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Protesi dentarie fisse ad arcata completa supportate da impianti prodotte attraverso un flusso di lavoro digitale diretto utilizzando una struttura di splintaggio calibrata: uno studio clinico retrospettivo

Filippo Rustichini[1], Roldano Romolini[1], Maria Chiara Salmi[1], Leonardo Gennai[2], Francesco Vermigli[2], Francesco Guido Mangano[3]

Obiettivi: Valutare la precisione clinica, la sopravvivenza a un anno e le complicanze delle protesi dentali fisse ad intera arcata su impianti (ISFAFDPs) realizzate mediante un protocollo completamente digitale, che ha previsto la scansione intraorale dell'arcata edentula con un framework di stabilizzazione calibrato (CSF; RingFix®; IOSFix Dental, Madrid, Spagna) e la progettazione e produzione assistita da computer di restauri in zirconia monolitica.

Metodi: Questo studio clinico retrospettivo ha coinvolto 37 pazienti (21 uomini e 16 donne) di età compresa tra 48 e 87 anni (età media: 68,8 ± 9,7 anni), i quali sono stati riabilitati con 45 ISFAFDPs realizzate mediante un protocollo completamente digitale. Gli esiti primari considerati sono stati la precisione clinica delle ISFAFDPs, la loro sopravvivenza e l'incidenza di complicanze a un anno di follow-up. La correzione degli errori nella posizione degli impianti generati dalla scansione intraorale è stata calcolata utilizzando il CSF. I dati sono stati analizzati statisticamente.

Risultati: Al momento della consegna, tutte le ISFAFDPs erano clinicamente precise, mostrando un adattamento passivo ideale sugli impianti, confermato sia clinicamente che radiograficamente. Nessun impianto è stato perso durante il follow-up a un anno. L'incidenza delle complicanze protesiche (4,4%) è risultata relativamente bassa; una protesi si è fratturata, portando a un tasso di sopravvivenza della restaurazione del 97,8%.

Conclusioni: Nei limiti di questo studio, le ISFAFDPs in zirconia monolitica realizzate tramite scansione intraorale delle arcate edentule con un CSF si sono dimostrate clinicamente precise, presentando una bassa incidenza di complicanze a un anno.

Rilevanza clinica: L'utilizzo del CSF può migliorare l'accuratezza delle scansioni digitali delle arcate completamente edentule, consentendo la produzione di ISFAFDPs clinicamente precise.

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Implant-supported full-arch fixed dental prostheses manufactured through a direct digital workflow using a calibrated splinting framework: A retrospective clinical study

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ABSTRACT

Objectives: To evaluate the clinical precision, one-year survival, and complications of implant-supported full-arch fixed dental prostheses (ISFAFDPs) manufactured through a full-digital protocol, which involved intraoral scanning of the edentulous arch with a calibrated splinting framework (CSF; RingFix®; IOSFix Dental, Madrid, Spain) and computer-aided design and manufacturing of monolithic zirconia restorations.
Methods: This retrospective clinical study involved 37 patients (21 males and 16 females) aged 48–87 years (mean age: 68.8 ± 9.7 years) who had been restored with 45 ISFAFDPs manufactured using a full-digital protocol. The primary outcomes were the clinical precision of the ISFAFDPs and their survival and the incidence of complications at the one-year follow-up. The correction of errors in the position of the implants generated by the intraoral scan was computed using the CSF. The data were statistically analyzed.
Results: At delivery, all ISFAFDPs were clinically precise, showing ideal passive fit on the implants, confirmed clinically and radiographically. No implants had been lost at the one-year follow-up. The incidence of prosthetic complications (4.4 %) was relatively low; one prosthesis broke, giving a restoration survival rate of 97.8 %.
Conclusions: Within the limits of this study, monolithic zirconia ISFAFDPs manufactured through intraoral scanning of the edentulous arches with a CSF were clinically precise, presenting a low incidence of complications at one year.
Clinical relevance: Using the CSF can improve the accuracy of digital full-arch implant scans, allowing the manufacture of clinically precise ISFAFDPs.

1. Introduction

The digital revolution has changed the world of dentistry [1,2]. The introduction of intraoral scanners (IOSs) [3] and face scanners [4], cone beam computed tomography [5], and motion tracking technology [6] allows the acquisition of complete three-dimensional (3D) information about the patient's oral cavity. This information is processed using computer-aided design/ computer-assisted-manufacturing (CAD/CAM) software to design and manufacture through subtractive [7] and additive [8] technologies devices useful in the surgical, prosthetic, and orthodontic fields. Today, IOSs represent the gateway to digital dentistry because they allow dentists to directly capture an impression of the patient's arches in maximum comfort without using conventional analogic trays and materials. A plaster model does not need to be poured, and the files can be immediately shared with the dental laboratory, saving time and money [9,10].

However, using an IOS to capture impressions for the direct digital manufacture of complex implant rehabilitations, such as those for completely edentulous patients, is still being discussed [11–14]. Indeed, some recent systematic literature reviews report that the accuracy of

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current IOSs is insufficient to allow the direct digital manufacture of precise implant-supported full-arch fixed dental prostheses (ISFAFDPs), which can passively adapt to the implants [13,14]. This issue is due to the accumulation of errors during scanning (stitching errors), which are typical of IOSs [14–16], and the absence of congruence between the meshes of the scanbodies (SBs) and the corresponding implant library within the CAD software, which result in a shift in implant platforms from real to virtual [17–19].

However, some studies have reported that using IOSs can allow the manufacture of complex implant-supported rehabilitations through the careful control of all factors (IOS, patient-related, and operator-related) [19–23] and particularly through splinting the SBs [23–27]. Among them, the most relevant clinical study was by Imburgia et al. [28], who manufactured 35 ISFAFDPs in monolithic zirconia based on intraoral scans through a direct digital workflow following the continuous scan strategy and the splinting of the SBs in thermoplastic resin.

It remains unclear whether splinting itself can robustly improve the accuracy of intraoral scans because while some studies seem to support this concept [23,24], others do not [29–31]. Among other factors, since most of these studies were *in vitro*, their conclusions cannot be directly extrapolated to *in vivo*.

However, starting from this concept, several techniques have recently been proposed to facilitate the capture of implant scans for manufacturing ISFAFDPs, such as the use of solid indexes [32,33], auxiliary devices and/or calibrated splinting frameworks (CSFs) [34–36] (e.g., RingFix® from IOSFix Dental [37–39]), systems for splinting the SBs (e.g., the CAPS® [40] and Smart Flags® from Apollo), and SBs with modified shapes (e.g., the Scan Gauges® from Nexus IOS)—which screw onto the multi-unit-abutments (MUAs) and develop horizontally instead of vertically—to "close" the free spaces, guiding the scan [41,42].

Regarding using CSFs to correct the errors generated during IOS scans, no clinical studies have been conducted with sufficient treated patients to clinically validate the procedure [37–39]. Therefore, our retrospective clinical study involving 37 patients treated by the same experienced operator aimed to assess the clinical precision and one-year survival of ISFAFDPs produced through a full-digital protocol, which involved intraoral scanning of the edentulous arch with the RingFix® CSF, CAD modeling, and CAM in monolithic zirconia.

2. Materials and methods

2.1. Study design

This retrospective clinical study analyzed the medical records, clinical photographs, and X-rays of 37 patients who had been treated by the same experienced operator (F.R.) in one private dental center between 2022 and 2023 and received one (or two) ISFAFDP(s) manufactured through an entirely digital workflow, starting from an intraoral scan assisted by a CSF (RingFix®; IOSFix Dental, Madrid, Spain).

The patients were selected for this retrospective clinical study based on specific inclusion and exclusion criteria. The inclusion criteria were: (1) fully edentulous patients and/or patients with severely compromised dentition who had undergone extraction of all teeth and who had been treated with the placement of at least four implants (in the maxilla and/or mandible) and then rehabilitated with one (or two) ISFAFDP(s), fabricated through a direct digital workflow involving intraoral scanning using a CSF (RingFix®; IOSFix Dental, Madrid, Spain); (2) patients with medical records complete with all clinical, radiological and laboratory data, including the initial intraoral scans, the final ones with the CSF, and the CAD modeling of the definitive restorations, as well as reports of any complications that occurred with the restorations during the follow-up period; (3) patients who regularly attended the two check-ups scheduled yearly for professional oral hygiene; (4) patients with at least on year of follow-up from the delivery of the definitive ISFAFDP(s).

The exclusion criteria were: (1) patients with compromised systemic health due to compromised immune response (e.g., uncontrolled diabetes, HIV, or immunological disorders); (2) patients with a previous history or ongoing therapy with intravenous or oral amino bisphosphonates; and (3) patients who had undergone reconstructive bone insertion therapies (guided bone regeneration with membranes or treatment with autologous, homologous, or heterologous onlays/inlay grafts) to allow the insertion of the implants. Smoking and parafunctional habits (e.g., grinding and bruxism) were not criteria for exclusion from this study.

All patients included in this retrospective clinical study had been informed in detail about the type of implant-prosthetic treatment they had to undergo and about the surgical and prosthetic steps necessary to get to the delivery of the final prosthetic rehabilitation; the patients also signed an informed consent form for the implant-prosthetic treatment. This study was conducted in full compliance with and respected the guidelines of the Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects, revised in 2008).

