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IMPACT OF DIGITAL DENTISTRY IN DAILY PROSTHODONTICS

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1. Chapter 1: Introduction

Digital technologies have drastically changed the world of dentistry and in particular prosthodontics in the latest years. (1)

Intraoral Scanners, laboratory scanners, CAD software programs, CAM machines and 3D printers are some of the different digital technologies that altered completely the classical prosthodontic workflow in the dental offices as well as in the laboratories. Since the advent of them, not only the patient's impressions are acquired with an intraoral scanner and transfer digitally to the laboratory within a few minutes, but the manufacturing process is planned digital and then realized directly by a milling machine or a 3D printer. (2) (3)

The digital revolution in dentistry has been possible also thanks to the new materials arrived on the market that can be produced with the latest technologies such as lithium disilicate, zirconia and resin-based polymers. (4)

1.1 Digital workflow

In the modern digital workflow, the patients' impressions are captured using an Intraoral Scanner (IOS) and then saved in Standard Tessellation Language (STL), Tessellation with polygonal faces (OBJ) or Standard Triangle format (PLY) realizing a digital master model. This digital master model is made of a triangle mesh of the multiple sets of points or point cloud generated through the IOS. Once the digital master model is created and exported to the CAD software the technician will virtually design the dental device and obtain a STL file of the final project.

Depending on the manufacturing process selected such as subtractive or addictive methods, the STL file of the dental device is send respectively to a milling machine or to a 3D printer. CAM procedures include the physical realization of the virtual design of the dental device. Subtractive methods are the processes that include a sequence of rotatory cutter to remove material from a block until the desired shape, while addictive manufacturing technologies consists of the fabrication of an object in a layer-by-layer technique.

In the present thesis, specific steps of the digital workflow both in fixed and removable prosthodontics were analyzed with particular attention to in vitro and in vivo performances of IOS in terms of scanning accuracy in different clinical situations, and the quality of the final dental devices realized with new materials such as lithium disilicate with a completely digital workflow.

1.2 Intraoral Scanners

Intraoral scanners (IOS) are devices for capturing direct optical impressions in dentistry (5,6). They project a light source (laser or structured light) onto the object to be scanned, in this case the dental arches, including prepared teeth and implant scanbodies. The images of the arches captured by imaging sensors are processed by the scanning software, which generates point clouds. (7,8) These point clouds are then triangulated by the same software, creating a 3D surface model (mesh). The 3D surface models of the dental arches are the result of the optical impression and are the digital equivalent to gypsum master models (9).

Existing IOSs devices are based on different non-contact optical technologies such as interferometry and phases shift principles, confocal microscopy, active and passive stereovision and triangulation, and optical coherence tomography. (10,11)

Essentially, all IOSs conglomerate more than one of the mentioned procedures; furthermore, various structured light technologies and optical apparatuses are selected: (12)

- Active wavefront sampling is an imaging method that necessitates a camera and an off-axis aperture module. The module moves on a circular path around the optical axis and produces a rotation of point of interest (POI). Distance and depth information are then derived and calculated from the pattern produced by each point. (10,12)
- Triangulation technique is based on a principle that the position of a point of a triangle (the object) can be calculated knowing the positions and angles of two points of view. These two points of view may be produced by two detectors, a single detector using a prism, or captured at two different points in time. (10,12)
- Confocal imaging technique patented is a method based on acquisition of in-focused images from selected depths. This technology can detect the sharpness area of the image to infer distance to the object that is correlated to the focal length of the lens. The 3D surface geometry of the scanned area can be reconstructed by using the successive images recorded at different focuses and aperture values and from different angles around the object.(13)
- Stereophotogrammetry estimates all coordinates (x, y, and z) only through an algorithmic analysis of images as this approach relies on passive light projection and software.(12)

