Journal of Dentistry 139 (2023) 104741

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent

Full-arch restoration with the NEXUS IOS® system: A retrospective clinical evaluation of 37 restorations after a one year of follow-up

Michael Klein [a,*], Frank J. Tuminelli [b], Anthony Sallustio [c], Graziano D. Giglio [d], Henriette Lerner [e], Robert W. Berg [d], Allon Waltuch [a]

[a] Private Practice, Cedarhurst, NY, USA
[b] Diplomate & Director, American Board of Prosthodontics, Director, Graduate Prosthodontics VA NY Harbor Healthcare System, Adjunct Clinical Instructor, NYU Dental School, Clinical Assistant Professor, Hofstra Northwell School of Medicine, New York, NJ, USA
[c] Chief of Maxillofacial Prosthetics, The Regional Craniofacial Center, St. Joseph's Hospital, Paterson, NJ, USA
[d] Private Practice, New York, NY, USA
[e] Academic Teaching and Research Institution of Johann Wolfgang Goethe-University, Frankfurt am Main, Private Practice, Baden, Germany

ARTICLE INFO

Keywords:
Full-arch implant restorations
Full digital workflow
Intraoral scanner
Implant impressions
Scan gauges
Implant supported full arch fixed dental prostheses
Precision, survival, complications

ABSTRACT

Objectives: Report the results with a novel workflow of digital restoration for completely edentulous patients with implant supported full arch fixed dental prostheses (ISFDP).
Methods: This multicenter retrospective clinical study was based on the evaluation from a cohort of 29 patients restored with 37 ISFDP designed and manufactured from the data captured by a direct intraoral scan, using a novel full digital system (NEXUS IOS®, Osteon Medical, a Keystone Dental Group company, Melbourne, Australia). Data was collected over a 3-year period, in six different dental centers. This study reported on the clinical parameters including: precision of marginal fit, functional and aesthetic integration of Nexus ISFDP. All patients were followed for a period of one year post delivery. Implant survival, biologic and prosthetic complications were assessed, at one year. A statistical analysis was conducted.
Results: All 37 ISFDP were deemed clinically acceptable on insertion. Implant survival at one year was 100 %. The biologic and prosthetic complications were minimal during the follow-up period.
Conclusions: ISFDP, designed and manufactured using the NEXUS IOS® system, are clinically acceptable, with a low incidence of complications at one year. Long-term clinical studies are needed.
Statement of clinical relevance: Within the limitations of this study (retrospective design, small patient sample, limited follow-up) the NEXUS IOS® system seems to represent a viable solution for the restoration of completely edentulous patients with ISFDP, in a full digital workflow.

1. Introduction

The innovative technology of intraoral scanners (IOS) has revolutionized restorative dentistry [1,2]. Studies have proven intraoral scanning to be precise and clinically predictable in capturing digital data that can be utilized in computer assisted design (CAD) software and processed with computer assisted manufacturing (CAM). The scanning for the fabrication of single crowns [3–5] and fixed partial prostheses [6,7] are universally accepted and rapidly becoming the standard of care.

The challenge presented by the scanning of 4–8 implants in the completely edentulous patient, with accuracy for full-arch (FA) restorations has not been predictable [8,9]. The literature indicates that IOS are not accurate enough due to stitching errors that accumulate during the scanning of the completely edentulous arch [8,9]. Thus, the acquisition of a clinically valid impression cannot be guaranteed [1,8-11].

A recent clinical study by Imburgia and colleagues [12] demonstrated that intraoral scanning can allow the milling of clinically precise monolithic zirconia for implant supported full arch fixed dental prostheses (ISFDP) in completely edentulous patients. This was accomplished with 6–8 implants. The authors reported, the key factors for

Abbreviations: Intraoral scanners, IOS; Implant supported full arch fixed dental prostheses, ISFDP; Computer-assisted-design, CAD; Computer-assisted-manufacturing, CAM; Full-arch, FA; Scanbody, SB; Scan gauges, SG; Multi-unit-abutments, MUA; Artificial intelligence, AI; Standard tesselletion language, STL; Polymethyl-methacrylate, PMMA; Bleeding on probing, BOP; Probing depth, PD; Confidence interval, CI; Polyether-ether-ketone, PEEK.

* Corresponding author.
E-mail address: mkdds@optonline.net (M. Klein).

https://doi.org/10.1016/j.jdent.2023.104741
Received 7 September 2023; Received in revised form 8 October 2023; Accepted 10 October 2023
Available online 11 October 2023

capturing a high-quality optical impression are: 1) the use of an accurate IOS [13]; 2) the scanning technique, with the proposal of a scanning strategy named "continuous scan strategy", consisting of connecting the scanbodies (SB) using thermoplastic resin; 3) the choice of metal SB, dimensionally stable over time with more stringent manufacturing tolerances [14]; 4) insuring congruence between the SB's meshes captured during the scan, and the corresponding library file [15]; and 5) the attention and care in the milling of the engagements between the selected bonding of bases and the prosthetic structure [16].

The meticulous control of all these factors, however, is not a trivial matter. This can make the capture of a FA implant impression extremely complex, unpredictable and cost prohibitive [9–18].

Recently, the scientific literature has proposed alternative systems to simplify the capture of the FA implant impression. Approaches such as the use of stereophotogrammetry [19], or the use of auxiliary devices [20–23] used to eliminate the stitching error and improve the quality of the scan have been reported. With photogrammetry there is a significant financial investment in addition to a conventional intraoral scanning system. When using auxillary devices the impression is made using an IOS, but there is a requirement to scan the patient twice: first an intraoral scan of the implants and soft tissue followed by the fabrication of an auxillary device with a second scan of the auxillary device connected to the implant abutments [20–23].

An alternative to the use of auxiliary devices is the NEXUS IOS® system. The NEXUS IOS® system uses modular scan gauges (SG), of different shapes, lengths and heights. These scan gauges are screwed onto the multi-unit-abutments (MUA) of the various implant systems on the market. The design of these scan gauges reduces or eliminates the distances between the implant positions allowing for a continuous scanning flow [12]. The SG are in titanium, and are coupled to fully customized libraries. This unique SG system is designed to simplify the scanning procedure, enable a more accurate scanning strategy, eliminate the negative influence of manufacturing tolerances, as well as the material distortion over time inherent with conventional SB [14].

The purpose of this clinical retrospective study is to present the results obtained with the NEXUS IOS® system. The cohort was collected from a group of experienced clinicians in the fabrication of full digital restorations for completely edentulous patients with ISFDP.

2. Materials and methods

2.1. Study design

This multicenter, retrospective report was based on a cohort of 29 patients that received an ISFDP (NEXUS IOS® system, Osteon Medical, a Keystone Dental Group company, Melbourne, Australia) following digital protocol. These restorations were delivered over a 3-year period (March 2020-May 2023), in 6 different dental centers. Patients were enrolled based on specific inclusion and exclusion criteria.

