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A retrospective clinical study of 145 patients with up to 2 years of follow-up

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Additively manufactured hybrid composite implant-supported restorations: A retrospective clinical study of 145 patients with up to 2 years of follow-up

Francesco Guido Mangano [a,*], Carlo Mangano [b], Marina Loktionova [a], Olesya Dudnik [a], Olga Malanova [a], Alina Elovskaya [a], Anna Maltseva [a], Andrey Dybov [a]

[a] Department of Pediatric, Preventive Dentistry and Orthodontics, I. M. Sechenov First State Medical University, Moscow, Russian Federation

[b] Department of Dental Sciences, San Raffaele University, Milan, Italy

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ABSTRACT

Objective: To present the 2-year clinical outcomes of short-span implant-supported hybrid composite restorations, namely single crowns (SCs) and fixed partial prostheses (FPPs), produced using tilting stereolithography (TSLA).

Methods: This retrospective study was based on data from a cohort 145 patients, treated between June 2021 and June 2023, with 185 fixed short-span implant-supported hybrid composite restorations (Irix Max®, RD Printing, Thiene, Vicenza, Italy) produced using tilting stereolithography (TSLA). The restorations were manufactured through a fully digital, model-free workflow, which included intra-oral scanning, computer-aided design (CAD) and additive manufacturing with the TSLA system (Dfab®, RD Printing). Primary outcome measures included marginal fit, occlusal and interproximal contact quality and colour matching of the restorations, all evaluated by two experienced clinicians (a prosthodontist and a periodontist, who were not directly involved in the treatment of the patients). Each restoration was rated at the time of delivery, using a 5-point scale (5 being excellent, 4 satisfactory, 3 acceptable, and 2 or 1 indicating poor quality). The secondary outcomes assessed comprised the survival and success (i.e. absence of complications) rates of the restorations, during the entire follow-up period. Statistical analysis was performed on the collected data.

Results: Among the 3D-printed hybrid composite restorations, 95 had a 2-year follow-up, whereas 90 had only a 1-year follow-up. Overall, the restorations demonstrated excellent performance in terms of marginal fit and contact accuracy, both occlusal and interproximal. Their aesthetic integration was also deemed satisfactory. During the follow-up period, all restorations remained functional, with a low complication rate (1.0 % biological and 3.7 % prosthetic complications), resulting in an overall success rate of 95.1 %.

Conclusions: Implant-supported short-span hybrid composite restorations manufactured using TSLA technology demonstrated high clinical accuracy and showed a low rate of complications over a 2-year period.

Clinical relevance: TSLA printing technology shows potential for the definitive prosthetic treatment of small edentulous spaces.

1. Introduction

The advent of the digital revolution has redefined workflows in implant prosthodontics [1,2]. Contemporary protocols for the fabrication of provisional and definitive single crowns (SCs) and fixed partial prostheses (FPPs) are initiated through the acquisition of optical impressions, obtained using intra-oral scanners (IOSs) [2,3]. The three-dimensional (3D) position of the implant is captured via IOS by scanning the master model with implant scan bodies (SBs), along with the opposing dentition and occlusal (bite) registration. This dataset is then transferred to the dental laboratory, where the prosthetic restoration is designed using computer-aided design (CAD) software [3,4].

Depending on the clinical approach, the prosthesis – whether provisional or definitive – can be digitally designed as a screw-retained

* Corresponding author at: Department of Pediatric, Preventive Dentistry and Orthodontics, I. M. Sechenov First State Medical University, 8-2 Trubetskaya Street, Moscow 119991, Russian Federation.

E-mail addresses: francescoguidomangano@gmail.com (F.G. Mangano), camangan@gmail.com (C. Mangano), loktionova_m_v@staff.sechenov.ru (M. Loktionova), dudnik_o_v@staff.sechenov.ru (O. Dudnik), malanova_o_a@staff.sechenov.ru (O. Malanova), elovskaya_a_a@staff.sechenov.ru (A. Elovskaya), maltseva_a_g@staff.sechenov.ru (A. Maltseva), dybov_a_m@staff.sechenov.ru (A. Dybov).

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superstructure, intended for extraoral cementation onto prefabricated titanium bonding base(s) [5–7], or alternatively, as a full-contour restoration, to be cemented onto custom abutment(s), designed via CAD [8,9]. Crowns and bridges designed in CAD are typically fabricated through computer-assisted manufacturing (CAM), employing subtractive techniques such as milling, using polymethyl-methacrylate (PMMA) for temporary restorations [10], and zirconia [11,12] or lithium disilicate [13,14] for definitive restorations. In cases where a cement-retained restorations are selected and custom abutments are used, the abutments can be milled in zirconia and extra-orally cemented to titanium bonding bases, to form hybrid abutments [8,9]. Alternatively, the abutments may be milled from titanium [15].

The clinical efficacy of definitive, short-span implant-supported prostheses fabricated from monolithic zirconia [2,5–9,11,12] or lithium disilicate [13,14,16], in screw-retained and cement-retained configurations, is well substantiated in the scientific literature.

In recent years, additive manufacturing (AM) has emerged as a viable alternative to traditional subtractive manufacturing techniques for producing provisional, short-span, fixed implant-supported prosthetic restorations [17–19]. The additive fabrication of short-span provisional SCs and FPPs has become prevalent in clinical practice [19,20], and is recognised as a reliable therapeutic option [20–22].

However, the application of AM for fabricating definitive restorations remains limited. Although there is growing research interest in the AM of high-performance ceramics such as zirconia [23,24] and lithium disilicate [25], no clinical studies have validated these techniques. This is largely due to ongoing concerns regarding the mechanical integrity and long-term performance of fully ceramic restorations produced through AM [26–29]. Hence, the AM of definitive fixed crowns and bridges has not been clinically adopted yet.

The most widely used techniques among vat-polymerisation AM printing modalities include stereolithography (SLA), digital light processing (DLP) and liquid crystal display (LCD) printing [22,30]. These methods cure photosensitive resins using different light sources: lasers (for SLA), projectors equipped with digital micromirror devices (for DLP) or backlit LCD screens (for LCD) [22,30].

Recently, an innovative SLA-based approach, tilting stereolithography (TSLA), was introduced [31–34]. TSLA enables the fabrication of not only temporary resin-based restorations but also definitive prostheses using composite resins reinforced with ceramic fillers [31–35]. In TSLA, the build platform is oriented at 45°, allowing the simultaneous production of up to four to five units per printing cycle [32–35]. This configuration confers multiple advantages, including reduced printing times, the use of high-viscosity resins, and the capacity to produce restorations with natural-looking, gradient coloration [32–35].

A recent *in vitro* investigation demonstrated that the TSLA-based AM of ceramic-filled nanocomposite SCs yielded restorations with high marginal precision [32]. These SCs showed comparable dimensional accuracy to five-axis milled zirconia restorations, and even outperformed chairside-milled lithium disilicate crowns in terms of accuracy, production efficiency and cost-effectiveness [32]. Moreover, a clinical study reported the results obtained with short-span, hybrid composite implant-supported SCs and FPPs fabricated through TSLA, after 1 year of follow-up [36]. The marginal closure and occlusal and interproximal contact points of these 3D-printed hybrid composite restorations were of high quality, and aesthetic integration was achieved [36]. Moreover, all restorations survived 1 year after placement, with a low incidence (4.2 % overall, 5.7 % SCs) of complications, resulting in a success rate of 95.8 % [36]. However, there is a need for more clinical data on the reliability of such restorations, with longer follow-up.

Therefore, this retrospective clinical study, which represents the development of the previous one [36], aimed to evaluate the clinical outcomes of fixed, short-span implant-supported hybrid composite restorations produced using TSLA technology, with up to 2 years of follow-up.

2. Materials and methods

2.1. Study design

This study was based on retrospectively collected data from electronic records of a cohort of patients treated at a single private dental centre between June 2021 and June 2023.

