tel +41 (0)31 / 632-9870 │ Fax +41 (0)31 / 632-4931
e-mail tim.joda@zmk.unibe.ch

Monolithic implant-supported lithium disilicate (LS2) crowns in a complete digital workflow: A prospective clinical trial with 3-year follow-up

ABSTRACT

Background: The technical development of digital processing allows the production of anatomically full-contoured implant-supported restorations.

Purpose: The aim of this prospective clinical trial was to analyze the treatment concept of monolithic lithium disilicate (LS2) single-unit restorations in a complete digital workflow.

Material and Methods: Forty-four patients were restored with 50 screw-retained monolithic implant LS2 crowns bonded to pre-fabricated titanium abutments in premolar and molar sites on Straumann Tissue Level Implants. All implant restorations were digitally designed after intraoral scanning (IOS) and CAD/CAM-processing without physical model situations. Study participants were clinically and radiographically examined based on an annually performed follow-up. The Functional Implant Prosthodontic Score (FIPS) was applied for objective outcome assessment after 3 years of prosthodontic loading.

Results: All implant restorations could be provided within 2 clinical appointments. No clinical modifications were necessary for seating of the monolithic crowns, neither for interproximal nor occlusal sites. The implant LS2 restorations demonstrated survival rates of 100 % without any technical or biological complications after 3 years. The mean total FIPS score was 7.7 ± 1.1, ranged from 6 to 10.

Conclusions: CAD/CAM-produced monolithic implant crowns out of LS2 in a complete digital workflow seem to be a feasible treatment concept for the rehabilitation of single-tooth gaps in posterior sites under mid-term observation.

<u>Keywords:</u>

dental implants; complete digital workflow, monolithic dental crown, lithium disilicate (LS2), prefabricated titanium abutment, intraoral scan (IOS), CAD/CAM

INTRODUCTION

In industrial processing, benefits of computerized engineering technology are associated with simplified fabrication procedures, high precision, and minimized manpower (Avery 2010; Dawood, et al. 2010). These advantages favor the digital workflow for quality, accuracy, and cost effective implementation in dental medicine (Fasbinder 2010; van Noort 2012).

The necessary step for digitization is to virtualize the individual patient situation – programmed in a binary code out of zeros & one's (Schoenbaum 2012). The 3D implant position can be captured digitally with a contact-free transfer immediately in the oral cavity using an intraoral optical scanner (IOS) (Christensen 2009; Garg 2008). The generated scanning data is stored as Standard Tessellation Language (STL) file (Abduo & Lyons 2013). STL-files describe any surface geometry of 3D objects by triangulation and can be used for CAD/CAM-processing in a complete digital workflow (Beuer, et al. 2012; Bindl, et al. 2005).

For implant-supported single-unit restorations, the overall treatment, starting clinically with an IOS, and following digital design without any physical models, is simplified by having the option of connecting fully anatomical restorations to pre-fabricated abutments (Martinez-Rus, et al. 2013). Demanding laboratory work steps are streamlined and the material-specific advantages are ensured due to standardized fabrication quality (Joda & Bragger 2016). Initial laboratory investigations have demonstrated promising mechanical results for monolithic implant crowns. The findings of the in vitro tests revealed constantly high values for stiffness and strength under quasi-static loading (Joda, et al. 2015; Joda, et al. 2014).

However, only limited clinical data, related to implant-supported LS2 crowns, is presently available in the scientific literature. Therefore, the aim of this prospective clinical trial was to analyze the treatment concept of monolithic implant-supported single-unit restorations out of LS2 connected to pre-fabricated titanium bonding base abutments in a complete digital workflow including IOS and CAD/CAM-technology without a physical model situation.

MATERIALS AND METHODS

Clinical Trial

The study was designed as a prospective clinical trial with a sample size of 44 subjects treated with 50 crowns on a soft tissue level type dental implant with regular neck (RN) and wide neck (WN) platform (Straumann TL RN / WN, Institut Straumann AG, Basel, Switzerland). Implant sites were located in maxillary and mandibular posterior single-tooth gaps with mesial and distal neighbors as well as antagonistic contacts [***Fig. 1***].

All implant crowns were planned as screw-retained monolithic restorations milled out of lithium disilicate (LS2) blanks (IPS e.max CAD, Ivoclar Vivadent, Schaan, Liechtenstein). Clinical and technical work steps followed a digitalized approach including IOS (iTero Scanner, Align Tech Inc., San Jose, USA) and CAD/CAM-processing with pre-fabricated titanium abutments (Variobase RN / WN, Institut Straumann AG, Basel, Switzerland). The entire treatment concept was performed in a virtual environment without any casting. Based on the gathered STL-files from the IOS, the anatomically full-contoured shaping of the implant crowns was designed completely digital.