Criteria for inclusion were: 1) fully edentulous patients who had received 4–8 implants in the maxilla and/or mandible, and subsequently restored with a final ISFDP following a full digital workflow, using the NEXUS IOS® system; 2) a complete dental record of each enrolled patient: including the complete clinical, radiological and laboratory dataset, inclusive of photographs, radiographs and a report of any complications. The data was collected both at the delivery of the provisional and final prostheses, and at the 1-year follow-up 3) compliance with biannual routine prophylaxis and exams; and (4) follow-up of at least 6-months after the delivery of the final prosthesis.

Exclusion criteria were: 1) patients with severely compromised systemic health (such us, immunocompromised status, uncontrolled diabetes, or other); 2) patients under treatment with oral and/or intravenous amino- bisphosphonates; 3) patients who had underwent major reconstructive bone surgery prior to implant insertion (guided bone regeneration with membranes, or treatment with autologous, homologous or heterologous onlays/inlay grafts). Smoking and a history of parafunctional habits (grinding, bruxism) was not a criteria for exclusion.

Prior enrollment patients received detailed information on the procedures, and their related risk. An informed consent was obtained for the intended procedures and prosthetic restorations. The study was conducted in full compliance with and respecting the guidelines of the Declaration of Helsinki (concerning the "Ethical Principles for Medical Research Involving Human Subjects", revision 2008).

2.2. Intraoral scan with NEXUS SG

After adequate time for osseointegration (4–6 months after implant placement), intraoral scans were made with the immediate provisional restoration in situ (maxilla, mandbile and occlusal relationship) the gingival presentation (emergence profile scans) around the fixtures, and after the removal of the provisional restoration. The final position of the implants was captured using the Nexus Scan Gauges (SG) (NEXUS IOS® System, Osteon Medical, Melbourne, Australia). The SG are in metal and of different sizes, each one with a specific code corresponding to a specific library file. The files are obtained by precision probing, positioned by the clinician in order to perfectly align the SG and to reduce the distances existing between the fixtures. The SG were screwed directly onto the MUA and were captured in full, with their alignment guiding the scan path utilized by the operator during the execution of the scan, the operator must capture 7 of the characteristic faces of each SG. This results in the best possible replication of implant positions, and completes the FA implant scan.

2.3. Design and manufacture of the final implant-supported FA restoration

The complete set of data (foundation scans, provisional scans, emergence profile scans, Nexus SG scans and patient photos) was sent to Osteon Medical with the digital prescription for the requested laboratory work. The Nexus Portal is utilized for this (nexusios.com). The specialists at Osteon Medical thru a series of reviews of all data for completeness and accuracy, with the use of proprietary artificial intelligence (AI) and technology was completed eliminating corrupted data and validating correct abutment position. The use of custom libraries for each SG, identified with AI and unique identifiers eliminated any error inherent in SG manufacturing tolerances. Following verification of accurate and complete data, a virtual waxup of the final prosthetic plan was made using a CAD software (DentalCad®, Exocad, Darmstadt, Germany). The design of the final prosthesis was based on an analysis of the provisional prosthesis, as well as on the specific instructions given by the prescribing clinician. This overall prosthesis design was mated with proprietary AI software to aid in designing the supporting titanium framework (bar). This software enforces mechanical engineering principles to ensure the strength of the bar, taking into consideration the individual esthetics, functional, and occlusal parameters designed in the virtual waxup. The prescribing clinician was emailed the digital plan for approval and comment. The clinician reviewed the design proposal via the Nexus Portal (nexusios.com) utilizing an Exocad 3D viewing tool and was able to approve the design or request modifications. Once approved, a Try-In version of the final prosthesis, can be requested in a standard tessellation language (STL) file. This file could be 3D printed or milled by the clinician or a lab, for purposes, evaluating the precision of the planned final restoration intra-orally. This process provides a significant advantage aiding in determining optimal function, esthetics and phonetics. The Try-In may be re-scanned if changes were made, and again uploaded to the Nexus Portal (nexusios.com). The necessary modifications to the final design are evaluated and implemented at Osteon Medical. The clinician may request a final review following these modifications or indicate that the design is approved pending Osteon making the requested modifications. Following final approval of the design proposal, manufacturing of the final prosthesis is commenced.

The final ISFDP in all cases consisted of a titanium frame, overlayed with zirconia or polymethyl methacrylate (PMMA) restoration. The bars were milled from titanium blocks (Ti-5) in a 5-axis industrial milling machine (DMG-Sauer Ultrasonic 20 linear®, DMG Mori Seiki Co. Tokyo, Japan). The tooth overlay was milled from the requested material (monolithic zirconia or PMMA) using a 5-axis milling machine (DWX-52D®, DGSHAPE a Roland, Hamamatsu, Japan). The zirconia tooth alveolar substitutes were stained and sintered. Tones for artificial gingiva were heated during sintering and hardened (Tabeo®, Mihm-Vogt Co., Stutensee, Germany).

Various post-sintering stain and glazing occurred with each case, based on requests by the clinician during ordering, including porcelan layered zirconia to the facial-side teeth. PMMA material overlays went through a process of adding acrylic composite for characterization and depth. The titanium bar went through a polishing process to achieve a high-shine finish on the intaglio surface where appropriate. Following the manufacture of the overlay component (zirconia, PMMA) the final prosthesis was completed by preparing and assembling the bar with the overlay using a proprietary luting process. Quality control was performed all steps of the manufacturing process. At delivery, the fit and adaptation of the final restoration was carefully checked. A mutually protected occlusion was verified with the use of articulating paper.

2.4. Outcomes variables

The following variables were reviewed from the medical records of patients who were retrospectively enrolled:

1 Fit and adaptation (i.e. Clinical Precision), functional and aesthetic integration of the final implant-supported fixed FA restoration;
2 Implant survival;
3 Biologic complications;
4 Prosthetic complications.

The clinical precision was the main outcome of this study, checked at the delivery of the final prosthesis. Implant survival, the incidence of biologic and prosthetic complications were the secondary outcomes, and were assessed at the 1-year follow-up.

2.4.1. Clinical precision

The marginal adaptation and passive fit (i.e. Clinical Precision) of the final restoration along with the accuracy of this digital workflow was the focus of this evaluation. This was recorded at the time of delivery of the final restoration. Passive fit and adaptation were checked clinically by the operator using the Sheffield test. Accuracy was also assessed by finger pressure as the prosthesis was seated onto the respective MUA. Accuracy of fit and marginal adaptation was confirmed radiographically.