Patients who had undergone treatment using a tapered implant system with self-cutting threads (AnyRidge®, Megagen, Gyeongbuk, South Korea) and who were prosthetically rehabilitated with short-span hybrid composite restorations made by AM (Irix Max®, RD Printing srl, Thiene, Vicenza, Italy) were eligible to participate in this study. The implants used in this study incorporate an internal hexagonal configuration coupled with a 5-mm-deep conical connection (10°), which ensures a tight seal and enhanced mechanical stability [37]. These fixtures are designed with built-in platform switching to help preserve crestal bone levels and promote increased soft tissue volume [38,39]. Additionally, these implants feature a nanostructured, calcium-incorporated surface [40]. The full-contour restorations, comprising SCs or two- to three-unit FPPs, were fabricated using a fully digital, model-free workflow. The protocol included intra-oral scanning (iTero Element™ 5D Plus imaging system or iTero Lumina™ scanner, Align Technology, Inc, San Jose CA, USA), computer-aided design (Galway®, Exocad, Darmstadt, Germany) and 3D printing of definitive full-contour restorations via TSLA, using a Dfab® 3D printer (RD Printing srl, Thiene, Vicenza, Italy). The restorations were supported by customised abutments, either composed of a zirconia coronal portion cemented onto a titanium bonding base, or monolithic custom titanium abutments. In addition, to be included in the study, patients were required to be in good general and oral health, and to have signed informed consent specific to the planned implant-prosthetic treatment.

Patients treated with implant systems other than the one specified, those rehabilitated through a full-digital, model-free workflow but with monolithic full-contour restorations milled in zirconia, patients restored with veneered zirconia restorations (e.g. zirconia copings or frameworks veneered with feldspathic ceramic) and requiring 3D printing of models, and patients restored using full-digital workflows involving screw-retained prostheses, with occlusal access holes cemented directly onto titanium bonding bases (i.e. not supported by customised abutments) were excluded from this study. Additionally, patients treated using conventional analogue protocols, based on impression-taking with trays and traditional materials, and patients who were unable to attend all the scheduled follow-up sessions (drop-outs) were excluded from the study.

This retrospective clinical study was conducted following the principles of the Declaration of Helsinki on Human Experimentation of 1975 (and Revision of 2008), and was approved by the local Ethics Committee.

2.2. Prosthetic procedures

The first clinical phase involved intra-oral scanning using a high-precision instrument (iTero Element™ 5D Plus imaging system or iTero Lumina™ scanner, Align Technology, Inc, San Jose CA, USA). After initialising the IOS software, the operator sequentially captured the following: the antagonist arch (or hemi-arch), the edentulous master model with soft tissue collars exposed (following the removal of healing abutments) and one or more bite registrations. SBs (WBSR00®, IPD Dental, Mataró, Barcelona, Spain) were then screwed on the implants and scanned at high resolution. The scan data were refined, saved in standard tessellation language (STL) and sent to the My iTero cloud.

These STL files were then accessed by the dental technician and imported into CAD software (Galway®, Exocad, Darmstadt, Germany). The SB mesh was aligned with the corresponding library file, using an initial point-based registration followed by an iterative closest point (ICP) algorithm for surface matching. This alignment was further optimised by selecting the most appropriate version of the library file from a custom CAD library. Two-dimensional and three-dimensional congruency between the mesh and the digital library file was mathematically validated. Next, the technician digitally positioned the necessary prosthetic components – either titanium bonding bases (for hybrid abutments) or implant connections (for full titanium custom abutments) – for abutment design. Upon completion of the digital abutment design, the definitive prosthetic restorations (either SCs or FPPS, up to three units) were modelled for cementation onto the abutments. These were designed as full-contour restorations – without occlusal access holes – suitable for cementation. Two abutment design strategies were used. For implants that were axially aligned or minimally angled, a custom hybrid abutment was fabricated by five-axis milling (DWX-52D®, DGSHAPE at Roland, Hamamatsu, Japan) of CAD-designed zirconia (Natura Z Alpha®, DMAX Dental CAD/CAM Solutions, Daegu, South Korea), using CAM software (MillBox®, CIMsystem, Milan, Italy). After sintering (Tabeo-1/M/ZIRKON-100®, Mihm Vogt GmbH & Co. KG), the zirconia coronal portion was cemented extra-orally onto a titanium bonding base. For implants requiring substantial angulation correction, a one-piece custom titanium abutment was milled using proprietary workflows provided by the implant manufacturer. All final restorations were fabricated from Irix Max® (RD Printing, Thiene, Vicenza, Italy), a CE-marked Class IIa hybrid composite containing approximately 42 % ceramic particles by weight. These restorations were produced using TSLA with the Dfab® 3D printer (RD Printing). The Dfab® system uses disposable cartridges in various sizes (small, medium and large), based on the volume of restoration required, optimising printing efficiency. Irix Max® is designed for definitive restorations including inlays, onlays, veneers, single crowns, and up to three-unit bridges. In this study, restorations were printed in the Photoshade® A1–A3.5 gradient shade. STL files of the designed restorations were uploaded into the printer's software, which automatically oriented them with the occlusal surface facing the platform and intaglio surfaces facing the resin tank. The operator selected the desired colour gradient and adjusted the cervical-incisal transition according to the clinical needs. Once the parameters were confirmed, the printer initiated the process. The Dfab® cartridge was loaded and automatically tilted to 45°, initiating continuous material flow via gravity and a peristaltic pump. The dual-shade resin was extruded in real time to reproduce the selected gradient. Polymerisation was performed layer-by-layer, using a UV laser, and the platform gradually descended until fabrication was complete. After printing, the machine was opened, the platform returned to a horizontal position and the printed restorations were removed. The restorations were cleaned in 95 % isopropyl alcohol, using a shaker bath for 2–3 min. Thin supports were manually detached under magnification (4.5 × ®, Zeiss, Oberkochen, Germany). Final post-curing was performed in a dual-energy (UV and heat) curing chamber (Dcure®, RD Printing), using a 10-minute automated cycle. Additional staining, glazing, finishing and polishing followed standard protocols for hybrid composites.

At the second clinical appointment, healing abutments were removed, and individualised abutments were placed, following the alignment determined by their hexagonal indexing. Teflon was inserted into the screw channels, and definitive restorations were cemented. The fit and quality of each restoration, including marginal adaptation and occlusal/interproximal contacts, were assessed by two independent evaluators who were not involved in the treatment procedures. Evaluation followed a standardised assessment protocol, detailed in Section 2.3.

2.3. Clinical outcome variables

The clinical performance of the restorations was assessed based on two categories of outcome variables:

- **Primary outcome variables**, evaluated at the time of prosthesis delivery and related to the restoration's clinical accuracy.
- **Secondary outcome variables**, assessed during follow-up visits, specifically at the 1- and 2-year post-delivery check-ups, and associated with the survival and overall success of the restorations.

All evaluations were performed by two independent examiners (a prosthodontist and a periodontist) with substantial experience in implant-supported prosthetic rehabilitation. These evaluators were not directly involved in the treatment of the enrolled patients. All findings were meticulously documented in the patients' medical records.

2.3.1. Primary outcome variables

The primary clinical performance criteria included:

1. Marginal adaptation quality
2. Occlusal contact quality
3. Interproximal contact quality
4. Chromatic (aesthetic) integration

Marginal adaptation was assessed through a combination of clinical and radiographic methods: visual inspection under magnification (4.5 × ®, Zeiss, Oberkochen, Germany), tactile evaluation using a circumferential periodontal probe, and, where needed, radiographic analysis with intra-oral X-rays. Occlusal contact points were assessed clinically using articulating paper (Bausch Articulating Paper®, Bausch Inc., Nashua, NH, USA). The quality of interproximal contacts with adjacent teeth was verified using dental floss. Visual examination was performed to evaluate chromatic and aesthetic integration.

Each restoration was scored independently by both evaluators on a 5-point scale for all four parameters:

- **5** = excellent (fully satisfactory)
- **4** = good (satisfactory)
- **3** = acceptable
- **2** or **1** = poor or unacceptable

Restorations receiving a score of <3 on any of the evaluated parameters were deemed clinically inadequate and returned to the dental technician for remaking. This included cases with inadequate marginal fit (e.g. gaps or overextensions), improper occlusal contacts (e.g. excessive contacts not manageable through adjustment or infra-occlusion), inadequate interproximal contact (e.g. food impaction risk) or unsatisfactory colour matching. In such cases, the entire digital workflow, including intra-oral scanning, was restarted.