Interproximal and occlusal contacts were defined according to the threshold settings of the laboratory design software with 20 µm (CARES, Institut Straumann AG, Basel, Switzerland) [***Fig. 2***].
After milling of the monolithic LS2 crowns (CARES X-Stream, Institut Straumann AG, Basel, Switzerland), the restorations were glazed, and finally, bonded to the pre-fabricated titanium abutments (Multilink Implant, Ivoclar Vivadent, Schaan, Liechtenstein) [***Fig. 3***].
First, the interproximal fit, and secondary, the marginal integrity of the restorations was clinically assessed. Identical continuity with dental floss was controlled for mesial and distal contacts surfaces. Then, the occlusal scheme was checked statically and dynamically with shimstock foil achieving light occlusal contacts without dynamic interactions. The monolithic LS2 restorations were screwed with a controlled torque of 35 Ncm according to the implant provider's recommendations. The screw access hole was sealed with teflon and composite application.

Follow-Up

All patients were included for follow-up with annual examinations and additional enrollment in a dental hygienist recall program every 6-12 months. Clinical assessments were made in order to record probing pocket depths (PPD), bleeding on probing (BoP), and a full-mouth plaque index (PI) [1] during every follow-up visit. Intraoral radiographic examinations were performed immediately after seating of the implant crowns and after 3 years of observation.
In addition, the Functional Implant Prosthodontic Score (FIPS) was applied at the time of the 3-year follow-up examination (Joda, et al. 2016). According to the definition of the previously published scoring protocol FIPS, 5 variables ('interproximal' – 'occlusion' – 'design' – 'mucosa' – 'bone') were used for clinical and radiographic evaluation. A scoring scheme of 0 – 1 – 2 was assigned for each variable, resulting in a maximum score of 10 (5 x 2) per implant restoration (Joda, et al. 2016) [***Fig. 4***].

Statistical Analysis

Descriptive statistics were calculated for mean scores including standard deviations (SD), minimum and maximum values. Statistic calculations were made with the open-source program "GraphPad Software" (http://www.graphpad.com). A level of significance was set at $p < 0.05$.
The prospective clinical study was officially approved and registered by the Ethics Committee Bern, Switzerland (www.kek-bern.ch).

RESULTS

Demographic patient data demonstrated an overall mean age of 58.1 ± 13.2 years (range: 24-81), and a gender distribution of 56 % females and 44 % males. All study participants could be followed-up for 3 years.
Survival rates for all implants and corresponding LS2 restorations were 100 %. Neither technical nor biological complications were observed. Clinical examinations exhibited mean full-mouth scores for PI of 19.2 ± 2.8 % (range: 13-24) at baseline and 20.6 ± 2.2 % (range: 15-23) at 3-year follow-up, PPD of 3.9 ± 0.8 mm (range: 2-6) and 3.5 ± 0.6 mm (range: 2-5) as well as BoP of 20.2 ± 2.9 % (range: 17-25) and 19.5 ± 1.9 % (range: 16-24), respectively.
Calculations of mean FIPS scoring including standard deviations, minimum and maximum values are summarized in Table 2. The mean total FIPS score for the included 50 monolithic LS2 crowns was

7.7 ± 1.1 (range: 6-10). In detail, all implants revealed stable bone levels for mesial and distal sites in the radiographic analysis ('bone': 2.0 ± 0.0; range: 2-2). Slightly lower mean scores were recorded for 'interproximal' (1.8 ± 0.4; range: 1-2) and 'occlusion' (1.7 ± 0.4; range: 1-2); whereas mean scores for 'mucosa' (1.2 ± 0.4; range: 1-2) and 'design' (1.1 ± 0.5; range: 0-2) were the most challenging to satisfy [***Tab. 1***].

DISCUSSION

Different ways of fabrication are applicable for the treatment with implant-supported fixed dental prostheses, a conventional and a mixed conventional-digital approach, using a technical concept of framework plus veneering technique, and in contrast, the design of full-contoured restorations (Avery 2010; Beuer, et al. 2012; Griffin 2013; Kim, et al. 2013).