2.4.2. Implant survival

Implant survival was assessed at the delivery of the final restoration, and at the 1-year follow-up via radiograph, and clinical examination inclusive of the peri-implant tissues. Implant failure necessitating removal was defined as loss of osseointegration, implant mobility, progressive marginal bone loss and implant body fracture.

2.4.3. Biologic complications

Biologic complications included: 1) pain or swelling; 2) peri-implant (hyperplastic) mucositis; 3) *peri* implantitis; and 4) progressive bone loss (>2.5 mm) in the absence of peri-implant infection. It was assumed this was attributed to mechanical overload. Peri-implant mucositis was a condition indicated by the presence of bleeding on probing (BOP) and/or suppuration, associated with probing depth (PD) >4 mm, with no evidence of radiographic bone loss beyond bone remodeling [24]. The threshold of peri-implantitis was at a PD≥6 mm, BOP, and/or exudate associated with clear evidence of radiographic bone loss (>3.0 mm) [24].

2.4.4. Prosthetic complications

The prosthetic and functional complications were recorded at the 1-year follow-up. These were drawn from individual patients' records. Among these complications, as described by Salvi and Bragger [25], were mechanical (i.e. complications affecting components directly supplied by the company, for example MUA, screw loosening), and technical (i.e. complications affecting the final FA restoration, for example prosthesis fracture, chipping, fracture of the veneering material, or wear). All complications were carefully registered and, if possible, managed directly during the follow-up visit, If the complication could not be managed at the one year follow-up additional appointments were made as needed, however this was very rare.

2.5. Statistical analysis

All clinical, radiological and laboratory data for the present study were retrospectively collected by a single experienced operator (M.K.). Customized dental records/folders of patients treated with a NEXUS IOS® ISFDP, from March 2020 to May 2023, served as the cohort. All data were entered into a spreadsheet (Excel 2003; Microsoft Corporation, Redmond, WA). Descriptive statistics were used stratify distribution of patients, the implants, and of the restorations. In addition it served to calculate the incidence of implant failures and biologic and prosthetic complications one year after the delivery of the final ISFDP. The qualitative variables (gender, smoking habit, bruxism, distribution of implants per location, position, length, and diameter) were expressed in absolute values and in a percentage of the total. For quantitative variables (age at surgery), mean, standard deviation, median, range and confidence interval (CI) 95 % were computed. A restoration-based approach was used to calculated the clinical precision, and an implant-based approach was used to calculate the implant survival rate. Once again the data was obtained one year after the delivery of the final restoration. In the implant-based approach, the implant was considered the statistical unit; in the restoration-based approach, the statistical unit was represented by the ISFDP.

3. Results

This retrospective clinical study consisted of 29 patients (14 males, 48.3 %; and 15 females, 51.7 %).

All members of the cohort had been rehabilitated with ISFDP for a total of 37 arches. The breakdown was: 8 patients, corresponding to 27.6 % received complete rehabilitation (maxilla and mandible); while 21 patients, 72.4 % were restored either with a single maxillary or mandibular prostheses. Ten patients were under 65 years of age (34.5 %), 19 were 65 years of age or older (65.5 %). The mean age at the time of surgery, for the cohort was 70.6 years (±12.6), median 74 years, range 41–89 years, CI 95 % 66.1–71.1 years. Among the selected patients, 5 (17.2 %) were smokers, and 7 (24.1 %) had a history of parafunctional habits.

Of the 37 ISFDP, 17 (45.9 %) were placed in the maxilla, and 20 (54.1 %) mandible. There was a total of 203 implants (85 in the maxilla, 41.9 %; and 118 in the mandible, 58.1 %). With regard to the implants used in the maxilla, 15 maxillary implants were anchored in the zygoma (19.4 %). The following is a breakdown of the implant manufacturers, brand, and frequency: 72 BLX® (Straumann, Basel, Switzerland), 37 Paltop® and 37 Prima Plus® (Keystone Dental, Burlington, MA, USA), 25 Biohorizon® (Biohorizon Implants, Birmingham, AL, USA), 20 NobelActive® (Nobel Biocare, Zurich, Switzerland), 8 Southern® (Southern Implants, Irene, South Africa) and 4 Genesis® implants (Keystone Dental, Burlington, MA, USA).

One hundred percent of the patients were evaluated at one year. All implants osseointegrated successfully and maintained osseointegration. The final ISFDP were delivered four months after the patients underwent

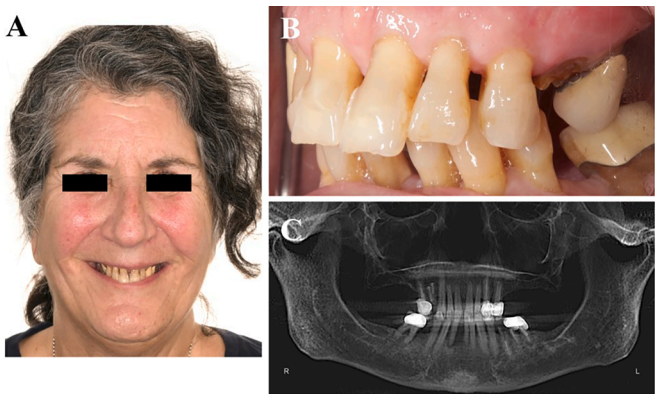

Fig. 1. Pre-operative status. (A) Patient with chronic periodontitis and (B) attachment loss with an unstable occlusion; (C) pre-operative panorex.

implant placement. Of the final ISFDP 11 (29.7 %) consisted of metal-acrylic and 26 (70.3 %) were zirconia.

All final restorations were screwed to the implants, demonstrated passive fit and marginal integrity . The digital radiographic examination confirmed the marginal integrity, coupled with the clinical evaluation of the superstructures, confirmed the findings of the Sheffield test.

The fixture survival rate was 100 %, at 1 year.

Crestal bone loss was < 3.0 mm for all implants at 1 year, and no incidence of peri-implantitis; however, one patient presented with peri-implant mucositis at 6 months, affecting two maxillary implants. This was successfully managed with professional oral hygiene sessions.

Finally, with regard to prosthetic and functional complications, two patients presented with prosthetic complications . One patient experienced decementation/debonding of the zirconia superstructure. This problem was solved by the dental technician by luting the components. Another second patient experienced fracture of the zirconia; the patient had a significant parafunctional habit (bruxing) The prostheses were re-designed and manufactured to this design. The remainder of the cohort did not report any complications. Two clinical cases solved with the NEXUS IOS® systems are presented in the Figs. 1-16.