2.2. Surgical phase and immediate provisionalization

The patients who were already edentulous were treated with the insertion of at least four implants per arch, following a classic surgical protocol that included local anesthesia for infiltration, crestal incision, lifting of a full-thickness flap, and preparation of the implant sites with progressive drills and subsequent manual insertion of the fixtures (JDIcon Plus® [JDentalCare, Modena, Italy] or Unifit® [Adin Implants, Tel Aviv, Israel]). The patients presenting with compromised terminal dentition underwent tooth extractions performed in the same surgical session dedicated to positioning the implants. Where necessary, and particularly where the bone crest proved thin, the surgeon could make small additions of biomaterial, with or without resorbable membrane, to protect the vestibular bone and/or to cover the most coronal threads of the implants. The need for major bone augmentation was considered an exclusion criterion for enrollment in this study.

Once the implants were inserted, the operator sutured around them, positioned the MUAs, transferred the impressions, and captured classic analog impressions with a standard tray and plaster and a waxing bite. These were used to manufacture an immediate provisional full-arch restoration in polymethyl-methyl methacrylate, delivered to the patient no later than 6–8 h after surgery.

Immediately after surgery, the operator prescribed a liquid diet for the next 3–4 days in addition to painkillers and antibiotics (amoxicillin + clavulanic acid, 1 g every 12 h for 6–7 days). The patients were free to go home for a few hours, and during this time, the laboratory manufactured an immediate provisional full-arch restoration, which was applied the same day. Then, 6–8 h after surgery, the patient was recalled to the dental office to immediately deliver the provisional ISFAFDP(s), which was screwed onto the MUAs and remained *in situ* for the entire healing period of the implants. The patients were recalled for a check-up and removal of sutures 8–10 days after surgery and were monitored for the following 3–4 weeks.

2.3. Prosthetic phase

After three months for the mandible and five months for the maxilla, it was possible to begin the prosthetic process, leading to the delivery of the definitive ISFAFDP(s). The patients were recalled for an appointment dedicated to a first intraoral scan with a IOS (Trios 3®; 3Shape, Copenhagen, Denmark), which was performed by the same experienced operator (F.R.) with the provisional restorations *in situ* (master model, antagonist and bite), and then without it, with and without the implant SBs (IPD Dental®; Matarò, Barcelona, Spain) for MUAs in position. This initial scan was sent digitally to the dedicated service for the CAD modeling and CAM of a custom CSF to connect the implant SBs (RingFix®; IOSFix Dental, Madrid, Spain). This metal CSF, manufactured by combining milled and additive approaches, contained milled truncated

cone-shaped markers, whose position was measured with a coordinate measuring machine (CMM) during the manufacturing process and was considered a reference. This CSF was then sent to the clinician, who used it to splint the selected implant SBs (ScanTranfer®; IPD Dental, Matarò, Barcelona, Spain) for MUAs. These SBs were blocked to the CSF (RingFix®; IOSFix Dental, Madrid, Spain) using low-shrinkage photopolymerizable resin to assist a second, definitive intraoral scan with the same IOS. This final scan was sent to the same service, and the CSF was used as a reference to correct errors in the IOS scan and thus to calculate the actual implant position on the virtual definitive implant cast based on the position of the calibrated markers as a reference.

The IOSFix® service then sent the file with the exact positions of the implants and with the corrections made using the CSF appropriately incorporated to the dental laboratory, which, along with the complete set of data (foundation scans, provisional scans, emergence profile scans, and bite), was used to model the monolithic ISFAFDP within prosthetic CAD software (DentalCad®; Exocad, Darmstadt, Germany, and Dental System®; 3Shape, Copenhagen, Denmark). The final prosthesis was designed based on an analysis of the immediate provisional prosthesis and the specific instructions given by the prescribing clinician, which considered the individual esthetic, functional, and occlusal parameters. Once approved, the clinician could request a try-in version of the final prosthesis in a standard tessellation language (STL) file, which could be 3D printed or milled to evaluate the intraoral precision, esthetics, and occlusion of the planned final restoration. This process provided a significant advantage in determining optimal function, esthetics, and phonetics. The try-in may be re-scanned if changes were made and resent to the laboratory to allow the necessary modifications to the final design to be incorporated into the final CAD model.

Once the final design of the ISFAFDP was approved, it was manufactured by the dental laboratory located in the dental office. The final ISFAFDP consisted of a Toronto in monolithic zirconia, milled with a powerful 5-axis milling machine (Ceramill Motion 2®; Amann Girrbach, Koblach, Austria) infiltrated, characterized, and then sintered (Ceramill Therm 3®; Amann Girrbach, Koblach, Austria). The tones for artificial gingiva were heated during sintering and hardened. Each ISFAFDP underwent various post-sintering stains and glazing based on the laboratory technician's needs and the clinician's requests, including layered zirconia to the facial-side teeth. Quality control was performed at all steps of the manufacturing process.

2.4. Clinical outcomes variables

The clinical variables examined in this study were as follows: (1) Fit, adaptation (i.e., clinical precision), and functional and aesthetic integration of the final ISFAFDP; (2) Any complications (biological and/or prosthetic) during the one-year follow-up; (3) The survival of the implants and the monolithic ISFAFDP at the one-year follow-up.

The primary study outcome was clinical precision, which was checked at the delivery of the final ISFAFDP. The incidence of complications and the survival of the implants and the ISFAFDP at the one-year follow-up were assessed.

2.4.1. Fit and adaptation (clinical precision)

The clinical precision (i.e., the marginal adaptation and passive fit of the final ISFAFDP) was recorded at delivery [41]. The operator checked the passive fit and adaptation clinically using the Sheffield test. Accuracy was also assessed by finger pressure as the prosthesis was seated onto the respective MUA [41]. The accuracy of fit and marginal adaptation was then confirmed radiographically.

2.4.2. Biologic and prosthetic complications

Any biologic [43] or prosthetic (i.e., mechanical and/or technical) complication, according to Salvi and Bragger [44] and Mangano et al. [45], encountered during the one-year follow-up period was registered in the patients' folders.

Biologic complications included: (1) pain or swelling after surgery, (2) peri-implant mucositis (i.e., a condition indicated by the presence of bleeding on probing and/or suppuration, associated with probing depth >4 mm, with no evidence of radiographic bone loss beyond bone remodeling [43]), (3) peri-implantitis (i.e., a condition indicated by the presence of probing depth ≥ 6 mm around the affected fixture, bleeding on probing, and/or exudate associated with clear evidence of radiographic bone loss >3.0 mm), and (4) progressive bone loss (>2.5 mm) without peri-implant infection [43].

Prosthetic complications included: (1) mechanical complications (i.e., problems affecting components directly supplied by the company, such as MUA screw loosening) [41,44,45], and (2) technical complications (i.e., problems affecting the final ISFAFDP, such as prosthesis fracture or chipping of the veneering material) [41,44–46].

The complications were carefully registered and, if possible, managed directly during the follow-up visit; if the complication could not be managed during the follow-up visit, an additional appointment was set to manage it.

2.4.3. Survival of the implants and the ISFAFDP

The survival of the implants and the ISFAFDP was clinically and radiographically assessed at the one-year follow-up. Implant failures due to a loss of osseointegration, implant mobility, progressive marginal bone loss, and/or implant body fracture were registered, as well as prosthetic failures (fractures) [46].

2.5. Mathematical outcome variables

The RingFix® (IOSFix Dental, Madrid, Spain) CSF was used to correct, within dedicated CAD software, position and distance errors between the centroids of the implants generated by the first intraoral scan with the SBs. Errors were classified and tabulated as follows: CenterDelta represented the overall position correction, which was divided into CenterDeltaZ (the error on the vertical axis) and CenterDeltaXY (the error on the implant support plane), and AxisDelta, which represented the angular correction relative to the vertical axis of the implant.

2.6. Statistical analysis

All clinical, radiological, and laboratory data for this study were retrospectively collected and evaluated by a single, experienced operator (M.F.) who had not been involved in the treatment of the patients. All data were entered into an Excel spreadsheet (version 2003; Microsoft, Redmond, WA, USA). Descriptive statistics were used to stratify the distribution of patients, implants, and ISFAFDPs and to compute the incidence of complications and implant and prosthetic failures. Qualitative variables (gender, smoking habit, bruxism, distribution of implants per location, and position) are expressed as numbers and percentages. Quantitative variables (age at surgery) are expressed as the mean, standard deviation, median, range, and 95 % confidence interval (CI).

A restoration-based approach was used to calculate clinical precision, and an implant-based approach was used to calculate the implant survival rate. The statistical unit was the implant in the implant-based approach and the ISFAFDP in the restoration-based approach.

Finally, a univariate descriptive analysis was conducted on the studied variables by calculating central tendency and variability indices for the four error measures. The effects of the arch (upper or lower) and the number of implants (four or more) were assessed using mixed-effects models to account for the dependence of some observations, as they belonged to the same patient. Therefore, the patient was included as a random effect, while the independent variables were treated as fixed effects. A significance level of 0.05 was used for all analyses.

Statistical analyses were performed using two statistical software: SPSS Statistics (version 30; IBM, Armonk, NY, USA) and R (version 4.3.1; R Project for Statistical Computing, Indianapolis, IN, USA).