The different technologies used by the numerous IOS present on the market may be one of the factors influencing the accuracy of each device. As reported in the "Glossary of digital terms" (14),the accuracy of a digital scanner is the closeness of agreement between a measured result and a reference value. It is described using trueness and precision. Trueness is the closeness between the

test object and the reference object, whereas precision is the variability of repeated measurements of the object. (15)

Accuracy analysis of intraoral digital scans is commonly measured by calculating the discrepancies between the virtual diagnostic cats (obtained by using the tested IOS) and the reference cast or typodont acquired with a reference lab scanner.(16-19)

The accuracy of an Intraoral scanner can also be affected by the software version because the multiple sets of points or point clouds generated through the optical sensors of the IOSs are subsequently registered and are converted into a surface model represented as a triangle mesh.(20-22) The algorithms used by the IOS software can produce files of different mesh densities that can be adaptively defined based on the curvature of the region in the mouth; high curvature regions often have highly dense meshing, while relatively flat regions have lower triangle mesh density.(12) The capabilities of the reproduction geometries of an IOS system are determined by its mesh quality.

Furthermore, many factors can influence the accuracy of the same intraoral scanner including calibration (23), presence of edentulous areas (24), tooth preparation (25,26), tooth type and position (27), implant position (28), scanbody type (29) and scanning protocol (30). In this thesis, different IOSs systems were compared namely Trios 3 (3Shape, Copenhagen, Denmark) , 1700 (Medit Corp, Seongbukgu, South Korea) , Vivadent (Ivoclar Schaan, Liechtenstein) and an Experimental IOS (GC Corp., Tokyo, Japan) in various situations such as different finish line designs on natural abutments, single or multiple implants and edentulous arches.

1.3 CAD software programs

CAD software programs can be defined as technology software designed to create virtual 3dimensional devices being manufactured using subtractive or additive manufacturing methodologies. Dental CAD software programs are developed specifically for the dental field being able to design diagnostic waxing, casts, interim restorations, tooth and implant-supported prostheses, frameworks for multiple implant impression techniques, custom trays, removable partial dentures, complete denture prostheses, occlusal devices, and surgical guides. Also, non-dental Cad software can be used by technicians to realize the final project of the restorations but usually the dental ones are used more in the labs thanks to the easier features. In fact, in dental cad programs , nowadays it is possible , not only to work on the digital master model, but also to integrate the patient's photography or the face scan so that the final project is customized to the patient's anatomy. (31,32) These feature becomes fundamental when a full mouth rehabilitation is required, and the final esthetic is realized by the technician with the reference of the patients' face. (33) When the project of the final restoration is ready is transformed in a .stl file that is send to the milling machine or 3D printer.

1.4 Subtractive manufacturing

Subtractive manufacturing plays a key role in the modern digital workflow in prosthodontics. Milling technology is a type of restoration fabrication that utilizes subtraction manufacturing technology from large solid blocks. Computer numerically controlled machining (CNC), which is based on processes in which power-driven machine tools are used with a sharp cutting tool to mechanically cut a block of material to achieve the desired geometry with all the steps controlled by a computer program. The selection of milling materials is based on application and clinical situation. Depending on the material used, these tools can be made of hardened tool steel or even be diamond coated. CAM software is responsible for positioning in the respective material and calculates the required milling paths for the machines based on the .stl project realized by the technician. It therefore creates the link between the digital design and physical production.(34) The milling units are categorized based on two characteristics:

- dry/wet milling in which some milling materials need dry milling and others need wet milling
- Or number of axes (3 axes or 4 axes or 5 axes) in which both the 4 axes and 5 axes move linearly up and down through different axes (X, Y, Z). The main difference is the number of rotations of the block/disk. Furthermore, restorations milled with a 5-axial milling unit have a greater accuracy than those milled with a 4-axial milling unit because 5-axial milling unit can mill undercuts in all directions.(35)