2.3.2. Secondary outcome variables

The secondary outcome measures focused on:

- Restoration survival
- Restoration success

A restoration was classified as a survivor if it remained functionally intact throughout the entire follow-up period. By contrast, it was considered a failure in the event of implant loss or prosthetic fracture.

A successful restoration was one that remained free of any biological or prosthetic complications during follow-up. Any incidence of such complications rendered the restoration unsuccessful.

Biological complications were defined as:

- **Peri-implant mucositis**: characterised by gingival inflammation, discomfort or bleeding, without radiographic evidence of bone loss [41].
- **Peri-implantitis**: involving clinical signs such as pain, suppuration, bleeding and radiographically detectable marginal bone resorption [41].

Prosthetic complications included:

- **Mechanical issues**: such as loosening of the abutment screw or detachment of the zirconia portion of the hybrid abutment [42,43].
- **Technical issues**: including debonding of the final restoration and chipping [42,43].

2.4. Statistical analysis

All data collected throughout the study, including at the time of prosthesis delivery (primary outcome variables: marginal adaptation, occlusal and interproximal contact quality, and chromatic integration) and at the 1-and 2-year follow-ups (secondary outcome variables: prosthetic survival and success), were systematically recorded in each patient's electronic record and subsequently analysed.

A descriptive approach was chosen, incorporating demographic variables (age, gender, smoking status and presence of parafunctional habits) and restoration-specific parameters (type of restoration, location, implant site, abutment type and implant dimensions, including length and diameter). For quantitative variables such as patient age, the mean, standard deviation (SD), median, range and 95 % confidence interval (CI) were calculated. For categorical variables, including gender, smoking status, parafunction, restoration type and position, abutment type and implant dimensions, absolute and relative frequencies (%) were computed.

For the primary clinical outcomes assessed at the time of final prosthesis delivery, mean observer scores (± SD) assigned by the two independent evaluators (prosthodontist and periodontist) were calculated and presented alongside absolute and relative frequency distributions. A paired *t*-test was performed to assess whether significant differences existed between the ratings of the two evaluators. Given that the sample size exceeded 30, the assumption of normality was supported by the central limit theorem. If the *p*-value was <0.05, the null hypothesis (i.e. the evaluators' scores are equal) was rejected, indicating a significant difference; otherwise, no significant difference was assumed. Additionally, unpaired independent-sample *t*-tests (Welch's test) were conducted for each parameter and evaluator to determine whether outcomes significantly differed between SCs and FPPs.

Regarding secondary clinical outcomes, evaluated at the 1- and 2-year follow-ups, the incidence of failures and complications was documented. Survival and success rates were calculated at the restoration level, with any occurrence of a complication leading to the classification of the restoration as unsuccessful.

3. Results

3.1. Patient demographics and restoration characteristics

A total of 145 patients meeting the inclusion criteria were identified through a detailed review of electronic medical records and documentation. The study cohort comprised 63 males and 82 females, aged between 21 and 84 years (mean age: 56.9 ± 13.7; median: 57; 95 % CI: 54.7–59.1). All patients were rehabilitated with short-span implant-supported restorations – either SCs or FPPs (up to three units) – fabricated from a ceramic-filled hybrid composite material, using TSLA technology, over a 2-year period (from June 2021 to June 2023). Among the participants, 25 were smokers and 44 exhibited signs of parafunctional activity (e.g. bruxism or clenching), although these conditions did not constitute exclusion criteria.

In total, 185 prosthetic restorations were delivered, with 40 patients receiving more than one. This included 138 SCs and 47 FPPs (38 two-unit and 13 three-unit bridges). Restoration site distribution included 95 prostheses in the mandible and 90 in the maxilla. In total, 95 restorations had a 2-year follow-up, whereas 90 restorations had only a 1-year follow-up.

A total of 240 implants (AnyRidge®, MegaGen, Gyeongbuk, South Korea), namely 130 mandibular and 110 maxillary implants, were placed. Regarding abutment types, 150 individual hybrid abutments (zirconia cemented on titanium bases) and 90 custom one-piece titanium abutments were used. Figs. 1–3 display the patient demographics, restoration distribution and the implants, respectively. Figs. 4–11 illustrate a representative clinical case.

3.2. Primary outcomes

Both operators assessed the quality of closure and marginal fit of the restorations as excellent. The prosthodontist (operator 1) gave a mean marginal fit score of 4.69 (± 0.57), a median of 5 and a 95 % CI of 4.60–4.77. The periodontist (operator 2) assigned a mean marginal fit score of 4.78 (± 0.47), a median of 5 and a 95 % CI of 4.72–4.85 (Fig. 12).

The quality of occlusal contacts was also adequate. The prosthodontist (operator 1) gave a mean occlusal contact quality score of 4.25 (± 0.82), a median of 4 and a 95 % CI of 4.13–4.37. The periodontist (operator 2) assigned a mean score of occlusal contact quality of 4.15 (± 0.77), a median of 4 and a 95 % CI of 4.04–4.26 (Fig. 13).

The quality of interproximal contacts was optimal. The prosthodontist (operator 1) gave a mean score of interproximal contact quality of 4.44 (± 0.68), a median of 5 and a 95 % CI of 4.34–4.54. The periodontist (operator 2) assigned a mean score of occlusal contact quality of 4.49 (± 0.73), a median of 5 and a 95 % CI of 4.39–4.60 (Fig. 14).

Finally, aesthetic integration was considered satisfactory by both operators. The prosthodontist (operator 1) gave a mean score of chromatic integration of 3.83 (± 0.84), a median of 4 and a 95 % CI of 3.71–3.96. The periodontist (operator 2) assigned a mean score of occlusal contact quality of 3.88 (± 0.84), a median of 4 and a 95 % CI of 3.76–4.00 (Fig. 15).

The comparison between the scores given by the operators (prosthodontist vs periodontist, paired *t*-test) revealed that none of the parameters (quality of the marginal adaptation, $p = 0.05$; quality of the occlusal contacts, $p = 0.09$; quality of the interproximal contacts, $p = 0.38$; chromatic integration, $p = 0.49$) presented a significant difference (all *p*-values > 0.05).

Similarly, none of the measured parameters (quality of the marginal adaptation, $p = 0.96$; quality of the occlusal contacts, $p = 0.34$; quality of the interproximal contacts, $p = 0.70$; chromatic integration, $p = 0.70$) exhibited significant differences in the mean scores assigned to SCs and FPPs (independent samples, *t*-test of Welch).

3.3. Secondary outcomes

At the 2-year follow-up, all 95 implant-supported restorations remained functional, with no reported fractures or failures. The same was true for the 90 restorations evaluated 1 year after delivery.

All implants were also functional and surviving, except for one located in the posterior maxilla, which was lost a few months after crown delivery due to peri-implantitis, and was, therefore, replaced. The implant survival rate was 99.5 % at the end of the study (239 out of 240 implants surviving and in function). Aside from the failure of that single implant, the only other biological complication was a case of peri-implant mucositis affecting a mandibular molar, which was successfully managed through multiple sessions of professional dental hygiene. Overall, the incidence of biological complications throughout the follow-up period was 1.0 % (2 out of 185 restorations).