For implant-supported single-unit restorations, the overall treatment, starting clinically with IOS, and following digital designing without any physical models, is simplified by having the option of connecting monolithic crowns to pre-fabricated abutments (Martinez-Rus, et al. 2013). Then, this flow can be really named 'digital' within a complete setting of bits & bytes (Joda & Bragger 2016). Demanding laboratory work steps are streamlined and the material-specific advantages are ensured due to standardized fabrication quality (Joda, et al. 2015).

Initial in vitro tests have demonstrated promising results for monolithic implant restorations (Joda, et al. 2015; Joda, et al. 2014). The findings of these laboratory trials revealed constantly values for stiffness and strength under quasi-static loading for pre-fabricated titanium abutments in combination with bonded full-contoured suprastructures with higher strength than the average occlusal force of naturally dentate patients (Joda, et al. 2015; Joda, et al. 2014).

However, only a limited number of clinical studies are available. The findings of an initial case series revealed that fully anatomic implant crowns seem to be a feasible treatment option with a reasonable cost-benefit-ratio using a complete digital approach (Joda & Bragger 2014).

The overall fit of the CAD/CAM-processed restorations was extremely accurate. No chairside corrections were necessary for seating the finalized restorations within this presented digitized treatment protocol. This reduces work time (Joda & Bragger 2015) but also decreases the potential risk for chipping due to the lack of veneering ceramics (Joda & Bragger 2015). [**Fig. 3**]

Besides the restrictions of the technical production, it is controversially discussed what type of restoration material would be suitable for monolithic implant restorations. On the one hand, these materials have to withstand high loading forces, and on the other hand, an increased risk for abrasions may occur at the antagonist over time, especially in case of naturally teeth. In addition, the visual appearance of monolithic restorations, regardless of the currently available materials, does not fulfill the expectations for the treatment in the esthetic zone (Joda, et al. 2016).

CONCLUSIONS

Anatomically full-contoured implant restorations out of LS2 seem to be a practicable treatment approach for single-tooth replacement in posterior sites. The combination of quadrant-like IOS and further CAD/CAM-processing offers the opportunity to operate the entire flow in a complete virtual environment. Applying the objective Functional Implant Prosthodontic Score (FIPS), both clinical and radiographic follow-up examinations demonstrated stable conditions without technical or biological complications under mid-term observation of 3 years.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Dental Technician Tom Furter (ArtDent, Bern, Switzerland) for the production of all implant-supported monolithic LS2-crowns in this investigation.