Not all 5-axes milling units are the same because of differences in the amount of disk and burns rotations. Rotatory cutting instruments with a smaller diameter result in a more accurate milling process.(36) A wide range of machinable materials like cobalt-chrome, titanium, zirconia, glass and hybrid ceramics, polymers, PEEK and wax are used in the prosthodontics field nowadays. Despite the benefits such as smoother surfaces and lower material stresses, subtractive manufacturing faces challenges such as potential milling shadows - areas that a milling tool cannot reach. In fact, the milling procedure accuracy is dictated by the diameter of the smallest bur.(37) Therefore, any surface details less than the diameter of the milling bur will be overmilled, and it will contribute to low retention of the restoration. Anadioti et al. (38) reported that the internal gap

of crowns obtained from a digital workflow were significantly greater than that obtained from the other groups (P < .001).

In this thesis different type of milled restorations produced with a completely digital workflow have been tested regarding marginal and internal fit in vitro and clinical performances in vivo.

1.5 Addictive manufacturing

3D printing, which is synonymous with additive manufacturing (AM) in non-technical fields, is one of the key symbols of the fourth industrial revolution. According to ISO/ASTM 52900:202, additive manufacturing is the process of joining materials to make parts from 3D model data, usually layer by layer, as opposed to subtractive manufacturing and formative manufacturing methodologies. In the field of prosthodontics, 3D printing has been used to produce master casts, patterns for fixed dental prostheses, interim restoration, removable dentures, and custom trays. (39) Today, the integration of 3D printing techniques into the field of prosthodontics is becoming more profound; the acceleration of the process and the satisfaction of aesthetic needs are taking prosthodontics to a new level.(40,41)

In fact, AM allows manufacturing complex geometry while spending less time and material compared to milling procedures where the bur size is a limitation on the geometry of the final object. (42,43) Additionally, is possible to print different materials including polymers, metals (cobalt-chromium and titanium) and zirconia.

Currently, according to EN ISO 17296-2, 3D printing techniques can be divided into seven types according to the printing steps: Binder Jetting (BJT), Directed Energy Deposition (DED), Sheet Lamination (SHL), Vat Photo Polymerization (VPP), Material Extrusion (MEX), Powder Bed Fusion (PBF), and Material Jetting (MJT).

Vat Photo Polymerization (VPP) where a liquid photopolymer resin is polymerized through selective exposure to light which initiate polymerization and converts the exposed areas to a solid part. Vat polymerization procedures can be distinct based on the different light source used: while Stereolithography laser based (SLA) use a UV laser that draws cross section of the object, DLP the photopolymer is exposed to a light from a projector that polymerize the whole layer at the same time.(44,45) The wavelength of the light, exposure time, layer thickness, built orientation and post curing protocols are some of the variable that can affect the mechanical properties of the final object as discussed later in the thesis.(46) In the present thesis a DLP printer (ASIGA MAX UV) has been used to test different materials samples in combination with different printing and post curing protocols.

1.6 Digital materials

In the last decade, the development of new technologies has moved in parallel with a rapid evolution of restorative materials on the trails of Digital Dentistry, opening new horizons in the field of Prosthodontics. The implementation in the daily practice of the most advanced technologies, like CAD/CAM, laser-sintering/melting, and 3D-printing, has got a synergic impulse from the enhanced mechanical and manufacturing properties of the new generation of dental materials: high strength ceramics, hybrid composites and technopolymers, high precision alloys, and so forth. Among these, metal-free ceramics offer unchallenged advantages like high esthetic potential, astounding optical characteristics, reliable mechanical properties, excellent consistency in terms of precision and accuracy due to the manufacturing technologies, lower costs, and more convenient production timing. (47,48) Regarding fixed prosthodontics, the most significant advances in this field have been the production of high resistance monolithic restorations that can be produced with CAD/CAM systems such as zirconia and lithium disilicate.