Prosthetic complications, particularly mechanical and technical issues, were more common, including four instances of abutment screw loosening in single crowns (SCs) and three cases of decementation (two in SCs and one in an FPP), amounting to a total complication rate of 3.7 % (7 out of 185 restorations). Although these issues were resolved in a single visit by removing the crown and re-tightening the abutment screws, the restorations involved were classified as 'unsuccessful' because of the complexity of managing these complications. In particular, the decementation of a crown securely fixed on a loosened abutment presents a challenge because of the risk of damaging the implant-

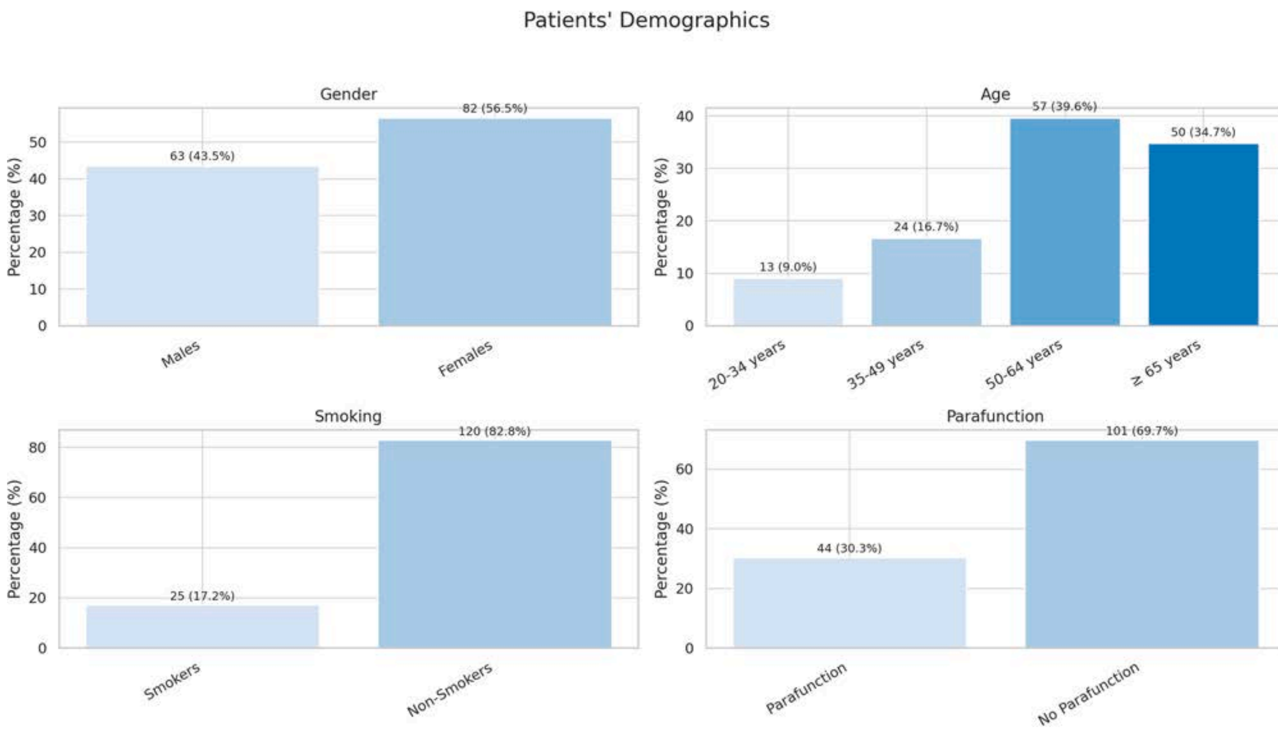

Fig. 1. Patients' demographics.

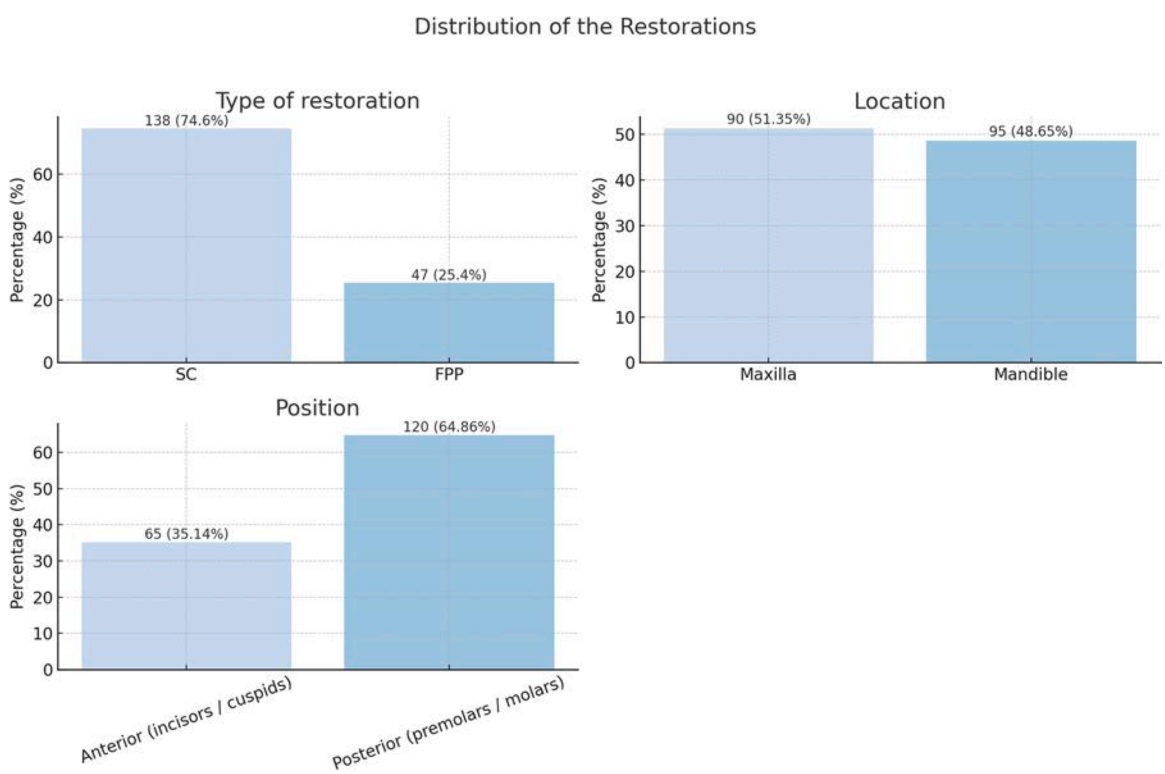

Fig. 2. Distribution of the restorations.

abutment connection. No abutment screw loosening occurred in the FPP group, where full screw stability was maintained. Among the SCs, decementation occurred in two cases – a maxillary canine and a mandibular premolar – considered minor complications that were quickly resolved, yet were still categorised as 'unsuccessful'.

By the end of the 2-year evaluation, the hybrid composite restorations fabricated with TSLA technology had a success rate of 95.1 % (176 out of 185 restorations).