Table 1
Descriptive analysis of the characteristics of the enrolled patients.

	Number of patients
Gender	
Males	21 (56.8 %)
Females	16 (43.2 %)
Age at surgery	
45- 54 years	1 (2.8 %)
55- 64 years	12 (32.4 %)
65- 74 years	15 (40.5 %)
≥ 75 years	9 (24.3 %)
Smoking habit	
Yes	10 (27 %)
No	27 (73 %)
History of parafunctional habits	
Yes	12 (32.4 %)
No	25 (67.6 %)
Total	37 (100 %)

Table 2
Descriptive analysis of the features of the delivered ISFAFDPs with the number of implants used.

	Number of ISFAFDPs	Number of implants used
Location		
Maxilla	25 (55.6 %)	113 (56 %)
Mandible	20 (44.4 %)	89 (44 %)
Configuration		
4 implant configuration	31 (68.9 %)	124 (61.4 %)
5 implant configuration	7 (15.6 %)	35 (17.3 %)
6 implant configuration	6 (13.3 %)	36 (17.9 %)
7 implant configuration	1 (2.2 %)	7 (3.4 %)
Implant type		
JDIcon Plus®	20 (44.4 %)	99 (49 %)
Unifit®	25 (55.6 %)	103 (51 %)
Total	45 (100 %)	202 (100 %)

3. Results

Based on the retrospective analysis of the electronic folders of treated patients, 37 subjects (21 males and 16 females) aged 48–87 years (mean age: 68.8 ± 9.7 years, 95 % CI: 65.7–71.9) were considered eligible for enrollment in this study according to the inclusion and exclusion criteria. They were treated with 45 ISFAFDPs (eight patients required complete rehabilitation of both the maxilla and mandible) supported by 202 implants (31 prostheses supported by four implants, 7 supported by five implants, 6 supported by six implants, and 1 supported by seven implants). The characteristics of the enrolled patients and the delivered ISFAFDPs are summarized in Tables 1 and 2, respectively.

At delivery, all ISFAFDPs (45/45, 100 %) were clinically precise, showing an ideal passive fit on the implants, confirmed clinically by Sheffield tests and radiographically. The functional and aesthetic adaptation was entirely satisfactory from the perspective of the clinician and the patient.

The data from the position corrections made due to RingFix® and, thus, by the IOSFix® software, revealed error corrections consistent in the different spatial planes, as reported in Table 3 and Fig. 1 (general deviations for the four parameters: CenterDelta, CenterDeltaZ, CenterDeltaXY, and AxisDelta) and Table 4 and Fig. 2 (deviations for the four parameters: CenterDelta, CenterDeltaZ, CenterDeltaXY, and AxisDelta by arch [i.e., the maxilla and mandible]). According to the mixed effects model used to investigate whether the arch affected the error measures, AxisDelta differed significantly between the lower and upper arches ($p < 0.001$; Table 5). The coefficient was −0.29598, indicating that, on average, the AxisDelta value was 0.29598 lower for the upper arch than the lower arch. Finally, according to the mixed effects model used to investigate whether the number of implants affected the error measures, AxisDelta differed significantly between those with >4 implants and those with 4 implants ($p < 0.001$; Table 6). The coefficient was −0.23288, indicating that, on average, the AxisDelta value was 0.23288 lower for ISFAFDPs with >4 implants than ISFAFDPs with 4 implants.

Regarding complications, no biological complications involving the implants occurred during the entire follow-up period. In contrast, two

Table 3
Overall descriptive statistic for the deviations and corrections made by the IOSfix software.

	Mean	Standard Deviation	Median	Percentile 25	Percentile 75	Minimum	Maximum
CenterDelta	,08	,04	,07	,05	,10	,01	,26
CenterDeltaZ	,02	,01	,02	,01	,02	,00	,08
CenterDeltaXY	,07	,04	,07	,05	,10	,01	,24
AxisDelta	,62	,52	,50	,28	,79	,00	3,70

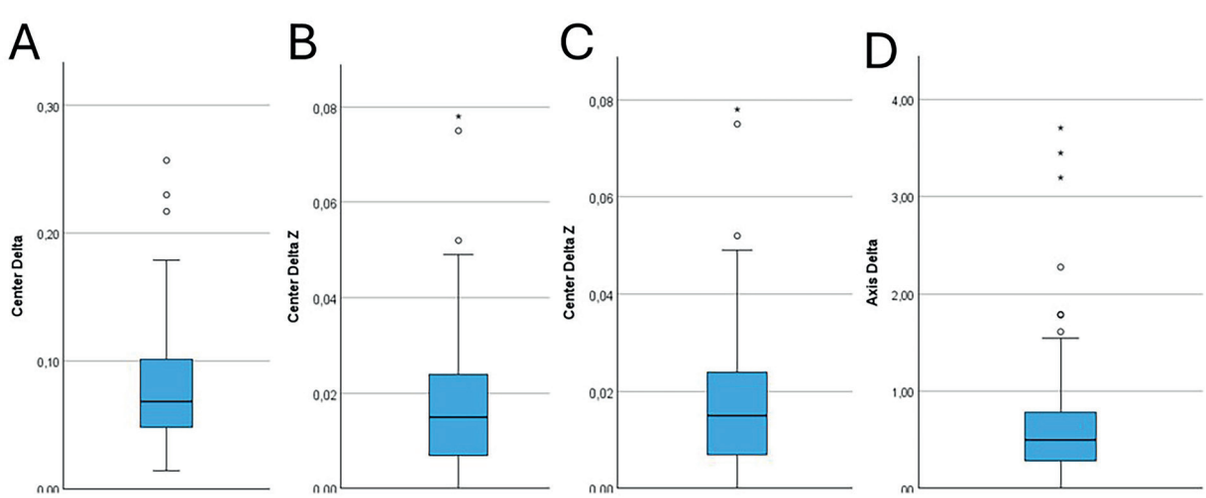


Fig. 1. Overall descriptive statistics.

Table 4
Descriptive statistic for the deviations and corrections made by the IOSFix software, by arch (upper vs lower jaw).

			Mean	Standard Deviation	Median	Percentile 25	Percentile 75	Minimum	Maximum
Arcata	**Lower**	***Center Delta***	,08	,04	,07	,05	,10	,01	,22
		Center Delta Z	,01	,01	,01	,01	,02	,00	,04
		Center Delta XY	,08	,04	,07	,05	,09	,01	,22
		Axis Delta	,75	,66	,63	,34	,99	,00	3,70
	Upper	***Center Delta***	,08	,05	,07	,05	,11	,02	,26
		Center Delta Z	,02	,01	,02	,01	,02	,00	,08
		Center Delta XY	,07	,04	,07	,04	,10	,01	,24
		Axis Delta	,52	,34	,47	,27	,64	,03	1,79

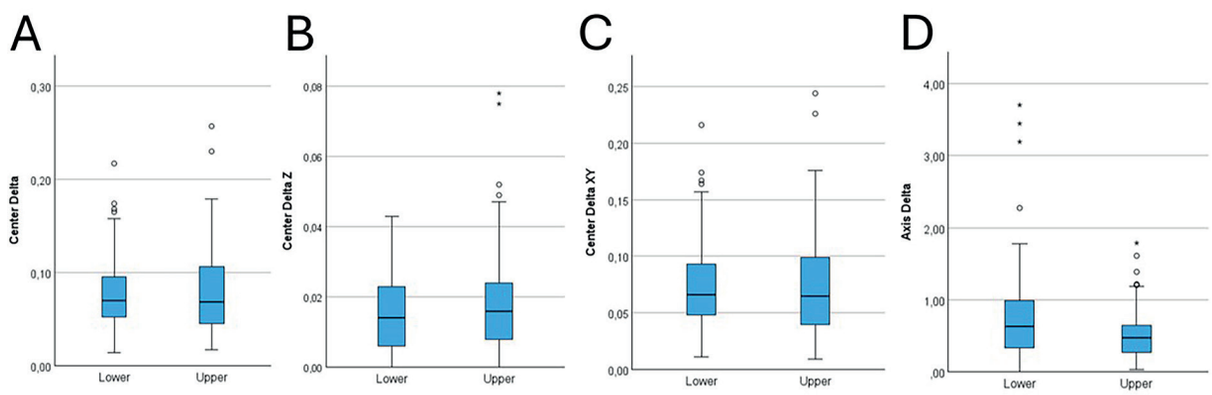


Fig. 2. Descriptive statistics by arch (upper versus lower jaws).

Table 5
Linear mixed model with Arch as dependent variable (upper vs lower jaw).