4. Discussion

In this retrospective, multicenter clinical report, the NEXUS IOS® system demonstrated excellent clinical results, with an optimal passive fit and marginal integrity in 37 ISFDP. This was confirmed by Sheffield test in 100 % of the restorations and confirmed by radiographic evaluation. It is documented in the literature, that marginal integrity and passive fit are key prerequisites for a successful ISFDP [26,27]. Marginal discrepancies ranging from 10 to 150 micro-meters have been reported as clinically acceptable. Major misfits may evoke biological complications (peri-implant mucositis or peri-implantitis) [27]. In addition, although bone adaptation and decrease in misfit strain were observed in restorations when implants were loaded non-passively [28], mechanical

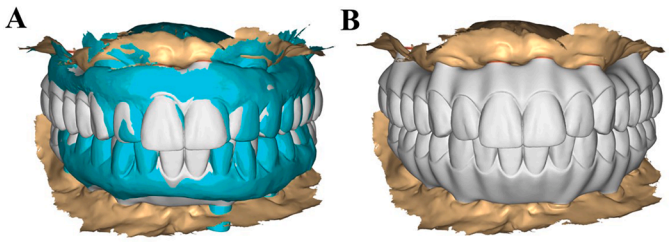

Fig. 3. (A,B). Preview of the prosthetic plan after upload of intraoral scans in addition to soft tissue and provisional scans.

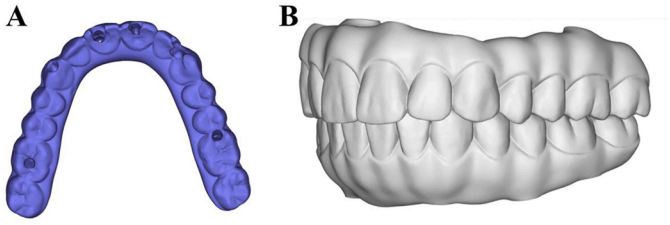

Fig. 4. Computer-assisted-design of the final restorations. (A) Screw channel corrections needed for final prosthetics; (B) lateral view of the prosthetic project.

Fig. 5. Definitive monolithic prostheses with titanium bar optionally anodized gold.

issues may arise, including screw loosening, fracture of the framework, chipping and implant failure [27,29].

In this report, all implant-supported restorations were deemed clinically accurate upon delivery. One can conclude this contributed to the biological and prosthetic complication rates being extremely low. In fact, no major biological complications were reported. Only two patients experienced technical complications. One patient had the mandible and maxilla restored with zirconia Nexus restorations. This patient experienced fracture of the zirconia prostheses at one year. Review of the

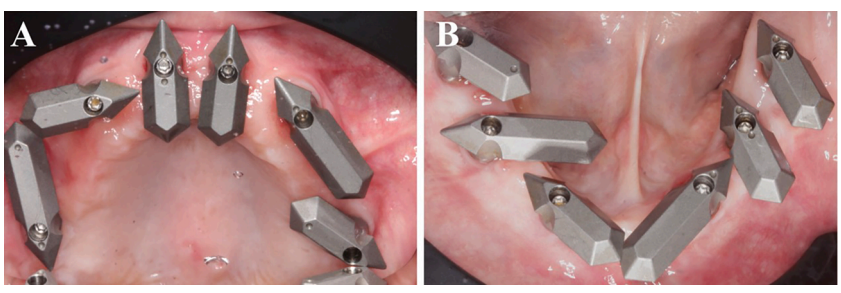

Fig. 2. Upper (A) and Lower (B) scan gauges positioned for intraoral scanning.

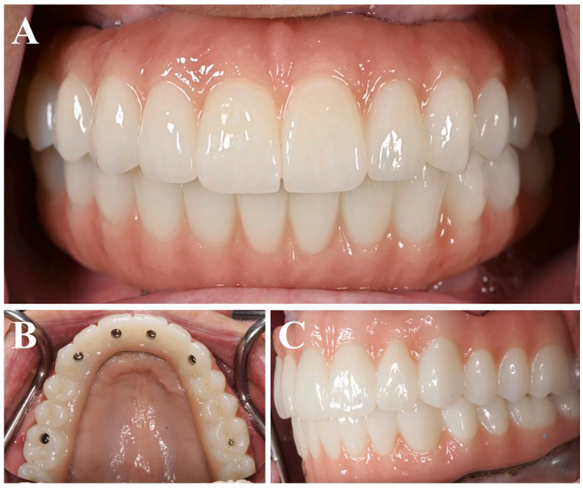

Fig. 6. Delivery of the final restorations. (A) Excellent functional and aesthetic integration with the new fixed full-arch restorations, designed and manufactured with the NEXUS IOS® (Osteon Medical, Melbourne, Australia) system; (B) Detail of the final upper restoration with angulated screw channel corrections; (C) post-operative lateral view with final monolithic zirconia restorations.

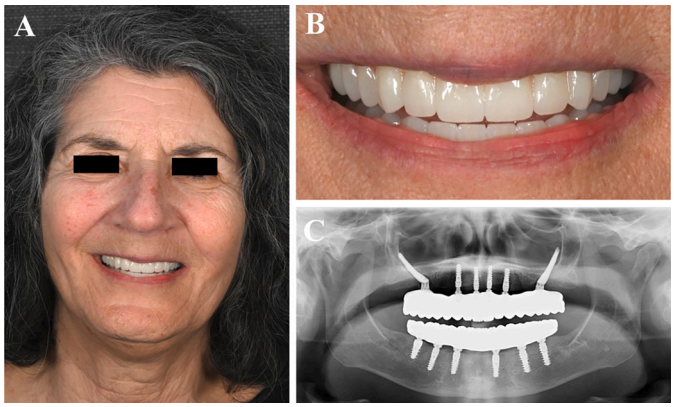

Fig. 7. Post-operative control. (A) Patient face; (B) Patient smile. A significant improvement of the function and esthetics was obtained with a 3-appointment definitive prosthetic workflow; (C) panorex - Straumann BLT® and Zygoma® (Straumann, Basel Switzerland) fixtures with multi-unit abutments.

patients history revealed extreme powerlifting. A redesign of the restorations was required to accomodate for excessive clenching forces. The incidence of technical complications amounted to 8.1 % and is in line with the evidence from the current literature on full arch zirconia restorations [30]. In a recently published retrospective case series, in fact, aiming to evaluate the short-term clinical advantages and limitations of full-arch implant-supported restorations made of monolithic zirconia suprastructures passively luted to titanium bar infrastructures, the authors reported no implant failures and no major prosthetic complications, with a follow-up duration ranging from 12 months to 20 months [30]. In two cases, a fracture line was observed in the zirconia suprastructures, but this did not require any intervention [30].

The results of this report support when optimal prosthetic fit and marginal adaptation are achieved, the prosthetic complications are low, independent of the material choice [29,31]. In a recent systematic review of ISFDP fabricated from monolithic zirconia [31] the authors described satisfactory clinical and aesthetic outcomes with a low incidence of prosthetic and technical complication rate related to this type of prosthesis, with high survival rates [31].

The potential benefits of using the NEXUS IOS® system for scanning are two.