Zirconia is a polymorphic material that occurs in 3 forms. At its melting point of 2680°C, the cubic structure exists and transforms into the tetragonal phase below 2370°C.(49) The tetragonal-to-monoclinic phase transformation occurs below 1170°C and is accompanied by a 3-5% volume expansion which causes high internal stresses.(50) Yttrium-oxide (Y2O3 3% mol) is added to pure zirconia to control the volume expansion and to stabilize it in the tetragonal phase at room temperature. This partially stabilized zirconia has high initial flexural strength and fracture toughness.(51) Yttrium-oxide partially stabilized zirconia (Y-TZP) has mechanical properties that are attractive for restorative dentistry; namely, its chemical and dimensional stability, high mechanical strength, and fracture-toughness.(52) Zirconia have a radiopacity comparable to metal which enhances radiographic evaluation of marginal integrity, excess cement removal, and recurrent decay. Zirconia restorations can be manufactured completely digital without the production of a physical master model additionally it has been documented that the mechanical properties of zirconia are the highest ever reported for any dental ceramic with fracture strength values of 1240 MPa but with very high aesthetic results. (53,54)

Lithium disilicate is another material that has spread in the last years in dentistry since it gives to clinicians the best compromise in terms of aesthetics and strength for all-ceramic monolithic restorations.(55,56) Lithium disilicate is offered into the market in two different formulations, press and blocks. The two lithium disilicate have different formulations and differ in their composition, giving them similar, but not identical, mechanical and optical properties. The main advantages of

pressed porcelain are that the resulting restorations have a high level of accuracy since the manufacturing process may assure greater marginal flow and great aesthetics that allow its use for anterior crowns and veneers. (57) While restorations from glass-ceramic blocks are spreading since the production can be completely digital.(58)

In the present thesis in vitro marginal and internal fit of lithium disilicate milled crowns have been investigated. Additionally in vivo performances of lithium disilicate partial restorations and veneers have been evaluated in randomized clinical trials.

Another great revolution of the last years has been the introduction of 3D printers in dentistry. In the field of prosthodontics, 3D printing materials mainly include metals and alloys, ceramics, and polymers. Regarding metals the most used ones are cobalt–chromium and titanium alloys that have an important role in the digital production of removable partial dentures. 3D printed ceramic materials are represented by zirconia and alumina ceramic. Studies on these materials when addictively manufactured are still scarce and their performances have to be investigated better. (59) Zirconia seems to have lower flexural strength when 3D printed than milled, but this property was shown to be highly dependent on the building direction.(60) Milled zirconia crowns showed significantly higher fracture resistance compared to the 3D printed crowns and better characteristics in terms of surface porosity. (61,62)

3D printable Polymers are currently the most studied and promising materials in dentistry. Polymethyl methacrylate (PMMA) is the most used vinyl polymer in dental 3D printing. PMMA has strong mechanical properties, good corrosion resistance and biocompatibility and is compatible with stereolithography (SLA) 3D printing technology. (63) During the printing process, the focused UV light activates the liquid chemical monomers to link together and form a solid polymer. In the post-curing process, the strength of PMMA can also be increased by heating or light curing.(64) Some studies found that the mechanical properties of PMMA-based 3D printing products were not as good as those of conventionally manufactured PMMA.(65-67) Lately, new interesting materials with different types of addictives have been lunched on the market with the possibility to remain intraorally for a longer period of time due to their characteristics of occlusal stress dispersion and high durability under occlusal loadi.(68,69) Anyway it must be considered that combining PMMA with different materials can enhance the mechanical and physical properties of these materials and additionally the productions parameters and post curing methods plays a fundamental role in the final restorations' characteristics (70) 3D printed resins have large applications in fixed and removable prosthodontics and their role have been investigated in the present thesis. 3D printed resins specimens have been tested in vitro and compared to traditional and milled resins for the production of complete digital dentures.

The performances of 3d printed partial restorations have been investigated in a RCT study and compared to pressed and milled lithium disilicate.

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2. Chapter 2: Digital Workflow for a single crown — in vitro studies

2.1 Comparison of internal fit of lithium disilicate crowns fabricated with CAD/CAM technology using two different intraoral scanners.