Dependent	Effect	Estimate	Standard error	t-value	p-value
Center Delta	**Fixed effect**				
	Intercept	0.076930	0.00564	13.634	<0.001
	Arch (Upper)	0.00100	0.00676	0.149	0.882
	Random effect (Patient) Variance				
	(Intercept)	0.0003405			
	Residual	0.0015292			
Center Delta Z	**Fixed effect**				
	Intercept	0.01550	0.00171	9.092	<0.001
	Arch (Upper)	0.003154	0.00209	1.508	0.134
	Random effect (Patient) Variance				
	(Intercept)	0.0000255			
	Residual	0.0001576			
Center Delta XY	**Fixed effect**				
	Intercept	0.07400	0.00562	13.16	<0.001
	Arch (Upper)	0.00034	0.00678	0.05	0.960
	Random effect (Patient) Variance				
	(Intercept)	0.0003232			
	Residual	0.0015660			
Axis Delta	**Fixed effect**				
	Intercept	0.78318	0.06577	11.908	<0.001
	Arch (Upper)	−0.29598	0.07951	−3.723	<0.001
	Random effect (Patient) Variance				
	(Intercept)	0.04302			
	Residual	0.21794			

technical prosthetic complications occurred during the follow-up period. One was classified as minor, involving the chipping of the zirconia in an upper arch (area #12) in a patient treated with two

Table 6
Linear mixed model with number of implants as dependent variable.

Dependent	Effect	Estimate	Standard error	t-value	p-value
Center Delta	**Fixed effect**				
	Intercept	0.073494	0.004912	14.962	<0.001
	Number of Implants > 4	0.010812	0.007602	1.422	0.161
	Random effect (Patient) Variance				
	(Intercept)	0.0002966			
	Residual	0.0015343			
Center Delta Z	**Fixed effect**				
	Intercept	0.017678	0.001559	11.337	<0.001
	Number of Implants > 4	−0.000996	0.002416	−0.412	0.134
	Random effect (Patient) Variance				
	(Intercept)	0.0000292			
	Residual	0.0001574			
Center Delta XY	**Fixed effect**				
	Intercept	0.069957	0.004864		<0.001
	Number of Implants > 4	0.011423	0.007548		0.137
	Random effect (Patient) Variance				
	(Intercept)	0.0002746			
	Residual	0.0015719			
Axis Delta	**Fixed effect**				
	Intercept	0.70911	0.05265		<0.001
	Number of Implants > 4	−0.23288	0.08257		0.007
	Random effect (Patient) Variance				
	(Intercept)	0.01966			
	Residual	0.23848			

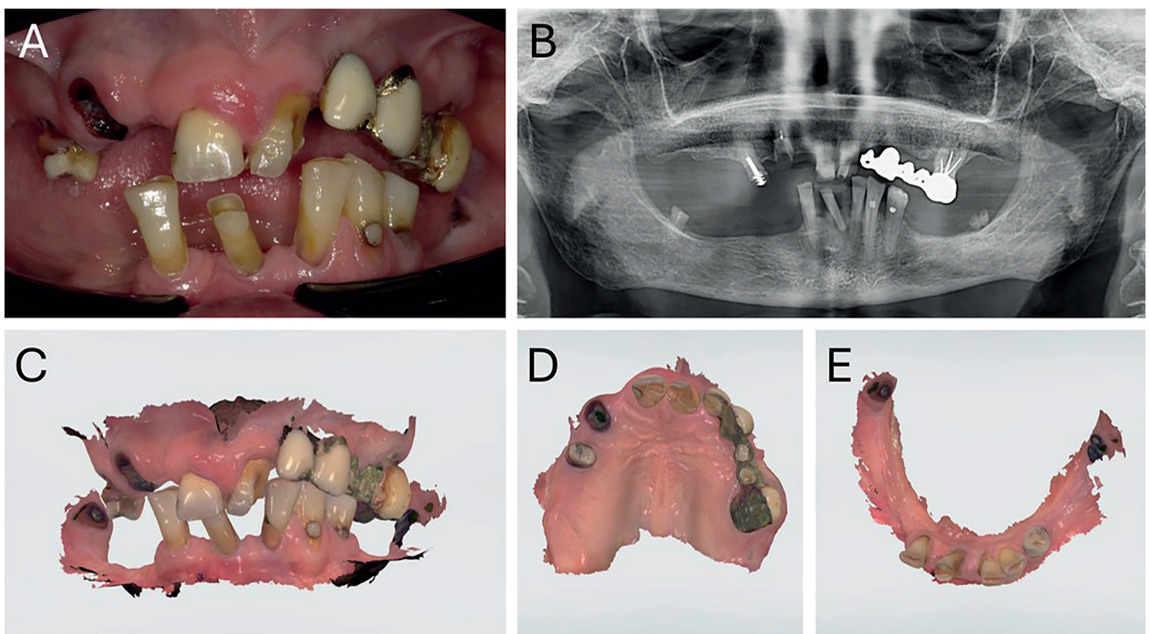


Fig. 3. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs): intake.
(A) Pre-operative clinical picture, frontal view; (B) Pre-operative panoramic radiograph; (C) Initial intraoral scan (Trios 3®, 3SHAPE, Copenhagen, Denmark), frontal view; (D) Initial intraoral scan, upper jaw, occlusal view; (E) Initial intraoral scan, lower jaw, occlusal view.

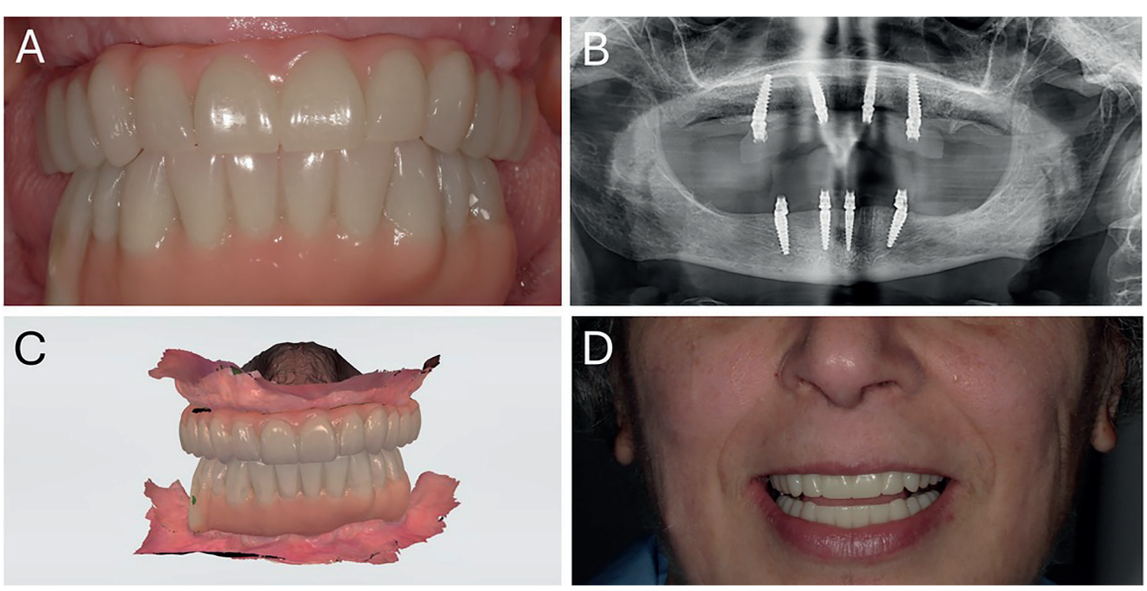


Fig. 4. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDP). Surgery and delivery of the immediate temporary prosthesis.
(A) Post-operative clinical picture with the immediate temporary prosthesis, frontal view; (B) Post-operative panoramic radiograph; (C) Post-operative intraoral scan (Trios 3®, 3SHAPE, Copenhagen, Denmark) with the immediate temporary prosthesis, frontal view; (D) Smile with the temporary prosthesis.

ISFAFDPs supported by four implants in the upper jaw and five in the lower jaw. The other was classified as major, a fracture developed in the upper prosthesis (element #13, exactly in correspondence with the fixture) in a patient with a history of parafunction (bruxist) treated with two monolithic zirconia ISFAFDPs supported by six implants in both the upper and lower jaws, which required redoing the restoration.

Therefore, all implants (202/202) had survived at the one-year follow-up, giving an implant survival rate of 100 %. In contrast, the one-year survival rate of the restorations was 97.8 %, as one fractured and needed replacement.

Figs. 3–18 and Videos 1–3 show two complete clinical cases resolved with the IOSFix® system.

4. Discussion

Our retrospective clinical study demonstrated the reliability of the RingFix® CSF for fabricating ISFAFDPs directly from intraoral scans. All 45 ISFAFDPs exhibited high clinical precision at delivery in the 37 treated patients, with an excellent passive fit and adaptation from clinical and radiological perspectives.