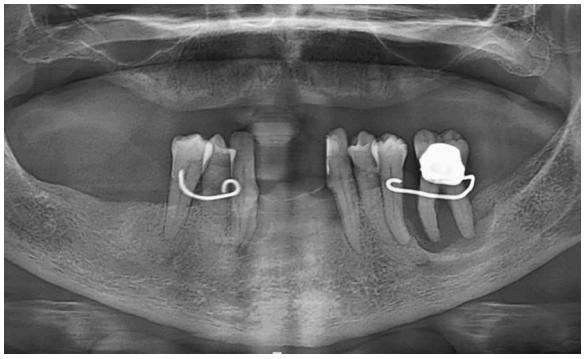

Fig. 8. Second clinical case. The patient's pretreatment panorex demonstrates an edentulous maxilla and failing mandibular dentition.

The use of SG of different heights and lengths, positioned on the MUA arranged horizontally (and not vertically, as is normally the case for SB) allows the SG to be arranged in a configuration eliminating empty spaces and "jumps" between the different scan abutments. In addition the horizontal SG design enables all scannable planes to be seen from the z axis creating a one pass scanning strategy. This horizontal design of different lengths reduces the distances between the implants and minimizes stitching errors caused by stitching multiple images of the same area over each other as the clinician proceeds along the arch scanning the same area multiple times. This is in line with the concept proposed by Imburgia and colleagues [12]. In their clinical study, 35 monolithic zirconia implant-supported full arch restorations were produced by direct intraoral scanning performed with the "continuous scan strategy" by connecting the SB to each other with thermoplastic resin. Recently, In an in vitro study, Pradies and colleagues [32] reported the use of connection devices between different implant SB increased the overall accuracy of intraoral scanning; similar results were reported by Pozzi and colleagues [33,34], in two in vitro studies.

NEXUS IOS® utilizes metal SG. Every SG has a specific geometry and code linked to its unique corresponding library file. This is accomplished by a proprietary process of analyzation and measurement using AI algorithms of every SG. Since the library is specific to each SG, it is possible to minimize errors resulting from manufacturing tolerances. Manufacturing tolerances unfortunately exist with standard SB's, as demonstrated by Lerner and colleagues [14]. The use of a SG system where every SG has a unique library enables optimization of the scanned implant position by comparing the scanned geometry to the actual libraried gauge geometry. The SG has 7 planes allowing the AI algorithms to eliminate scanned planes that do not have adequate data points for accurate matching of the scanned gauges to the known libraried geometries. This leaves only good data for the library matching algorithms. Furthermore, the choice of opting for metal SG avoids geometric distortions over time [15]. SB in polyether-ether-ketone (PEEK) are prone to distortion, particularly after sterilization [15]: the metal is stable and the SG have no limit of use.

NEXUS IOS® relies on a proprietary algorithm, which uses the different faces or facets of the SG to enhance the alignment between the mesh and the library file. This approach insures any distances between the mesh and the implant library which is detrimental and causes a shift of the implant platform from the real to the virtual is reduced or eliminated [29]. It has been demonstrated that an error per SB greater than 20 micro meters can cause a prosthetic misfit of the structure [12]. It is evident that this type of error, combined with stitching, represents one of the major limitations of the direct intraoral FA implant scanning. The ability to reduce or eliminate dimensional discrepancies allows the NEXUS IOS® system to locate the position of the implant in a precise and reliable manner. Thanks to these advantages, the NEXUS IOS® system has the potential to reduce intraoral scanning errors and make scanning for FA implants clinically predictable, resulting in definitive restorations

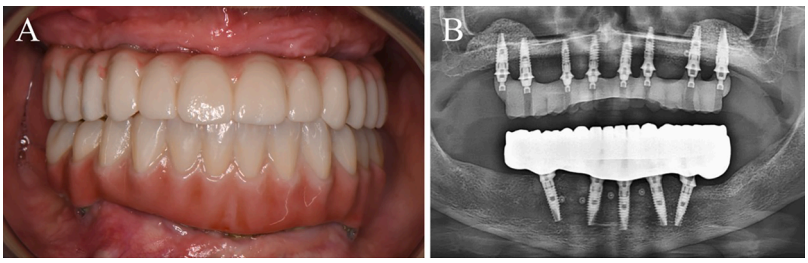

Fig. 9. A maxillary fixed provisional restoration (A) was placed on multi-unit abutments secured to well healed implants; radiographic control (B).

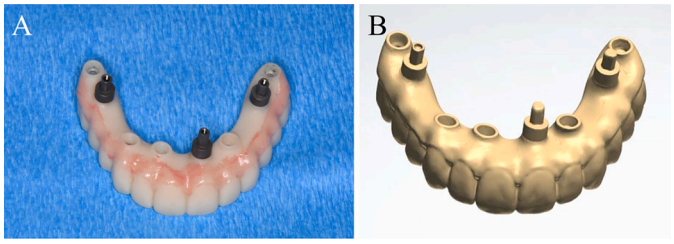

Fig. 10. (A) Three scan analogs are inserted in the provisional restoration in a wide A-P spread; (B) The provisional restoration is scanned with the scan analogs to transfer the existing provisional design.

characterized by optimal fit, passivity and precision. Intraoral scanning for FA becomes accessible, with the entire workflow managed potentially in two appointments. When compared to systems using auxiliary devices to improve the quality of the scan, the advantage here is the reduction in number of appointments and chair time since with NEXUS IOS® a single series of scans is sufficient to be able to obtain a clinically reliable FA implant impression.

Among the limitations of the NEXUS IOS® system, we must include that it is not yet available for direct to implant connections, and that the SG are used on MUA connections exclusively at this time. In addition, the system is not compatible with all the implant brands available on the market (The NEXUS IOS® system is available for most of the larger implant companies as well as MUA restorative platforms that may be

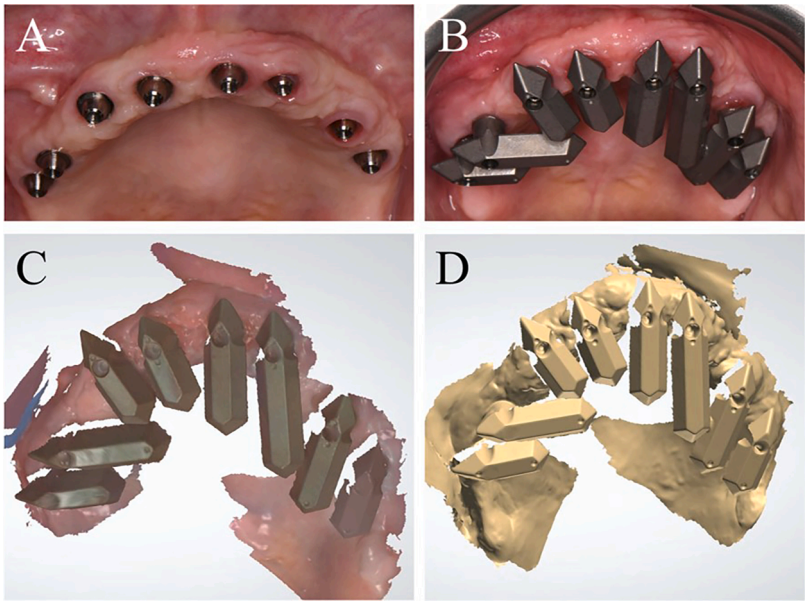

Fig. 11. (A) Well healed soft tissues surround all the maxillary multi-unit abutments; (B)The Nexus scan gauges are secured to the multi-unit abutments; (C,D) The scanning protocol requires two scans, one from a right to left path, and a second from a left to right path.