4. Discussion

AM is increasingly being adopted as a manufacturing technique in

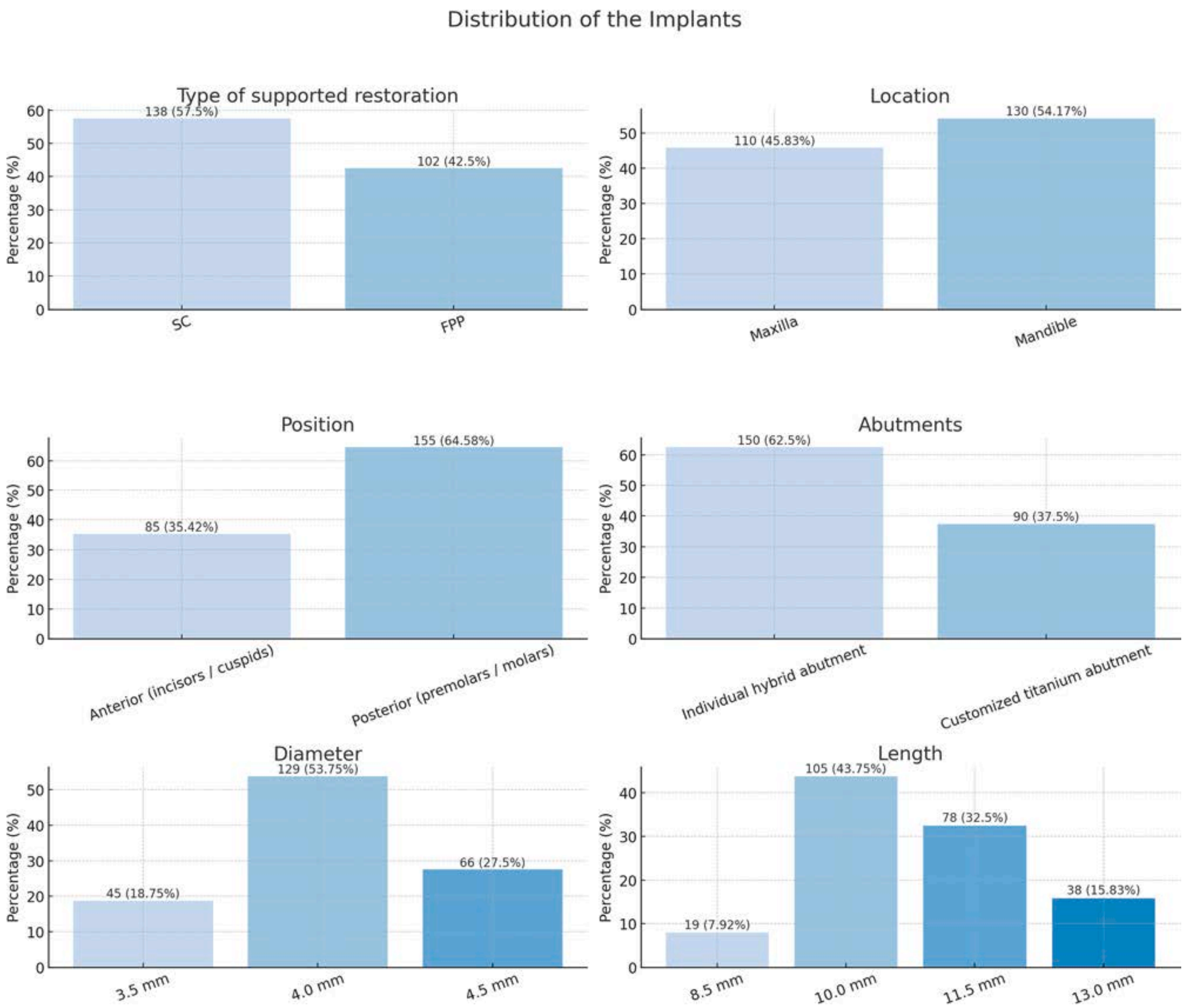

Fig. 3. Distribution of the implants (AnyRidge®, Megagen, Gyeongbuk, South Korea).

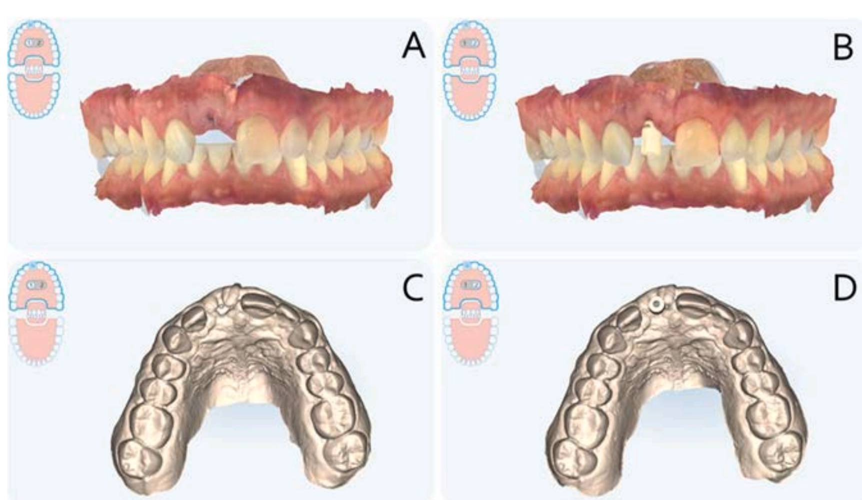

Fig. 4. Initial intra-oral scan (iTero Element™ 5D Plus imaging system, Align Technologies, San Jose, CA, USA). A. Scan without the scan body, frontal view; B. Scan with the scan body (WBSR00®, IPD Dental, Mataró, Barcelona, Spain), frontal view; C. Master model without the scan body, occlusal view; D. Master model with the scan body, occlusal view.

Fig. 5. Details of the scan with the scan body (WBSR00®, IPD Dental, Mataró, Barcelona, Spain) in position.

implant prosthodontics [17–19]. However, its application is primarily confined to the fabrication of provisional restorations [19–22] because the AM of all-ceramic restorations remains technically challenging [24, 25] and raises concerns regarding mechanical performance and long-term reliability [26–29].

Recently, novel 3D-printable hybrid composite materials have been introduced to the market [31–35,44–49]. These materials consist of a resin-based matrix reinforced with a dispersion of ceramic particles [32–34]. Although not directly equivalent to high-performance ceramics such as zirconia or lithium disilicate in terms of physical properties, these composites avoid many of the critical limitations typically associated with 3D-printed ceramics. Preliminary evidence suggests they exhibit enhanced and more predictable mechanical behaviour, and are potentially suitable for use in definitive prosthetic applications [31–35, 44–50].

TSLA represents a notable advancement in 3D printing for dental

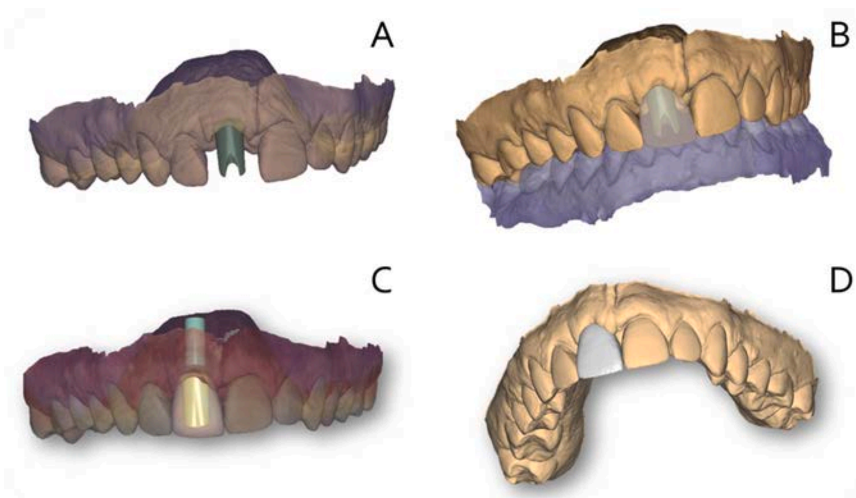

Fig. 6. CAD modelling (Galway®, Exocad, Darmstadt, Germany). A. Individual hybrid abutment; B. Crown in transparency; C. Crown in transparency, individual hybrid abutment and implant; D. Final crown design.

Fig. 7. CAD modelling (Galway®, Exocad, Darmstadt, Germany) of the crown in relation to the patient's face, acquired with a face scanner (RAYface®, Ray, Hwaseong, South Korea).

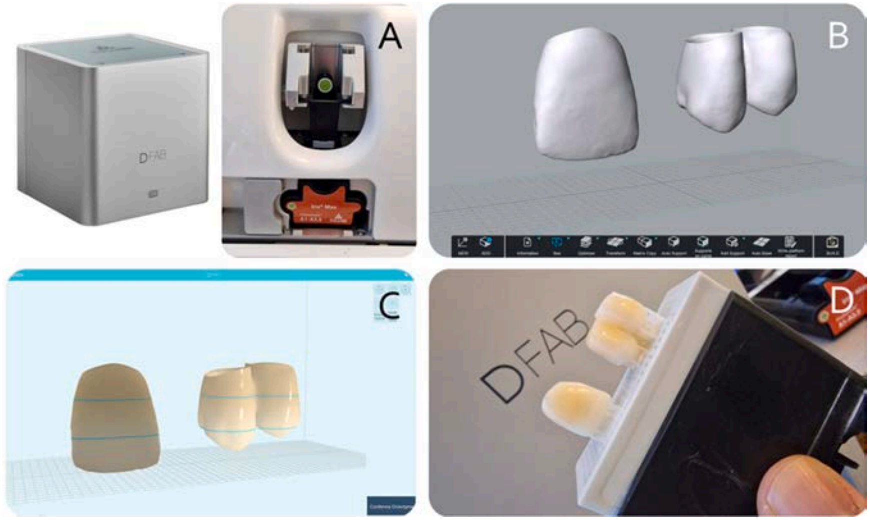

Fig. 8. Restorations printed in a hybrid composite (Irix Max®, RD Printing, Thiene, Vicenza, Italy), using a TSLA chairside 3D printer (Dfab®, RD Printing, Thiene, Vicenza, Italy). A. TSLA printer; B. Restoration in the proprietary CAD software (Nauta®, RD Printing, Thiene, Vicenza, Italy); C. Colour layers, as established in the proprietary software (Nauta Photoshade®, RD Printing, Thiene, Vicenza, Italy); D. The restorations are printed in Photoshade® (RD Printing, Thiene, Vicenza, Italy) in the A1–A3.5 gradient in 15 min.