ABSTRACT

The aim of this in vitro study was to compare variations in the internal fit of lithium disilicate single crowns fabricated with computer-aided design and computer-aided manufacturing (CAD/CAM) technology using two digital impression systems. 20 molars were prepared for lithium disilicate single crowns with vertical margins. The teeth were scanned using a model scanner in order to create master scans. Then, two intraoral scanners (IOS) were used to take impressions of the 20 teeth: Trios 3 Basic (3Shape, Copenhagen, Denmark) and Aadva (GC, Tokyo, Japan). The 40 .stl files of the impressions were exported and overlapped with the master scans using the software Aadva GC 2.1.2 Dental DB that, using colors from blue to red, highlights (in red) the areas of discrepancy along the impressions of the abutments. The ratio of red was evaluated to assess if there were any statistically significant differences between the two scanners. The digital impressions were used to fabricate 40 lithium disilicate crowns by means of CAD/CAM technology (for each abutment two crowns were fabricated with both devices). Then, 20 crowns, 10 from each IOS device, were randomly selected and luted to the 20 prepared teeth. Teeth were embedded in selfcuring transparent resin and then cut into 1 mm thick slices by means of a low speed, precision cutting machine (Buehler Isomet) using a diamond blade. Slices were then observed under optical microscope (Nikon) to evaluate cement thickness around the abutments. No statistically significant differences were found, regardless of precision discrepancies in the impressions taken with the two tested IOS systems. The marginal fit of complete lithium disilicate crowns made with a complete digital workflow from the impression taken with the two tested devices showed comparable levels of marginal fit. Both intraoral scanners tested showed good performance and, based on the results of this in vitro study, they both can be considered useful for clinical application.

INTRODUCTION

Complete coverage crowns are one of the most common fixed prosthodontic treatments performed by dentists. Long term success of these rehabilitations is based on an accurate cast. For many years such step has been achieved by means of conventional impressions, but nowadays the performances of the new intraoral scanners (IOS) have opened new perspectives in fixed prosthodontics. Recently, many technological advances improved the quality of the impressions performed by IOS to the point that the level of optical impressions for the fabrication of fixed restorations is as accurate as or even better than that of traditional methods.(1, 2) Marginal and internal fit are the two main clinical factors for the achievement of a good and long- lasting restoration.(3, 4) Many studies have shown the importance of accuracy of fit for clinical success, but they mostly limited their analysis to single crown fit and in particular to marginal accuracy.(5-7) Many studies investigating internal fit of crowns and FDPs are based on measurements of distinct points of sectioned toothcrown assemblies (8,9) without taking into consideration the whole surface of the restoration. The internal fit is also an important criterion and has a direct effect on the seating of the crown and subsequently on the marginal fit. An incongruous internal fit of the restoration can in fact lead to pre- contacts between the restoration's material and some areas of the abutment that can create a variable thickness of cement along the surface and especially an exposition of it at the margin. The exposition of cement at the margin leads to dissolution of the material by oral fluids, microleakage, and biofilm accumulation with consequences such as caries or endodontic and periodontal problems. (10,11)

Traditional impression workflow has been performed for many years using polyether (PE) or polyvinylsiloxane (PVS) with great results. The final outcome is strongly affected by dimensional changes of both impression materials and gypsum, due to variation in temperature, time elapsed between impression making and pouring, surface wettability of the gypsum, and disinfection procedures.(12-15) All such possible errors in the traditional procedure are eliminated in the digital one. Digital impression taking by means of IOS has changed all the workflow, because the acquisition of patients' anatomy is directly transformed in a .stl file that can be sent to the lab in a few minutes. Thus, the technician works directly on the .stl file and, thanks to specific softwares (CAD technology), can realize a digital project of the final restoration that is sent directly to the CAM machine. In this workflow fixed restorations are fabricated with new materials, such as lithium disilicate or zirconia, that present excellent esthetics also in monolithic use and great mechanical properties. Advances in both CAD-CAM technology and in the use of new materials have led to the production of more accurate milled restorations,(16) so that the use of IOS in a complete digital workflow is going to be the immediate future of clinical practice. Currently, there are many different scanners on the market, so the purpose of the present in vitro study was to evaluate the internal fit of crowns made from impressions taken by two different IOS. More specifically, the aim of the study was first to compare impressions of abutments made using