REFERENCES

FIGURES

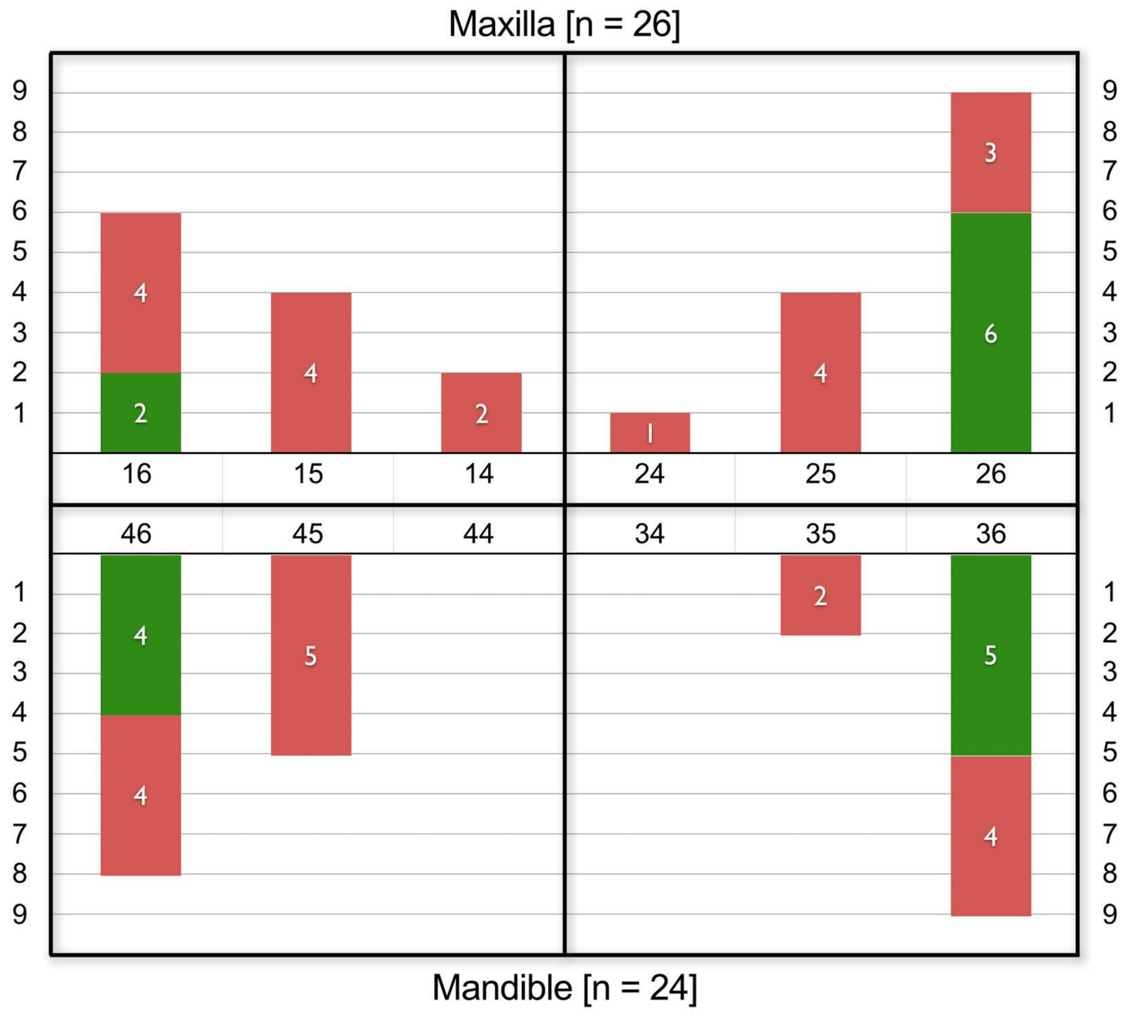
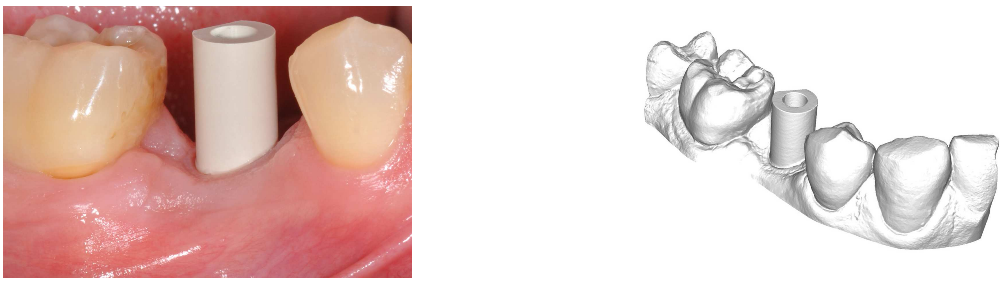


Figure 1. Distribution of the 50 monolithic LS2 restorations (FDI-positioning) including type of implant platform (Straumann TL RN / WN, Institut Straumann AG, Basel, Switzerland).
[red = regular neck (RN) | green = wide neck (WN)].



(a) (b)

Figure 2. Clinical situation with screwed monotype scanbody for capturing of the 3D implant position in regio FDI 45 with IOS (**a**); screenshot of the interpolated surface mesh-structure gathered from the STL-file (**b**).

FIGURES

(a) (b)

Figure 3. Based on the STL file gathered from the IOS, virtual design for a screw-retained anatomically full-contoured crown in regio FDI 45 (**a**); finalized implant restoration with LS2 crown bonded to a prefabricated titanium abutment (**b**).

(a) (b) (c)

Interproximal		**1**	
Occlusion			**2**
Design			**2**
Mucosa		**1**	
Bone			**2**
Total Score			**8**

Figure 4. Implant-supported monolithic LS2 crown in regio FDI 45 after 3 years of loading: (**a**) lateral and (**b**) occlusal views as well as (**c**) 2D radiographic imaging. Application of the Functional Implant Prosthodontic Score (FIPS) revealed a total score of 8.

TABLES

N = 50 restorations	Mean	SD	Minimum	Maximum
Interproximal				
Contacts & Papillae	1.8	0.4	1	2
Occlusion				
Static & Dynamic	1.7	0.4	1	2
Design				
Contour & Color	1.0	0.5	0	2
Mucosa				
Quality & Quantity	1.2	0.7	1	2
Bone				
X-Ray	2.0	0.0	2	2
Maximum Score	**7.7**	**1.1**	**6**	**10**

Table 1. Summarized mean FIPS scores of the included 50 implant-supported monolithic LS2 restorations, including standard deviations (SD) and minimum / maximum values for each variable.