This clinical precision contributed to a relatively low incidence of complications at the one-year follow-up: one minor (the chipping of a

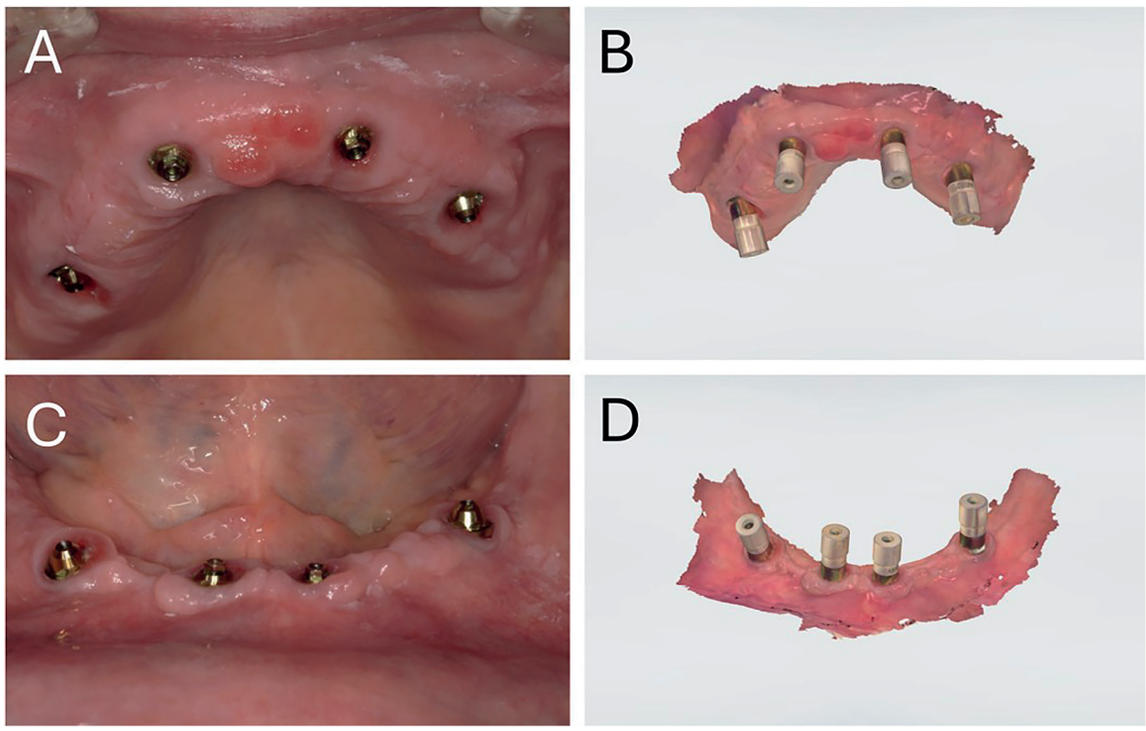


Fig. 5. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). First intraoral scan with the implant scanbodies (SBs).
(A) The soft tissues before the first intraoral scan, upper jaw; (B) Intraoral scan with the scanbodies (SBs) (IPD Dental®, Matarò, Barcelona, Spain) in position, upper jaw; (C) The soft tissues before the first intraoral scan, lower jaw; (D) Intraoral scan with the scanbodies (SBs) in position, lower jaw.

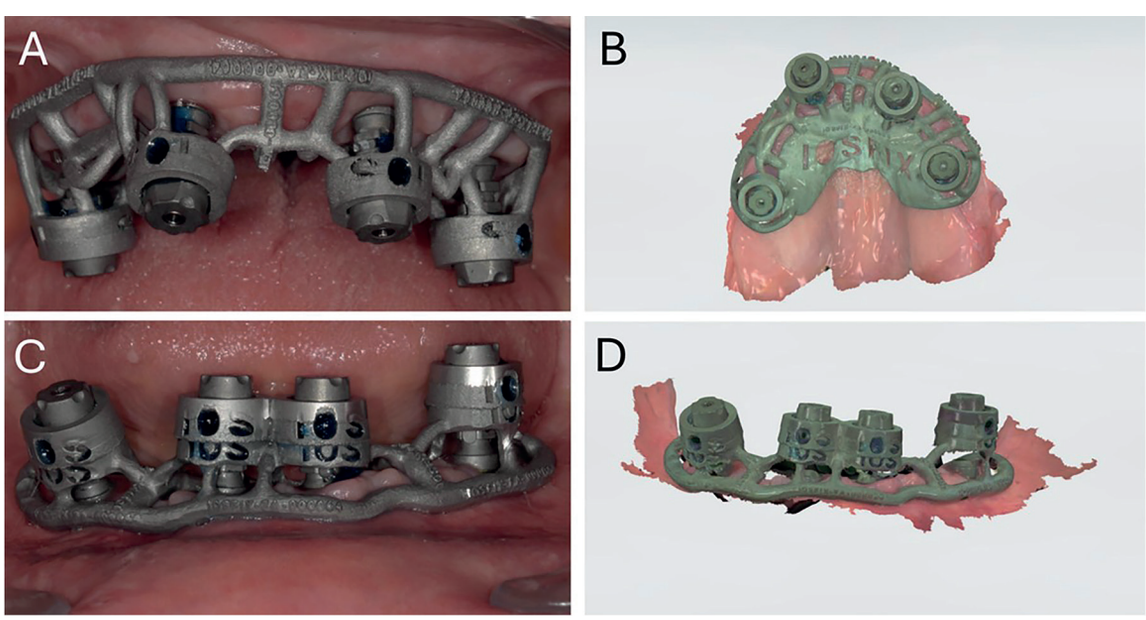
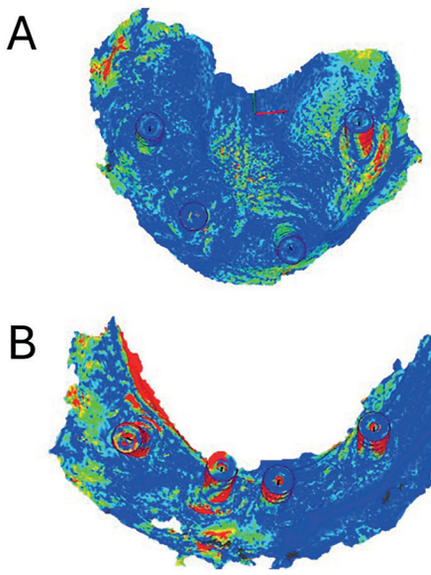


Fig. 6. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). Second intraoral scan, with the calibrated frameworks (RingFix®, IOSFix Dental, Madrid, Spain).
(A) Clinical picture of the calibrated framework positioned in the upper jaw, frontal view; (B) Intraoral scan with the calibrated framework in the upper jaw, occlusal view; (C) Clinical picture of the calibrated framework positioned in the lower jaw, frontal view; (D) Intraoral scan with the calibrated framework in the lower jaw, frontal view.

restoration) and one major (a full-arch fracture) technical complication. No mechanical complications occurred. Therefore, the incidence of prosthetic and technical complications was 4.4 % (at the restoration level).

IOSFix® is a system designed to correct the cumulative errors that arise in intraoral scans [37–39]. Initial STL files often carry inaccuracies due to the inherent limitations of IOSs, SBs, and external factors such as lighting, temperature, patient movements, scanning strategies, implant angles and distances, and material tolerances [14–19,23]. IOSFix® uses a calibrated framework with known distances and references to analyze



	CenterDelta	CenterDeltaZ	CenterDeltaXY	AxisDelta
Abutment1U	0.059	0.000	0.059	0.318
Abutment2U	0.072	0.006	0.072	0.499
Abutment3U	0.040	0.017	0.036	0.134
Abutment4U	0.077	0.023	0.074	0.377
Mean	0.062	0.012	0.060	0.332
SD	0.014	0.009	0.015	0.132

	CenterDelta	CenterDeltaZ	CenterDeltaXY	AxisDelta
Abutment1L	0.128	0.024	0.126	3.704
Abutment2L	0.158	0.010	0.157	1.069
Abutment3L	0.039	0.002	0.039	0.497
Abutment4L	0.047	0.003	0.047	1.030
Mean	0.093	0.010	0.092	1.575
SD	0.051	0.009	0.051	1.250

Fig. 7. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). Corrections of the implant position through the calibrated framework.
(A) Colorimetric map of the upper jaw mesh correction with tabulated details of the related corrections; (B) Colorimetric map of the lower jaw mesh correction with tabulated details of the related corrections.

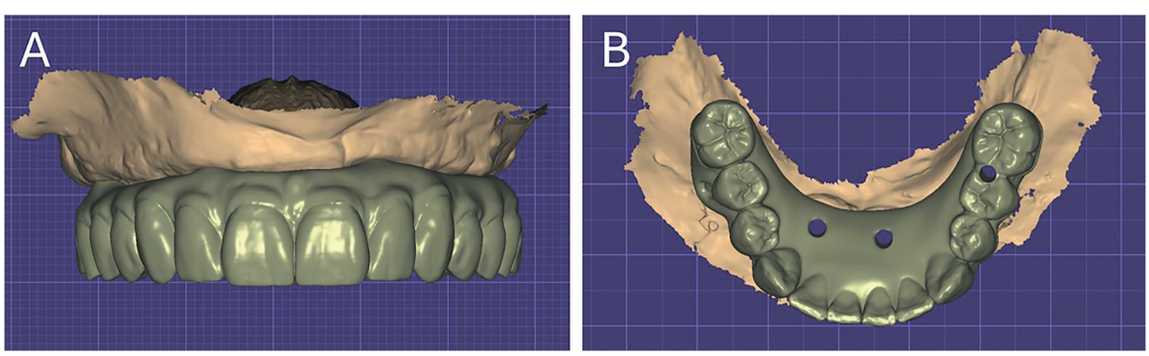


Fig. 8. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). Computer-aided-design (CAD) (Galway®, Exocad, Darmstadt, Germany) project based on the corrected implant positions.
(A) Upper jaw ISFAFDP CAD project, frontal view; (B) Lower jaw ISFAFDP CAD project, occlusal view.