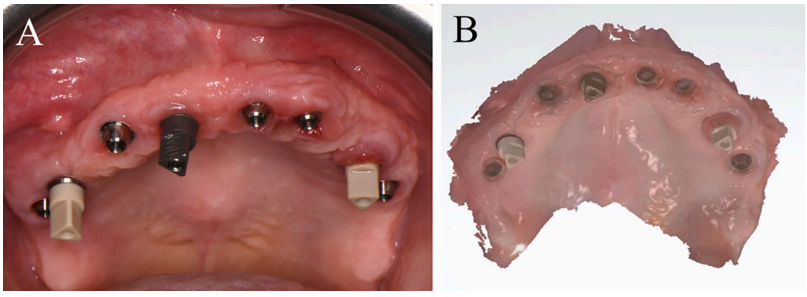

Fig. 12. (A,B) Three narrow scanbodies of the more conventional vertical style are placed on 3 multi-unit abutments in a wide A-P spread, and scanned for emergence profile and intaglio surface design of the restoration.

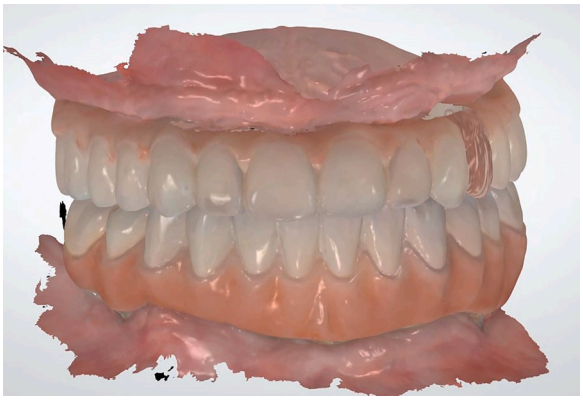

Fig. 13. Foundation scans of the existing provisional restoration, opposing arch and bite are taken.

considered universal). Furthermore, it is necessary to use Osteon Medical to process the data fabricate the final restoration. This may be seen as an advantage as it ensures strict adherence to the designed protocols and controls. This results in a product with precision that is predictable. The present clinical evaluation also has limitations. Firstly, the retrospective design is not the best for drawing specific conclusions regarding the reliability of the method [34]. Second the relatively small number of patients and the short follow-up (1 year after the delivery of the restorations) is a significant consideration. Therefore, prospective studies or randomized controlled trials are needed to confirm the current data in this initial clinical report, and to further validate the system. Third, different implant brands have been used in this study. This may represent a limitation of the present study, but also demonstrates the high level of compatibility of the NEXUS IOS system, with the implant brands currently available on the market.

5. Conclusions

ISFDP, designed and manufactured by a direct intraoral scans, utilizing the NEXUS IOS® systems, are clinically accurate and present high survival and low complication rates, in the short term. Long-term follow-up studies on a larger cohort are needed to confirm these outcomes.

Disclaimer

Dr. Michael Klein, the corresponding author for this study, is a consultant for the Keystone Dental Group. However, the authors report no conflict of interest related to the present study. In fact, all the material used for the preparation of this study belongs exclusively to the authors, who have not received any grant, material, or financial support for the preparation of the present research.

CRediT authorship contribution statement

Michael Klein: Methodology, Software, Visualization, Investigation, Formal analysis, Writing – original draft, Writing – review & editing. **Frank J. Tuminelli:** Conceptualization, Investigation, Supervision, Writing – review & editing. **Anthony Sallustio:** Visualization, Investigation, Formal analysis, Writing – review & editing. **Graziano D. Giglio:** Visualization, Investigation, Formal analysis, Writing – review &

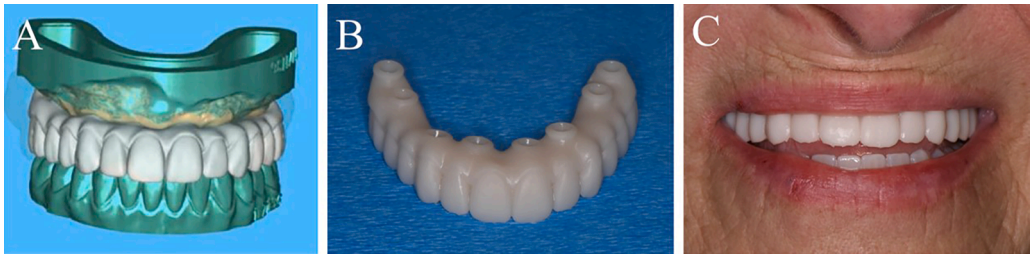

Fig. 14. (A) The design proposal by Osteon is evaluated. (B) The STL file of the design proposal is downloaded and 3D printed. (C) The 3D printed design proposal is tried-in and evaluated for esthetics, phonetics, occlusion and patient approval.

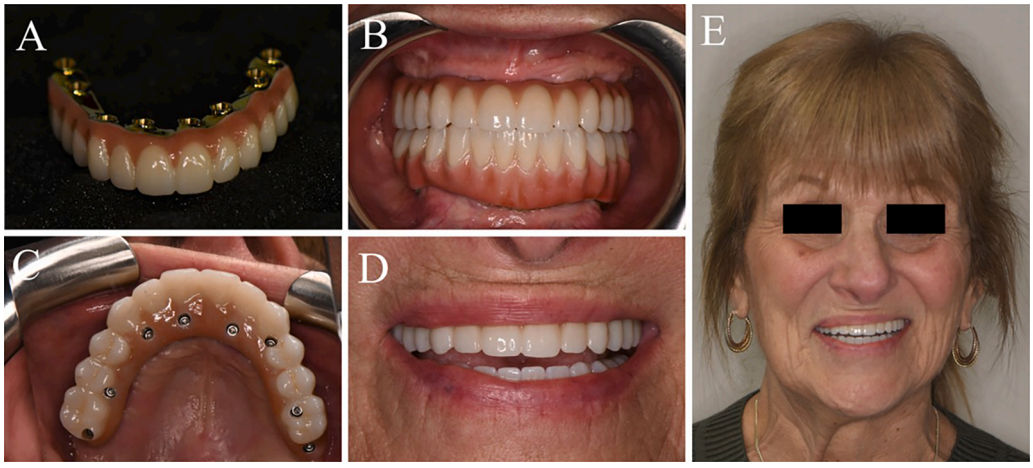

Fig. 15. (A) The final restoration was manufactured from monolithic zirconia and overlaid on a milled titanium bar; (B,C,D,E) the final prosthesis was delivered and evaluated for passive fit, occlusion, soft tissue contact, phonetics and esthetics. Although the patient was recovering from Bell's palsy an acceptable aesthetic result was obtained.