Fig. 9. Delivery of the final additively manufactured hybrid composite (Irix Max®, RD Printing, Thiene, Vicenza, Italy) restoration. A. Individual hybrid abutment screwed in position; B. Final Irix Max® (RD Printing, Thiene, Vicenza, Italy) crown delivered to the patient.

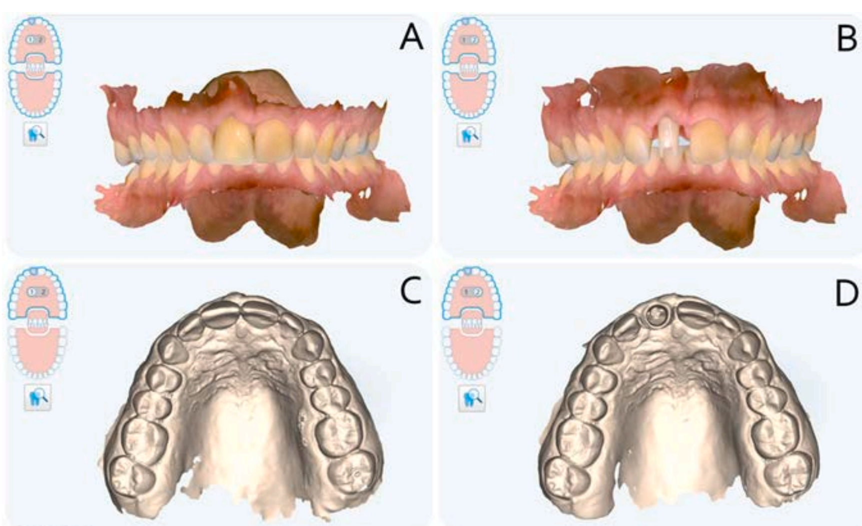

Fig. 10. Intra-oral scan (iTero Lumina™ scanner, Align Technology, San Jose, CA, USA) at the 2-year follow-up. A. Frontal view of the Irix Max® (RD Printing, Thiene, Vicenza, Italy) crown; B. Frontal view of the individual hybrid abutment; C. Occlusal view of the master model with the crown in position; D. Occlusal view of the master model with the individual hybrid abutment.

applications [31–33]. This method enables the fabrication of definitive fixed restorations – up to four or five units per printing cycle – with customisable gradient coloration, in as little as 15–30 min, making it suitable for chairside workflows [32,33]. TSLA builds upon conventional SLA technology, using a tilted build platform and a dynamic, high-viscosity resin environment, which creates a ‘waterfall’ mixing effect. This mechanism facilitates the uniform dispersion of heavy ceramic fillers during printing [32–35]. The resulting restorations are definitive hybrid composite prostheses with adequate aesthetic and mechanical properties [32–35]. The process is designed for simplicity

Fig. 11. Final 2-year follow-up of the additively manufactured hybrid composite (Irix Max®, RD Printing, Thiene, Vicenza, Italy) restoration. A. Individual hybrid abutment in position; B. Final Irix Max® (RD Printing, Thiene, Vicenza, Italy) crown 2 years after delivery.

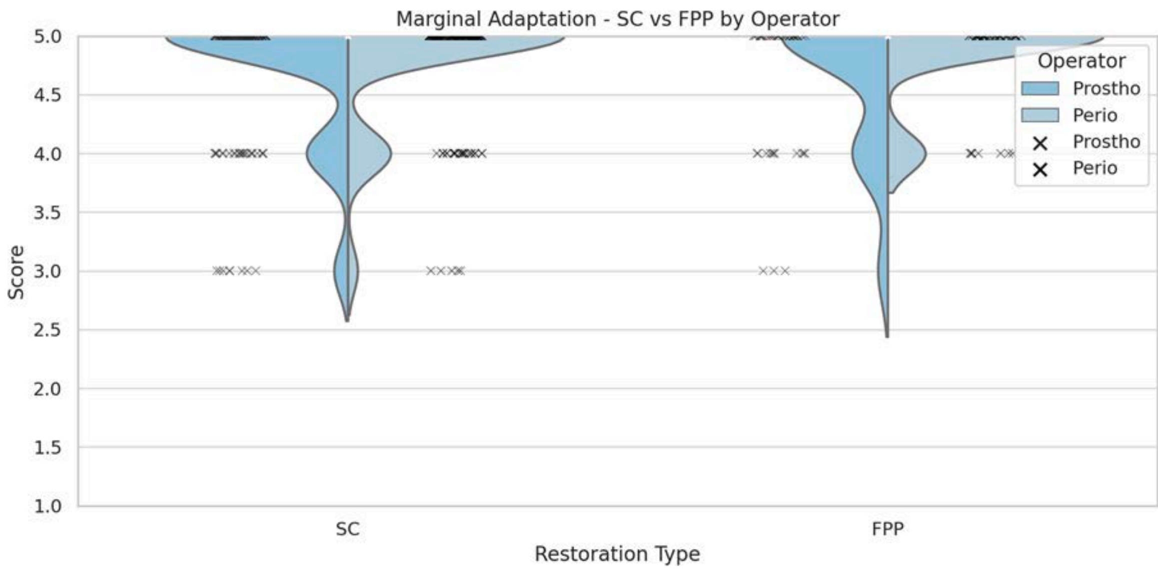

Fig. 12. Quality of the marginal adaptation of single crowns (SCs) and fixed partial prostheses (FPPs) according to the different operators. The distribution (blue) and individual observations (black dots) help visualise differences.

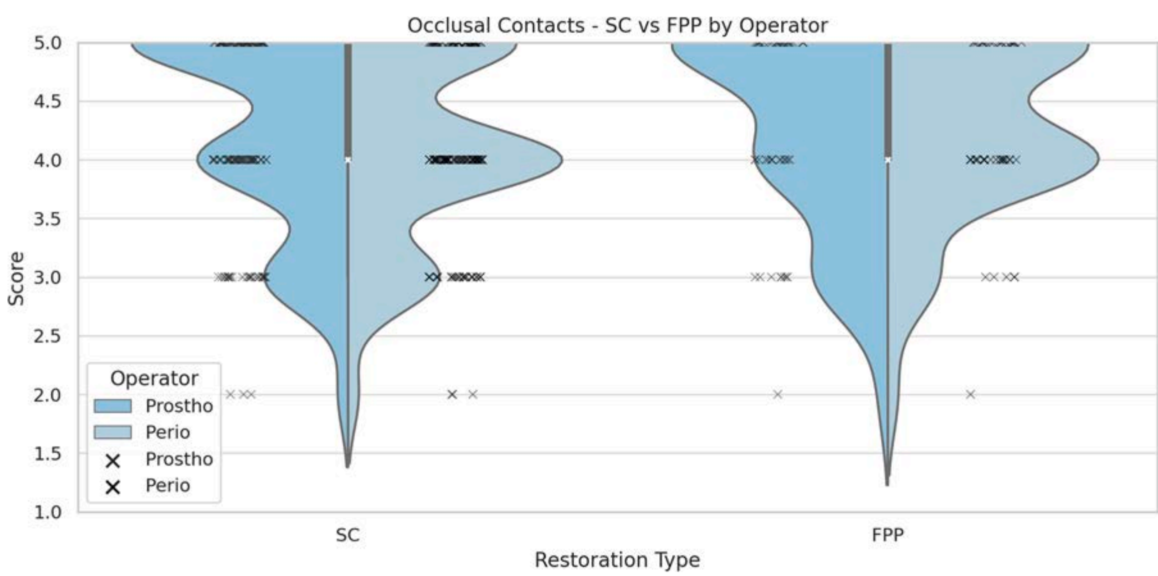

Fig. 13. Quality of the occlusal contacts of SCs and FPPs according to the different operators. The distribution (blue) and individual observations (black dots) help visualise differences.

and efficiency, using resin cartridges and an optimised workflow suitable for clinical settings. Post-processing involves optional characterisation followed by rapid post-curing in a dedicated unit, typically completed within 5–15 min [32,34].