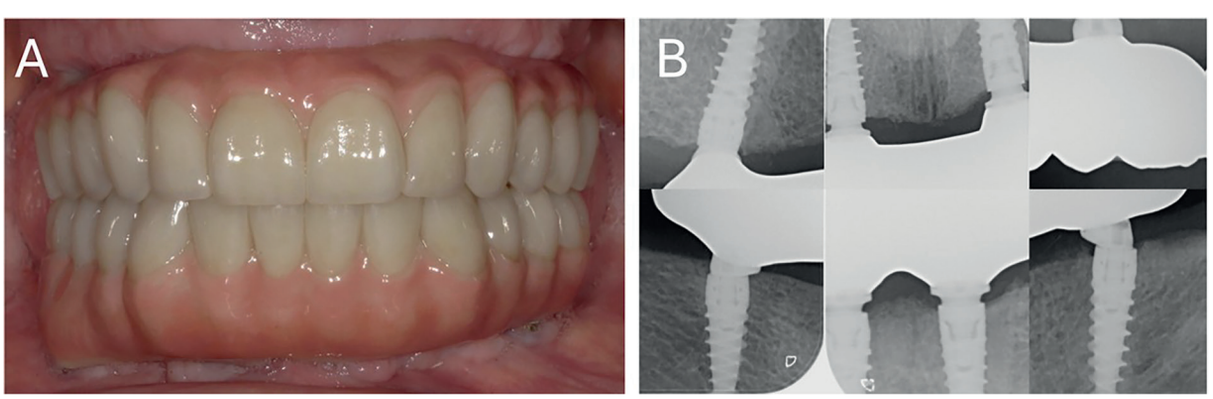


Fig. 9. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). Delivery of the final monolithic zirconia ISFAFDPs.
(A) Clinical picture of the final monolithic zirconia ISFAFDPs in occlusion, frontal view; (B) Radiographic control of the marginal adaptation.

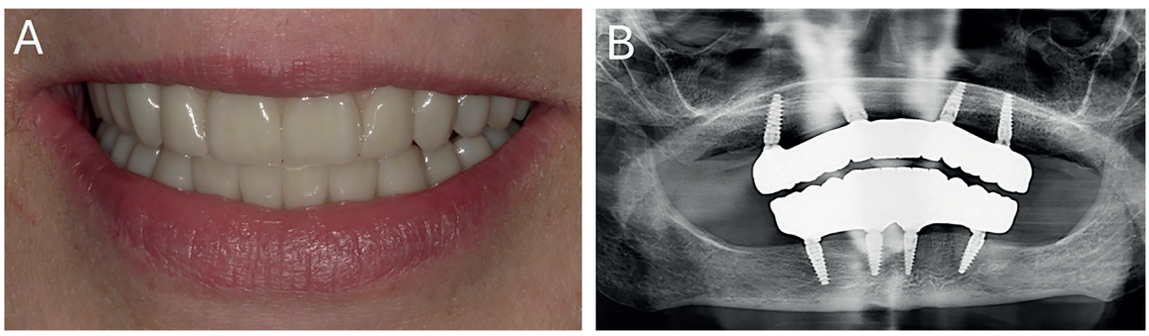


Fig. 10. First case. Rehabilitation of the upper and lower jaws with two implant-supported full-arch fixed dental prostheses (ISFAFDPs). One year follow-up control. (A) Clinical picture of the final monolithic zirconia ISFAFDPs 1 year after the delivery, frontal view; (B) Panoramic radiograph 1 year after the delivery of the final ISFAFDPs.

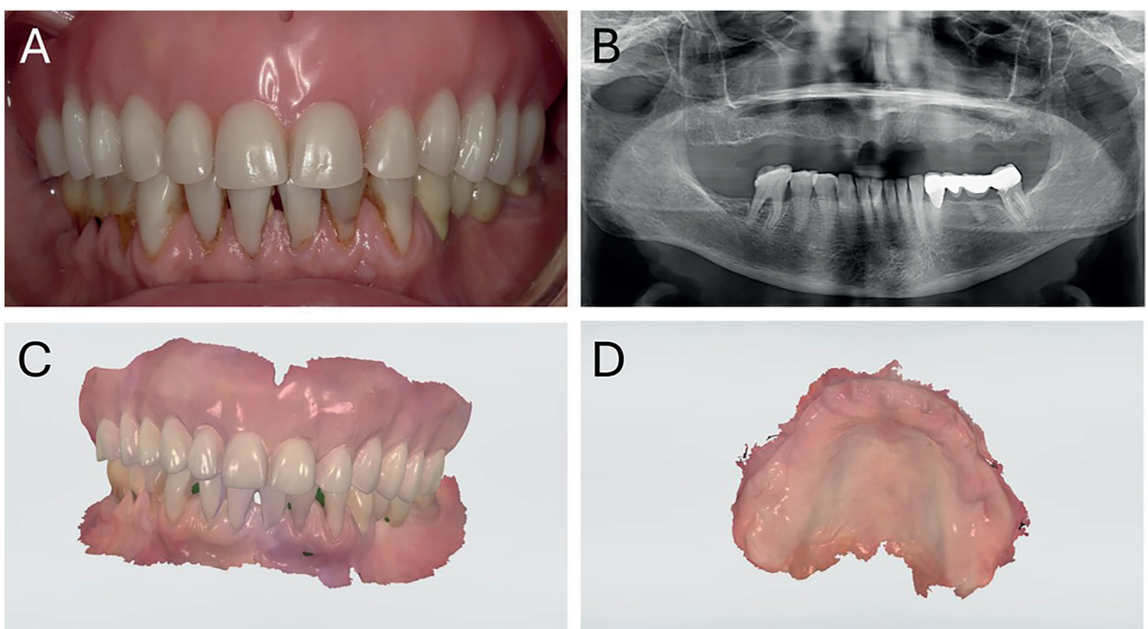


Fig. 11. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Intake.
(A) Pre-operative clinical picture, frontal view; (B) Pre-operative panoramic radiograph; (C) Initial intraoral scan (Trios 3®, 3SHAPE, Copenhagen, Denmark) with the pre-existing complete removable denture frontal view; (D) Initial intraoral scan, upper jaw without the pre-existing complete removable denture, occlusal view.

and automatically compensate for these deviations [37–39]. It corrects deformations and ensures that the final model is accurate and repeatable, which is challenging to achieve with a conventional scan alone [37–39]. The calibrated framework eliminates errors, enhances precision, and guarantees reliable results for prosthetic manufacturing [37–39].

The data from the position corrections conducted using RingFix® and, thus, the IOSFix® software revealed error corrections consistent in the different spatial planes during the conventional IOS scans; without the corrections provided by the CSF, the clinical precision of the restorations upon delivery would likely have been lower due to these errors. Additionally and unsurprisingly, according to the mixed effects model used to investigate whether the arch affected the error measures, AxisDelta differed significantly between the lower and upper arches ($p < 0.001$). Specifically, the upper arches had lower AxisDelta values than the lower arches. This finding is logical and consistent with the reported evidence [11–14,16–19] since scanning the edentulous lower jaw is much more complex than scanning the upper jaw due to the lack of stable landmarks (the hard palate) and the presence of mobile elements (tongue). Finally, AxisDelta values were lower for restorations with >4 implants than those with 4 implants.

Our results are consistent with those reported in three studies [37–39]. A recent *in vitro* study by Revilla-León et al. investigated the accuracy of full-arch scans captured using an IOS, desktop scanner, and photogrammetry (PG), obtained with and without connecting the implant SBs [37]. A master model with six implant analogs was prepared and scanned using four different IOSs (Trios 4® [3Shape], i-700® [Medit], IS 3800® [DEXIS], and iTERO Element 5D Plus® [Align Technology]), a desktop scanner, and PG. The IOS and desktop scanner groups were divided into three subgroups: unconnected SBs, splinted SBs, and CSF (RingFix®; IOSFix Dental). The CSF was manufactured by combining milled and additive approaches and contained milled truncated cone-shape markers, whose position in the metal framework was measured during the manufacturing process with a CMM; this framework was used to splint the implant SBs and assists in the full-arch intraoral implant digital scanning since it allowed calculating the implant position on the virtual definitive implant cast by using the position of the calibrated markers as a reference. Fifteen scans were captured for each subgroup. Finally, scans were captured using a PG (PIC dental) for the PG group. The implant positions on the reference cast were measured using a CMM, and the Euclidean distances were used as a reference to calculate the discrepancies using the same distances