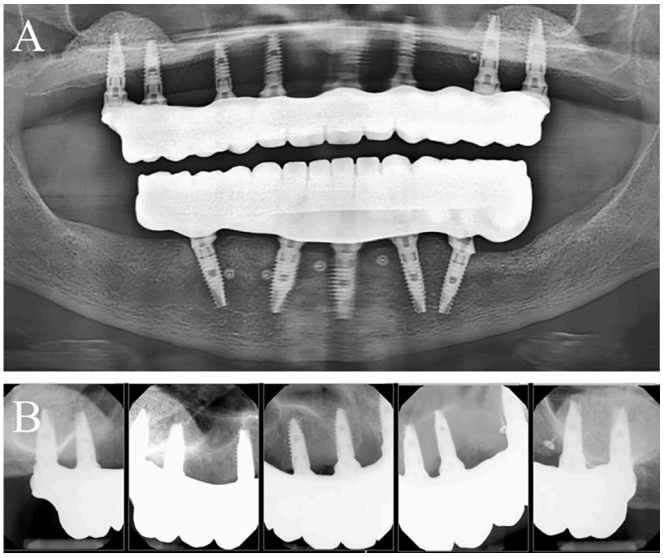

Fig. 16. (A) Radiographic confirmation of a passively seated Nexus restoration with well healed implants; (B) Maxillary and mandibular Nexus restorations (Osteon Medical a Keystone Dental Group company, Melbourne, Australia) supported by Paltop Dynamic implants (Keystone Dental, Burlington, Massachusetts).

editing. **Henriette Lerner:** Supervision, Writing – review & editing. **Robert W. Berg:** Visualization, Investigation, Formal analysis. **Allon Waltuch:** Visualization, Investigation, Formal analysis.

Declaration of Competing Interest

The materials in the present article belongs to the authors, therefore no conflict of interest related to this work is reported. Although Michael Klein is a consultant of Keystone Dental, this study was conducted independently and the authors did not receive any grant or material for the development of this research.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jdent.2023.104741.