To date, there is only one retrospective clinical study on the use of TSLA for manufacturing definitive, fixed short-span hybrid composite restorations [36]. In that study, 85 patients were treated with 95 fixed, short-span implant-supported hybrid composite (Irix Max®, RD Printing, Thiene, Vicenza, Italy) restorations (70 SCs and 25 FPPs, up to three units) fabricated through TSLA and followed for 1 year [36]. The workflow was based on intra-oral implant scanning, model-free CAD and 3D printing using TSLA [36]. The primary outcomes were marginal

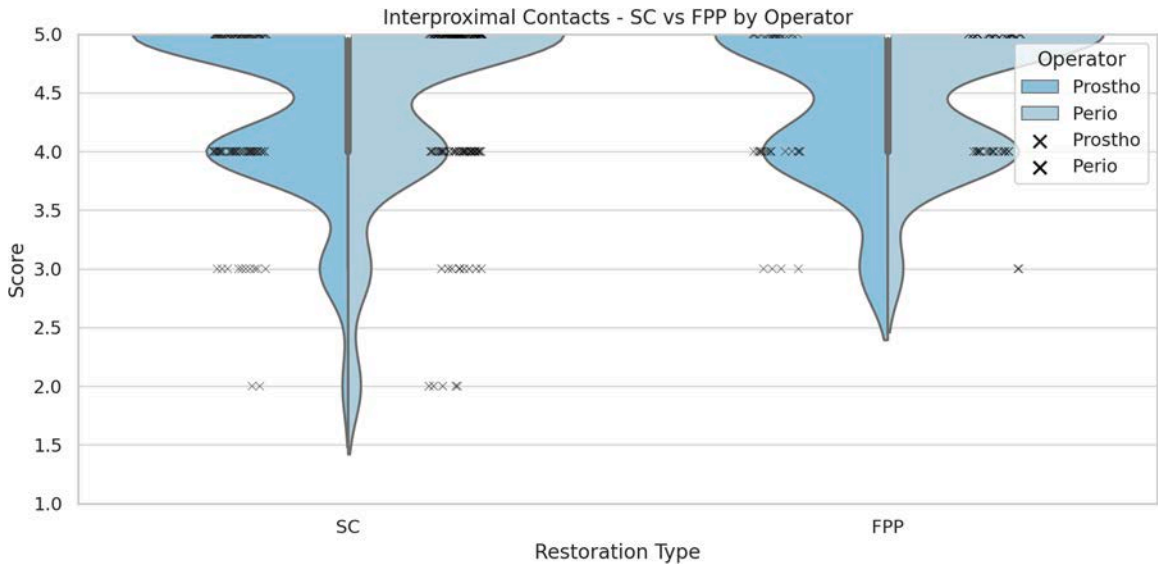

Fig. 14. Quality of the interproximal contacts of SCs and FPPs according to the different operators. The distribution (blue) and individual observations (black dots) help visualise differences.

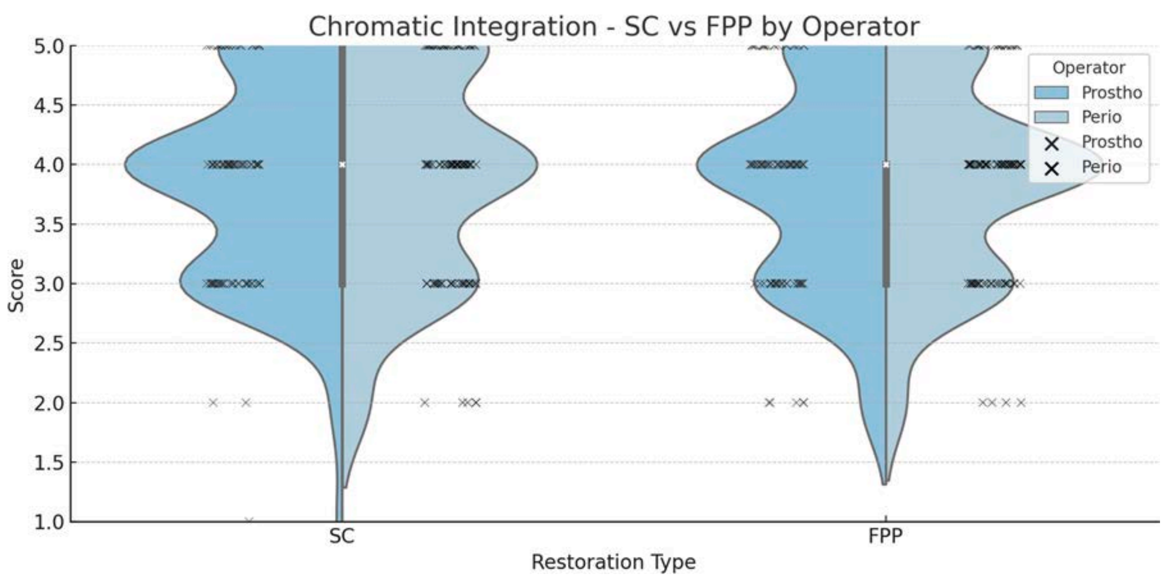

Fig. 15. Quality of the chromatic integration of SCs and FPPs according to the different operators. The distribution (blue) and individual observations (black dots) help visualise differences.

adaptation, the quality of occlusal and interproximal contact points, and chromatic integration of the restorations, assessed independently by two experienced operators. Additionally, the secondary outcomes were the survival and success of the restorations at the 1-year follow-up [36]. The operators assigned a score from 1 to 5 (with 5 as the highest value, 4 for satisfactory quality, 3 for acceptable quality, and 2 and 1 as the lowest values, indicating unsatisfactory quality) to each restoration at delivery [36]. At that point, the marginal closure and occlusal and interproximal contact points of the 3D-printed hybrid composite restorations exhibited high quality, with excellent aesthetic integration [36]. Furthermore, all restorations survived 1 year after placement, with a low incidence (4.2 % overall, 5.7 % SCs) of complications (two abutment screw loosening, two restoration decementations and one upper portion of the hybrid abutment becoming decemented from the titanium base), for an overall success rate of 95.8 % [36]. The authors concluded that, within the limits of the study, fixed, short-span implant-supported hybrid composite crowns and bridges fabricated through TSLA were clinically precise, presenting a low incidence of complications at 1 year [36].

In the present retrospective clinical study, that represents the development of that study, 95 restorations were followed for a period of 2-years, and 90 restorations were followed for 1-year. Once again, the results were positive, with high accuracy of the restorations, satisfactory aesthetic integration, a low incidence of biological (1.0 %, 2 out of 185 restorations) and prosthetic complications (3.7 %, 7 out of 185 restorations) during the entire follow-up. In fact, excluding the failure of a single implant, the only biological complication observed was one case of peri-implant mucositis. This condition was effectively treated through multiple sessions of professional dental hygiene. Mechanical and technical complications were slightly more frequent, and included four cases of abutment screw loosening in single crowns (SCs) and three decementations; but no abutment screw loosening occurred within the FPP group. At the conclusion of the 2-year follow-up, the success rate of the hybrid composite restorations manufactured using TSLA technology was 95.1 % (176 out of 185 restorations).