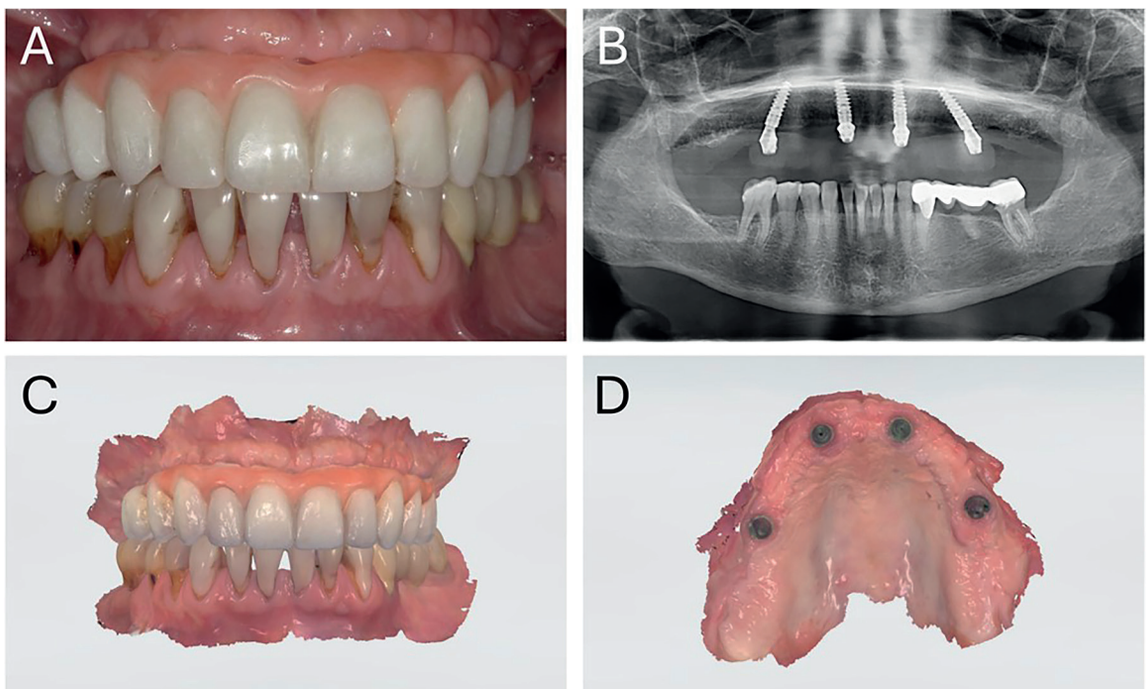


Fig. 12. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Surgery and delivery of the immediate temporary prosthesis.
(A) Post-operative clinical picture with the immediate temporary prosthesis, frontal view; (B) Post-operative panoramic radiograph; (C) Post-operative intraoral scan (Trios 3®, 3SHAPE, Copenhagen, Denmark) with the immediate temporary prosthesis, frontal view; (D) Post-operative intraoral scan without the immediate temporary prosthesis, occlusal view.

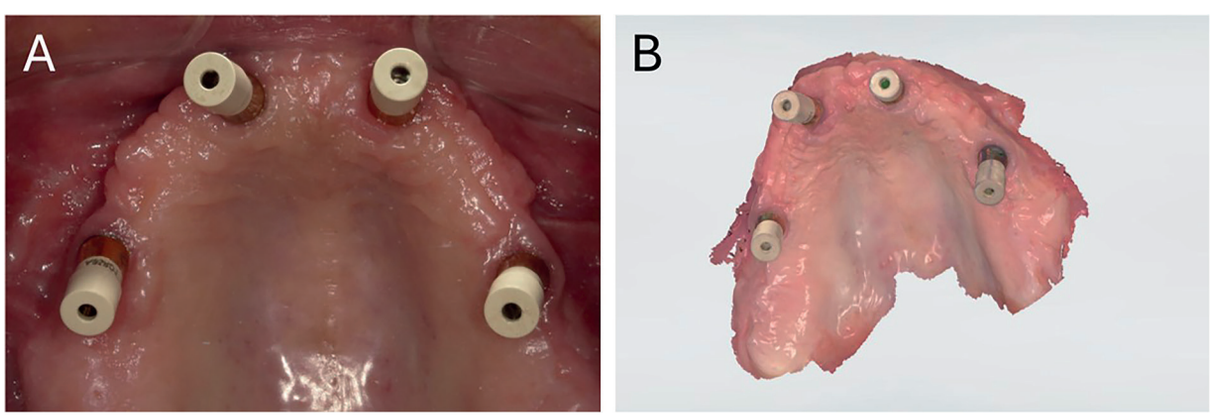


Fig. 13. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). First intraoral scan with the implant scanbodies (SBs).
(A) Clinical picture with the scanbodies (SBs) (IPD Dental®, Matarò, Barcelona, Spain) in position, occlusal view; (B) Intraoral scan with the scanbodies (SBs) in position, prospective jaw.

obtained on each experimental scan. The study found significant discrepancies and precision differences among the groups and subgroups, concluding that the digitizing method impacted the trueness and precision of the implant scans. The accuracy was highest in the PG and CSF (RingFix®) groups. Additionally, the CSF method improved the accuracy of the scans obtained using the tested IOSs (except for TRIOS 4®) [37]. These results confirmed what had emerged in previous clinical reports, where the same CSF (RingFix®) was used to splint the SBs and increase the accuracy of complete arch intraoral implant digital scans [38,39].

The concept of using a CSF to verify and correct stitching errors and distortions caused by intraoral scanning is not new since it has already been presented in prior *in vitro* studies [34–36] and *in vivo* clinical reports [34]. Iturrate et al. presented a methodology to evaluate the accuracy of IOSs *in vivo* [34]. A feature-based gauge was first designed, manufactured, and measured in a CMM to collect reference distances and angles. Then, 10 scans were taken using an IOS with the gauge in the patient's mouth, and from the obtained STL files, 40 distances and 150 angles were measured and compared to the reference values. The deviations in measured distances showed that accuracy worsened as the scanning area increased: trueness varied from 18 ± 21 μm in a distance equivalent to the space spanning a four-unit bridge to 106 ± 80 μm in a space equivalent to a full arch. In contrast, angle deviations did not worsen: they were low and did not differ significantly. The authors concluded that their proposed methodology could contribute to standardizing the procedure to assess the accuracy of IOS *in vivo* [34].

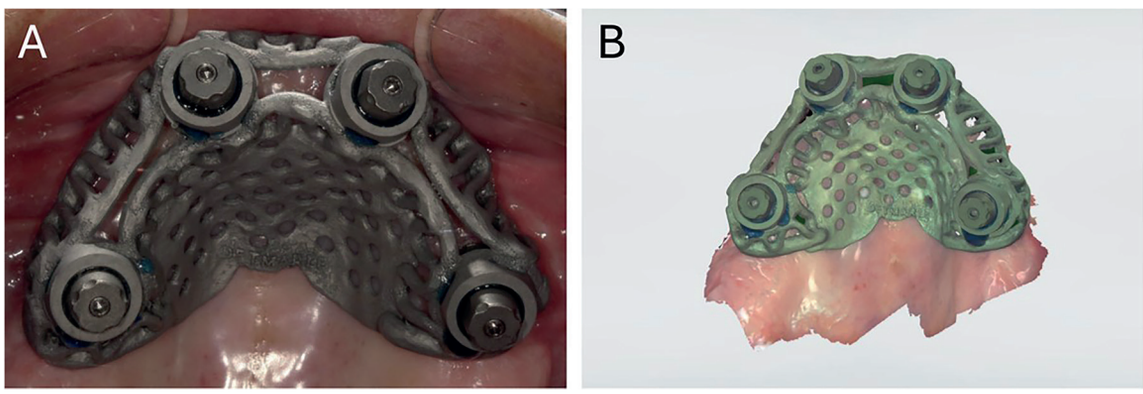
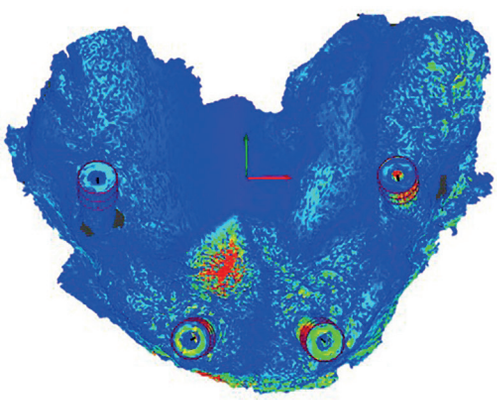


Fig. 14. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Second intraoral scan, with the calibrated framework.
(A) Clinical picture of the calibrated framework (RingFix®, IOSFix Dental, Madrid, Spain) in position, occlusal view; (B) Intraoral scan with the calibrated framework in position, occlusal view.



	CenterDelta	CenterDeltaZ	CenterDeltaXY	AxisDelta
Abutment1U	0.018	0.016	0.009	0.052
Abutment2U	0.050	0.039	0.032	0.600
Abutment3U	0.048	0.035	0.033	0.357
Abutment4U	0.017	0.010	0.014	0.415
Mean	0.034	0.025	0.022	0.356
SD	0.0	0.012	0.011	0.197

Fig. 15. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Corrections of the implant position through the calibrated framework. Colorimetric map of the upper jaw mesh correction with tabulated details of the related corrections.