References

[1] F. Mangano, A. Gandolfi, G. Luongo, S. Logozzo, Intraoral scanners in dentistry: a review of the current literature, BMC Oral Health 17 (2017) 149, https://doi.org/10.1186/s12903-017-0442-x. PMID: 29233132.
[2] T. Joda, F. Zarone, M. Ferrari, The complete digital workflow in fixed prosthodontics: a systematic review, BMC Oral Health 17 (2017) 124, https://doi.org/10.1186/s12903-017-0415-0. PMID: 28927393.
[3] C. Kunavisarut, W. Jarangkul, S. Pornprasertsuk-Damrongsri, T. Joda, Patient-reported outcome measures (PROMs) comparing digital and conventional workflows for treatment with posterior single-unit implant restorations: a randomized controlled trial, J. Dent. 117 (2022), 103875, https://doi.org/10.1016/j.jdent.2021.103875.
[4] T. Joda, A. Gintaute, U. Bragger, M. Ferrari, K. Weber, N.U. Zitzmann, Time-efficiency and cost-analysis comparing three digital workflows for treatment with monolithic zirconia implant fixed dental prostheses: a double-blinded RCT, J. Dent. 113 (2021), 103779, https://doi.org/10.1016/j.jdent.2021.103779.
[5] T. Joda, U. Bragger, N.U. Zitzmann, CAD/CAM implant crowns in a digital workflow: five-year follow-up of a prospective clinical trial, Clin. Implant Dent. Relat. Res. 21 (2019) 169–174, https://doi.org/10.1111/cid.12681.
[6] S. Mühlemann, G.I. Benic, V. Fehmer, C.H.F. Hämmerle, I. Sailer, Randomized controlled clinical trial of digital and conventional workflows for the fabrication of zirconia-ceramic posterior fixed partial dentures. Part II: time efficiency of CAD-CAM versus conventional laboratory procedures, J. Prosthet. Dent. 121 (2019) 252–257, https://doi.org/10.1016/j.prosdent.2018.04.020.
[7] G.I. Benic, I. Sailer, M. Zeltner, J.N. Gütermann, M. Özcan, S. Mühlemann, Randomized controlled clinical trial of digital and conventional workflows for the fabrication of zirconia-ceramic fixed partial dentures. Part III: marginal and internal fit, J. Prosthet. Dent. 121 (2019) 426–431, https://doi.org/10.1016/j.prosdent.2018.05.014.
[8] Y.J. Zhang, J.Y. Shi, S.J. Qian, S.C. Qiao, H.C. Lai, Accuracy of full-arch digital implant impressions taken using intraoral scanners and related variables: a systematic review, Int. J. Oral Implantol. 14 (2021) 157–179. PMID: 34006079.
[9] M.E. Jennes, M. Soetebeer, F. Beuer, In vivo full-arch accuracy of intraoral scanners: a narrative review, Int. J. Comput. Dent. 25 (2022) 9–16. PMID: 35322648Y.
[10] Chen, Z. Zhai, S. Watanabe, T. Nakano, S. Ishigaki, Understanding the effect of scan span on the accuracy of intraoral and desktop scanners, J. Dent. 124 (2022), 104220, https://doi.org/10.1016/j.jdent.2022.104220.
[11] D.S. Alpkılıç, S.I. Değer, Trueness evaluation of latest generation intraoral scanners on complete arch implant impressions, Int. J. Prosthodont. (2022), https://doi.org/10.11607/ijp.7824. Oct 21Online ahead of print.
[12] M. Imburgia, J. Kois, E. Marino, H. Lerner, F.G. Mangano, Continuous Scan Strategy (CSS): a novel technique to improve the accuracy of intraoral digital impressions, Eur. J. Prosthodont. Restor. Dent. 28 (2020) 128–141, https://doi.org/10.1922/EJPRD_2105Imburgia14.
[13] F.G. Mangano, O. Admakin, M. Bonacina, H. Lerner, V. Rutkunas, C. Mangano, Trueness of 12 intraoral scanners in the full-arch implant impression: a comparative in vitro study, BMC Oral Health 20 (2020) 263, https://doi.org/10.1186/s12903-020-01254-9.
[14] H. Lerner, K. Nagy, F. Luongo, G. Luongo, O. Admakin, F.G. Mangano, Tolerances in the production of six different implant scanbodies: a comparative study, Int. J. Prosthodont. 34 (2021) 591–599, https://doi.org/10.11607/ijp.7379.
[15] F. Mangano, H. Lerner, B. Margiani, I. Solop, N. Latuta, O. Admakin, Congruence between meshes and library files of implant scanbodies: an in vitro study comparing five intraoral scanners, J. Clin. Med. 9 (2020) 2174, https://doi.org/10.3390/jcm9072174.
[16] J. Pitta, V. Fehmer, I. Sailer, S.P. Hicklin, Monolithic zirconia multiple-unit implant reconstructions on titanium bonding bases, Int. J. Comput. Dent. 21 (2018) 163–171. PMID: 29967907.
[17] S. Mühlemann, R.D. Kraus, C.H.F. Hämmerle, D.S. Thoma, Is the use of digital technologies for the fabrication of implant-supported reconstructions more efficient and/or more effective than conventional techniques: a systematic review, Clin. Oral Implants Res. Suppl 29 (18) (2018) 184–195, https://doi.org/10.1111/clr.13300.
[18] V. Rutkunas, A. Gedrimiene, M. Akulauskas, V. Fehmer, I. Sailer, D. Jegelevicius, In vitro and in vivo accuracy of full-arch digital implant impressions, Clin. Oral Implants Res. 32 (2021) 1444–1454, https://doi.org/10.1111/clr.13844.
[19] M. Iturrate, H. Eguiraun, O. Etxaniz, E. Solaberrieta, Accuracy analysis of complete-arch digital scans in edentulous arches when using an auxiliary geometric device, J. Prosthet. Dent. 121 (2019) 447–454, https://doi.org/10.1016/j.prosdent.2018.09.017.
[20] M. Iturrate, H. Eguiraun, E. Solaberrieta, Accuracy of digital impressions for implant-supported complete-arch prosthesis, using an auxiliary geometry part-An in vitro study, Clin. Oral Implants Res. 30 (2019) 1250–1258, https://doi.org/10.1111/clr.13549.
[21] F. Llansana, S. Guirao, J.C. Kois, M. Revilla-León, Calibrated splinting framework for complete arch intraoral implant digital scans manufactured by combining milled and additively manufacturing technologies: a dental technique, J. Prosthet. Dent. (2022), https://doi.org/10.1016/j.prosdent.2022.08.031. Dec 17:S0022-3913(22)00558-3Online ahead of print.
[22] E. Roig, M. Roig, L.C. Garza, S. Costa, P. Maia, J. Espona, Fit of complete-arch implant-supported prostheses produced from an intraoral scan by using an auxiliary device and from an elastomeric impression: a pilot clinical trial, J. Prosthet. Dent. 128 (2022) 404–414, https://doi.org/10.1016/j.prosdent.2020.10.024.
[23] J.G. Wittneben, D. Buser, G.E. Salvi, W. Bürgin, S. Hicklin, U. Brägger, Complication and failure rates with implant-supported fixed dental prostheses and single crowns: a 10-year retrospective study, Clin. Implant Dent. Relat. Res. 16 (2014) 356–364, https://doi.org/10.1111/cid.12066.
[24] J.A. Shibli, L. Melo, D.S. Ferrari, L.C. Figueiredo, M. Faveri, M. Feres, Composition of supra- and subgingival biofilm of subjects with healthy and diseased implants, Clin. Oral Implants Res. 19 (2008) 975–982, https://doi.org/10.1111/j.1600-0501.2008.01566.x.
[25] V. Rutkunas, C. Larsson, P. Vult von Steyern, F. Mangano, A. Gedrimiene, Clinical and laboratory passive fit assessment of implant-supported zirconia restorations fabricated using conventional and digital workflow, Clin. Implant Dent. Relat. Res. 22 (2020) 237–245, https://doi.org/10.1111/cid.12885.
[26] J. Katsoulis, T. Takeichi, A. Sol Gaviria, P. Lukas, K. Katsoulis, Misfit of implant prostheses and its impact on clinical outcomes. Definition, assessment and a systematic review of the literature, Eur. J. Oral Implantol. Suppl 10 (2017) 121–138.
[27] S. Al-Tarawneh, G. Thalji, D. Shonberg, L. Fayz, L. Cooper, Retrospective cohort evaluation of full-arch zirconia implant-supported fixed prostheses, Int. J. Oral Maxillofac. Implants 38 (2023) 381–390, https://doi.org/10.11607/jomi.10022.
[28] M. Karl, T.D. Taylor, Bone adaptation induced by non-passively fitting implant superstructures: a randomized clinical trial, Int. J. Oral Maxillofac. Implants 31 (2016) 369–375, https://doi.org/10.11607/jomi.4331.
[29] S. Al-Tarawneh, G. Thalji, L. Cooper, Full-arch implant-supported monolithic zirconia fixed dental prostheses: an updated systematic review, Int. J. Oral Implantol. 14 (2021) 13–22.
[30] E. Mijiritsky, A. Elad, R. Krausz, V. Ivanova, S. Zlatev, Clinical performance of full-arch implant-supported fixed restorations made of monolithic zirconia luted to a

titanium bar: a retrospective study with a mean follow-up of 16 months, J. Dent. 137 (2023), 104675, https://doi.org/10.1016/j.jdent.2023.104675.
[31] M. Revilla-León, W. Att, M. Özcan, J. Rubenstein, Comparison of conventional, photogrammetry, and intraoral scanning accuracy of complete-arch implant impression procedures evaluated with a coordinate measuring machine, J. Prosthet. Dent. 125 (2021) 470–478, https://doi.org/10.1016/j.prosdent.2020.03.005.
[32] I. García-Martínez, C. Zarauz, B. Morejón, A. Ferreiroa, G. Pradíes, Influence of customized over-scan body rings on the intraoral scanning effectiveness of a multiple implant edentulous mandibular model, J. Dent. 122 (2022), 104095, https://doi.org/10.1016/j.jdent.2022.104095.
[33] A. Pozzi, L. Arcuri, F. Lio, A. Papa, A. Nardi, J. Londono, Accuracy of complete-arch digital implant impression with or without scanbody splinting: an in vitro study, J. Dent. 119 (2022), 104072, https://doi.org/10.1016/j.jdent.2022.104072.
[34] L. Retana, A.H. Nejat, A. Pozzi, Effect of splinting scan bodies on trueness of complete-arch implant impression using different intraoral scanners: an in vitro study, Int. J. Comput. Dent. 26 (2023) 19–28, https://doi.org/10.3290/j.ijcd.b2599297.