two different IOS and evaluate, in microns, possible discrepancies in all the 3D surfaces. Secondly, to compare the internal fit of lithium disilicate full crowns made from the two different impressions and observe cement thickness along the abutment-crown surface.

The null hypotheses tested were:

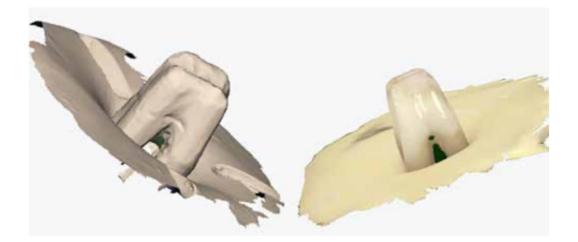
1) the .stl files generated by the two IOS had significant discrepancies when compared with a laboratory scanner;

2) the internal fit of the crowns generated from impressions taken with the two different devices has statistically significant differences.

MATERIALS AND METHODS

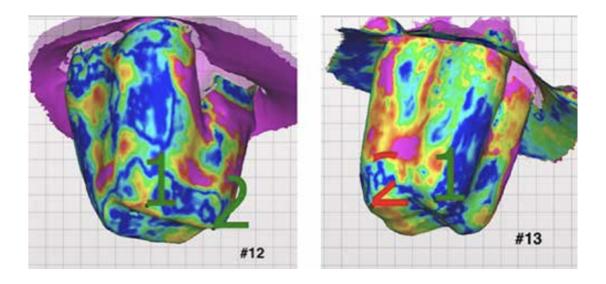
A total sample of 20 intact human molars, extracted for orthodontic reasons and stored in saline solution, were prepared, with appropriate tooth reduction for a complete crown and a vertical finishing line. The abutments were included in 20 customized supports made of putty polyvinyl siloxane and were scanned with a lab scan (Aadva Lab scanner 2, GC, Tokyo, Japan), used as controls. The 20 teeth were also scanned with two intraoral scanners, so that 20 digital impressions were made using Trios 3 Basic (3Shape, Copenhagen, Denmark) and 20 using Experimental Aadva (GC, Tokyo, Japan) (Fig. 1); in total 40 digital impressions were taken according to the manufacturers' protocols.

FIGURE 1. Digital impression obtained by the two IOS (Trios 3 basic, left, and Experimental Aadva, right).



The 40 .stl files obtained were exported in a computer and matched: each control .stl file obtained from the lab scanner was matched with the .stl file obtained by Trios 3 Basic and with the .stl file obtained by Aadva. The superimpositions of the two impressions and the control one, taken with the lab scan, were analyzed with the software Aadva 2.1.2 Dental DB, GC (Fig. 2). This program, thanks to the "register mesh" function, permits to superimpose two impressions and detect all differences between them in microns, evaluating among the 3D surface and highlighting the areas where there are more discrepancies through a color scale from 0 to 100 micron, from blue to red.

FIGURE 2. Superimposition of IOS and lab scanner .stl files.