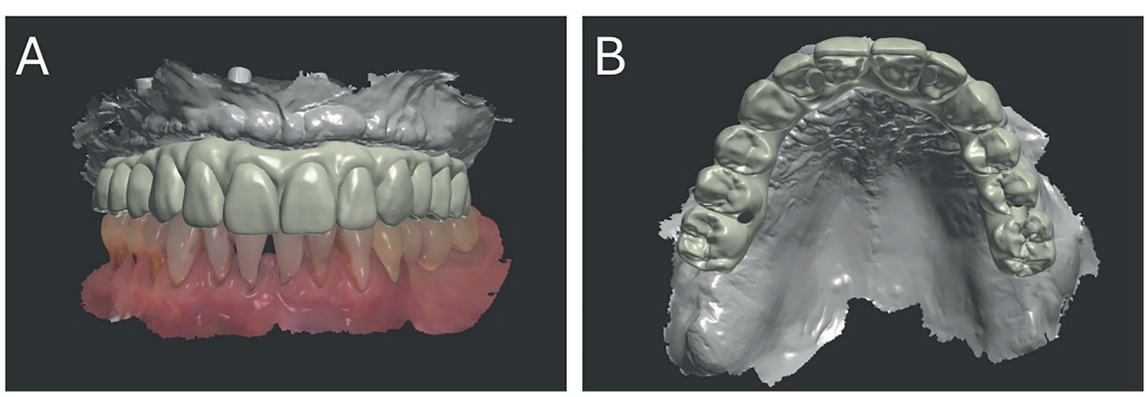


Fig. 16. Second case. Rehabilitation of the upper jaws with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Computer-aided-design (CAD) (Galway®, Exocad, Darmstadt, Germany) project based on the corrected implant positions.
(A) Upper jaw ISFAFDP CAD project, frontal view; (B) Upper jaw ISFAFDP CAD project, occlusal view.

Another similar proof-of-concept study by Schmidt et al. [47] introduced a method based on a custom-made measuring aid (CMA) to assess inter-implant dimensions. An implant master model was digitized using computed tomography, a CMA was fixed on the impression posts, and the inter-implant dimensions were recorded using a CMM. Ten impressions per group were taken to compare conventional and digital impression techniques. The CMA method and the two impression techniques were then compared. Finally, the new 3D method was applied in vivo to three patients. The mean deviation in inter-implant distances ranged from 10.3 ± 18 μm (CMA) to 41.7 ± 36 μm (conventional). Differences existed between the CMA and different impression techniques. In vivo, the inter-implant distances ranged from 42.3 to 376.7 μm (digital) and from 58.3 to 274.0 μm (conventional). Differences existed between techniques. The authors concluded that the developed method using a CMA was helpful in assessing the true inter-implant distances with higher accuracy than conventional or digital implant

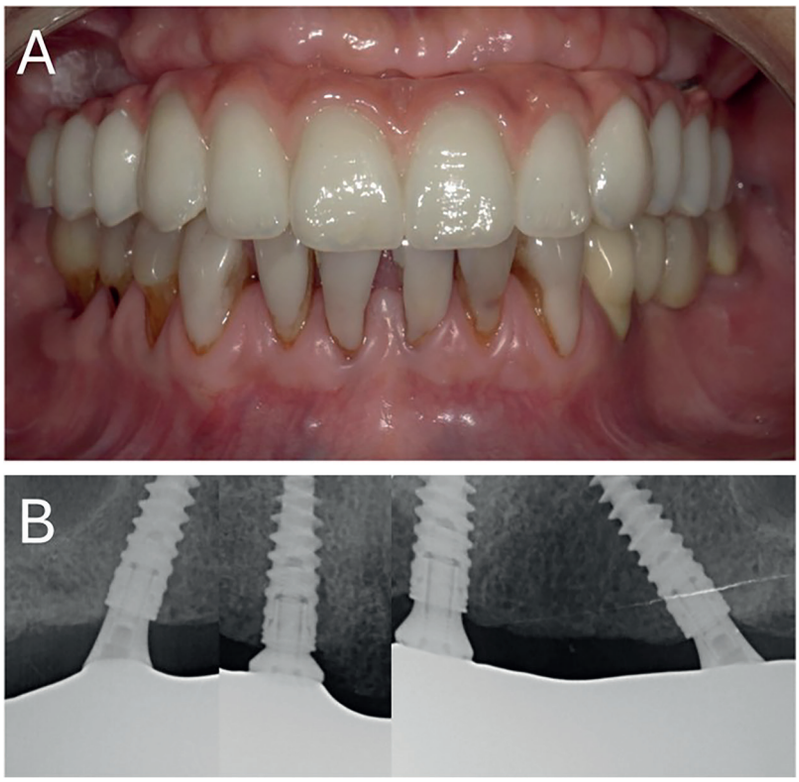


Fig. 17. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). Delivery of the final monolithic zirconia ISFAFDP.
(A) Clinical picture of the final monolithic zirconia ISFAFDP in occlusion, frontal view; (B) Radiographic control of the marginal adaptation.

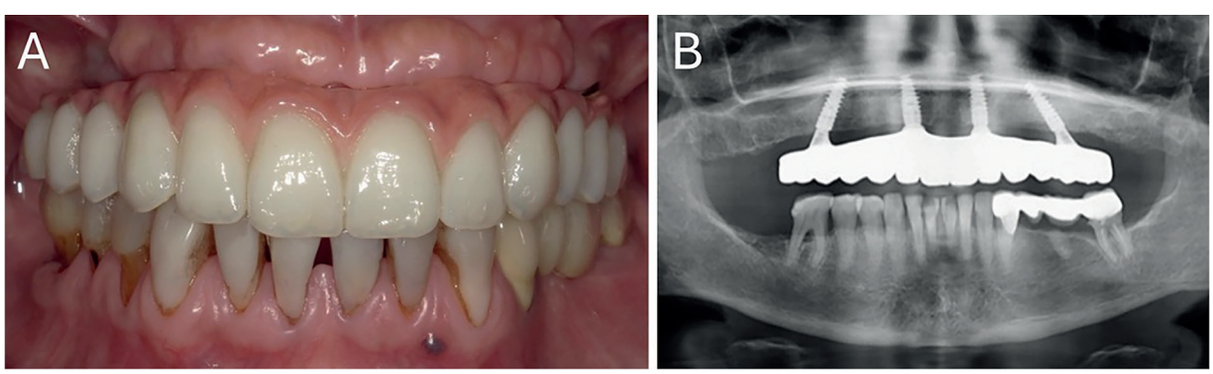


Fig. 18. Second case. Rehabilitation of the upper jaw with an implant-supported full-arch fixed dental prosthesis (ISFAFDP). One year follow-up control.
(A) Clinical picture of the final monolithic zirconia ISFAFDP in occlusion 1 year after the delivery, frontal view; (B) Panoramic radiograph at 1 year.

impressions [47]. In vivo, the CMA generated clinically useful results for assessing inter-implant positions.

Our study has the merit of reporting clinical results obtained by applying these principles to a cohort of 37 patients successfully, as the ISFAFDPs were clinically precise at delivery in all cases, showing perfect fit and passive adaptation. This precision may have contributed to the low prosthetic complication rate (4.4 %) during the one-year follow-up.

Naturally, our study had limitations. It was retrospective, conducted on a restricted cohort of patients ($n = 37$), and had a limited follow-up (one year after delivery of the definitive ISFAFDP). Therefore, further prospective clinical studies and possibly randomized controlled clinical trials are needed to clarify the effectiveness and accuracy of using calibrated frameworks for splinting implant SBs. Finally, the specific system used in this study (RingFix®; IOSFix Dental) has proven predictable and can represent a valid solution for clinicians who want assistance from a system with sustainable costs and that is open (i.e., allows the modeling of the final restorations by dental technicians and not external services, as is the case with other systems). However, the present system is limited by the need for two intraoral scans (an initial scan to model the CSF, which is manufactured by an external service, and a final scan with the CSF *in situ*) at two times and, thus, a minimum of two appointments to finalize the case; furthermore, connecting the scan transfers to the CSF takes time and is operator-dependent.

5. Conclusions

Within its limitations (retrospective design, limited number of patients enrolled at a single clinical center, and short follow-up time), our retrospective clinical study has demonstrated in a cohort of 37 patients that all 45 monolithic zirconia ISFAFDPs manufactured using a direct

digital workflow (based on an IOS scan of implant position corrected using a CSF) were clinically precise at delivery, showing excellent adaptation onto the fixtures and ideal fit, both clinically and radiographically. This precision may have contributed to the low prosthetic complication rate (4.4 % at the restoration level) of the ISFAFDPs during the one-year follow-up, with an overall survival rate of 97.8 % at the restoration level, with only one fractured prosthesis. However, further prospective multicenter clinical studies with larger patient cohorts are needed to confirm the positive clinical outcomes emerging from our study.

Abbreviations

IOS: intraoral scanner; FS: face scanner; CBCT: cone beam computed tomography; 3D: three-dimensional; CAD: computer-aided-design; CAM: computer-assisted-manufacturing; ISFAFDP: implant-supported full arch fixed dental prosthesis; CSF: calibrated splinting framework; SB: scanbody; MUA: multi-unit abutment; CAPS: complete-arch pillar system; CMM: coordinate measuring machine; STL: standard tesselletion language; CI: confidence interval; PG: photogrammetry; CMA: custom-made-measuring-aid.

CRediT authorship contribution statement

Filippo Rustichini: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Conceptualization. **Roldano Romolini:** Visualization, Software, Resources, Methodology, Investigation, Formal analysis. **Maria Chiara Salmi:** Writing – review & editing, Validation, Supervision. **Leonardo Gennai:** Supervision, Funding acquisition. **Francesco Vermigli:** Writing – review & editing, Project administration, Funding acquisition. **Francesco Guido Mangano:** Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

No conflict of interest is reported for this retrospective clinical study.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2025.105605.

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