The material used in this study, Irix Max®, a hybrid composite incorporating 42 % ceramic filler, has previously demonstrated excellent marginal accuracy *in vitro* [32] and is the only material of this type supported by a clinical study [36].

The aforementioned *in vitro* study compared three workflows for the fabrication of SCs: an additive chairside TSLA protocol, a chairside subtractive technique using lithium disilicate and conventional laboratory-based five-axis zirconia milling [32]. Optical scanning revealed that both the TSLA and laboratory-milled workflows achieved superior marginal trueness compared to the chairside milling approach [32]. Although these differences were not clinically perceptible, as all three methods yielded restorations with adequate marginal adaptation, TSLA was more time- and cost-effective [32]. That study concluded that additive manufacturing via TSLA offers a viable alternative for definitive SC fabrication, combining high precision, operational efficiency and economic viability [32].

Additional *in vitro* studies have underscored the promising mechanical behaviour of the Irix Max® hybrid composite material [31,33–35, 45].

Similar findings have been corroborated in studies evaluating other ceramic-filled hybrid composites, such as VarseoSmile Crown Plus® (Bego), Flexcera Smile Ultra+® (EnvisionTEC) and OnX Tough 2® (SprintRay), supporting the broader applicability of this material class [46–50]. However, there are no prospective or retrospective *in vivo* studies highlighting or reporting on the clinical performance of these other hybrid composite materials.

The present clinical investigation was the first to evaluate the use of short-span, 3D-printed hybrid composite restorations in the implant-supported prosthetic rehabilitation of patients with single or partially edentulous spaces, 2 years after insertion. Its innovative contribution lies in the novel application of this technology and the robustness of the results, which are reinforced by an adequate sample size. The outcomes are promising, confirming the clinical fit of TSLA hybrid composite restorations, along with favourable short-term clinical performance. At the 2-year follow-up, a 100 % survival rate was recorded for TSLA-fabricated restorations, with minimal biological complications and a low incidence of prosthetic issues. Again, patients reported high satisfaction with the aesthetic and functional quality of the restorations.

Nonetheless, this study has limitations. Its retrospective design and the short follow-up (up to only 2 years) preclude definitive conclusions regarding the long-term clinical reliability of the material and technique. Thus, future investigations with longer-term, preferably prospective, follow-up are warranted to establish the sustained clinical performance of the proposed approach. Furthermore, in this study, all restorations were cemented onto individual abutments. In contemporary digital workflows, clinicians often favour screw-retained restorations (i.e. cemented directly onto bonding bases with occlusal access holes) over cemented prostheses, except in cases where aesthetics is paramount. Screw-retained designs differ structurally and may exhibit distinct mechanical behaviours because of discontinuities introduced by the screw channel. Thus, the results of this study, which exclusively involved cemented restorations, may not be generalisable to all screw-retained prosthetic designs. Additionally, two types of individualised abutments were used: hybrid zirconia-titanium abutments and monolithic custom titanium abutments. Therefore, further research is needed to delineate the clinical reliability of TSLA-printed ceramic-filled hybrid composite restorations across varying abutment configurations.

5. Conclusions

Notwithstanding the constraints of this study and its limited follow-up period, fixed, short-span implant-supported restorations manufactured using TSLA and a hybrid composite material demonstrated adequate clinical accuracy and a low complication rate. In fact, the restorations demonstrated excellent performance in terms of marginal fit and contact accuracy, both occlusal and interproximal, at delivery. Their aesthetic integration was also satisfactory. Moreover, during the follow-up period, in fact, all hybrid composite restorations remained functional, with a low complication rate (1.0 % biological and 3.7 % prosthetic complications), resulting in an overall success rate of 95.1 %. Nonetheless, longitudinal studies with extended observation periods are necessary to confirm these favourable outcomes.

Abbreviations

SC, single crown; FPP, fixed partial prosthesis; IOS, intraoral scanner; 3D, three-dimensional; SB, scan body; CAD, computer-aided-design; CAM, computer-assisted manufacturing; PMMA, polymethylmethacrylate; AM, additive manufacturing; SLA, stereolithography; DLP, digital light processing; LCD, liquid crystal display; TSLA, tilting stereolithography; STL, standard tessellation language; ICP, iterative closest point; SD, standard deviation; CI, confidence interval.

Disclosure: Given his role as Section Editor of the Digital Dentistry Section of the Journal of Dentistry (or, Editor-in-chief of the Digital Dentistry Journal), Dr. Francesco Mangano had no involvement in the peer review of this article and had no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to another journal editor.

CRediT authorship contribution statement

Francesco Guido Mangano: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Carlo Mangano:** Writing – review & editing, Supervision. **Marina Loktionova:** Writing – original draft, Data curation. **Olesya Dudnik:** Writing – original draft, Data curation. **Olga Malanova:** Visualization, Investigation. **Alina Elovskaya:** Validation, Software. **Anna Maltseva:** Validation, Software. **Andrey Dybov:** Writing – review & editing, Supervision, Resources, Project administration, Funding acquisition.

Declaration of competing interest

The authors report no conflict of interest related to the present clinical study. The materials presented in the study belong to the authors, who have not received any grant or financial support for the preparation of the present research.

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3D-printed Short-span Hybrid Composite Implant-supported Restorations Fabricated Through Tilting Stereolithography: A Retrospective Clinical Study on 85 Patients with 1 Year of Follow-up

Francesco Guido Mangano [a], Kyung Ran Yang [b], Henriette Lerner [c], Tommaso Porrà [d], Lusine G. Khachatryan [e], Igor Dmitrievich Gordienko [a], Oleg Admakin [a]

a Department of Pediatric, Preventive Dentistry and Orthodontics, I. M. Sechenov First State Medical University, Moscow, Russian Federation
b MIR Dental Hospital, Daegu, South Korea
c Academic Teaching and Research Institution of Johann Wolfgang Goethe University, Frankfurt, Germany
d Private Practitioner, Timisoara, Romania
e Department of Pediatric Diseases, N. F. Filatov Clinical Institute of Children's Health, I. M. Sechenov First State Medical University, Moscow, Russian Federation

Abstract

Purpose: To report the clinical results obtained with fixed short-span (single crowns [SCs] and fixed partial prostheses [FPPs]) implant-supported hybrid composite restorations fabricated through tilting stereolithography (TSLA).

Methods: This retrospective clinical study included 85 patients who had been restored with 95 fixed short-span implant-supported hybrid composite (Irix Max®, DWS Systems) restorations (70 SCs and 25 FPPs up to three units) fabricated with TSLA. The full-digital model-free workflow was based on intraoral implant scanning, computer-assisted design (CAD) and 3D printing using TSLA (Dfab®, DWS Systems). The primary outcomes were the marginal adaptation, the quality of the occlusal and interproximal contact points, and the chromatic integration of the restorations, assessed independently by two experienced operators (a prosthodontist and a periodontist). A score from 1 to 5 (with 5 as the highest value, 4 for satisfactory quality, 3 for acceptable quality, and 2 and 1 as the lowest values, expressing unsatisfactory quality) was assigned by each operator to each restoration at delivery. The secondary outcomes were the survival and success of the restorations at the 1-year follow-up. The restoration was defined as successful in the absence of any complications throughout the follow-up period. A statistical analysis was conducted.

Results: For the quality of the marginal closure and occlusal and interproximal contact points, the 3D-printed hybrid composite restorations scored highly; the aesthetic integration was satisfactory. One year after placement, all restorations survived, with a low incidence (4.2% overall, 5.7% SCs) of complications (two abutment screw loosenings, two decementation of the restorations, and one upper portion of the hybrid abutment decemented from the titanium base), for a success rate of 95.8%.

Conclusions: Within the limits of this study (retrospective design, follow-up limited to 1 year from delivery, and only cemented restorations included) fixed short-span implant-supported hybrid composite crowns and bridges fabricated through TSLA were clinically precise, presenting a low incidence of complications at 1 year.

Statement of clinical relevance: The use of TSLA printing technology can open new perspectives for the treatment of small edentulous gaps with definitive implant-supported prosthetic restorations.

Dfab

3D FOR PATIENTS