Then the amount of surface discrepancy from 0.08 to 0.1 mm, highlighted in red, was calculated and reported in tables in form of percentage, showing the percentage of discrepancy between impressions taken using Trios 3 Basic and those of the lab scan (Table 1) and the discrepancies between Aadva and the lab scan (Table 2).

nple N	%	Sample N	%
1	4.88%	1	5.01
2	3.21%	2	3.93
3	5.02%	3	7.4
4	3.98%	4	4.32
5	2.21%	5	5.2
6	5.89%	6	6.1
7	7.63%	7	4.23
8	7.51%	8	3.55
9	2.71%	9	2.16
10	3.21%	10	3.43
11	4.21%	11	4.43
12	2.98%	12	3.12
13	3.87%	13	4.4
14	9.11%	14	14.9
15	0.74%	15	1.3
16	0.97%	16	1.02
17	10.33%	17	22.3
18	2.07%	18	1.7
19	0.49%	19	0.99
20	1.98%	20	1.78
Average	4.15%	Average	5.07

TABLE 1. Percentage of red of 3Shapeimpressions (.stl).

impressions (.stl).

TABLE 2. Percentage of red of Aadva GC

In this way it was possible to compare the precision of the two scanners in micron, taking the lab scanner as a reference. In order to evaluate the statistical significance of the difference in the percentages of red between the two scanners, since the data did not pass the normality test (test of Shapiro-Wilk: p<0,05), the Mann-Whitney U test was performed.

The generated .stl files were delivered to a milling center and then crowns were fabricated. After that, 10 crowns from each group were randomly selected and then luted in the corresponding abutments with a resin cement (LinkForce; GC Co., Tokyo, Japan). For luting the lithium disilicate crowns, the following adhesive protocol was performed: hydrofluoric acid at 9% in the internal part of the crown, wash, dry and primer with silane, orthophosphoric acid 37% on the abutment, wash, dry, adhesive, polymerization. The cement was placed in the internal part of the crowns, and they were positioned on the abutments and light- cured from all sides. The teeth were embedded in transparent self-curing acrylic resin and then sliced using a low-speed diamond saw under water cooling (Buehler, Isomet). The result was to have 1 mm thick slices along their long axis and perpendicularly to the proximal margins, so that the thickness of the resin cement was calculated with an optical microscope

(Nikon) along the surface of the abutment (Fig. 3).

FIGURE 3. Optical microscope image of cement along the crown-abutment surface.



Cement thickness (Table 3, 4) was analyzed with Student t test, after validating the assumptions of normality (Shapiro-Wilk's test, p>0.05) and variance (Levene test, p>0.05) homogeneity in the two groups.

	Cervical marginal A	Cervical margin B	Axial wall A	Axial wall B	Occlusal wall
3	55	65	45	65	140
8	70	75	70	75	180
10	55	70	85	75	100
12	75	105	80	45	120
14	120	130	95	75	200
15	135	95	75	80	180
16	115	90	55	90	155
17	105	120	60	75	165
19	105	105	75	90	170
20	120	130	50	75	210
Average	95.5	98.5	69	74.5	162

TABLE 3. Cement thickness of 3Shape crowns

TABLE 4. Cement thickness of Aadva GC crowns

	Cervical margin A	Cervical margin B	Axial wall A	Axial wall B	Occlusal wall
1	110	90	55	65	185
2	55	75	70	85	210
4	60	55	45	65	220
5	75	65	90	75	190
6	55	70	75	60	155
7	110	90	80	90	170
9	100	120	50	55	190
11	125	135	55	75	195
13	100	90	70	80	180
18	75	65	60	75	210
Average	86.5	85.5	65	72.5	190.5

RESULTS

Descriptive statistics of cement thickness measured in microns and the statistical significance of the differences between the two experimental groups in these variables are reported in the tables. Table 5 shows the descriptive statistics of discrepancy bigger than 0.08 mm in the two groups.

TABLE 5. Descriptive statistics of the discrepancy bigger than 0,08 mm in the two groups.

Scanner	Ν	Median	Interquartile Range
3Shape	10	4.08	1.97-5.10
GC	10	3.54	2.14-5.45

The Mann-Whitney U test revealed that there were no statistically significant differences in the orange/red percentages between the two scanners.

The result of the statistics of cement thickness are reported in tables 6-10.

TABLE 6 Descriptive statistics of cement thickness measured in µm at cervical margin A.

Scanner	Ν	average	Standard deviation	Statistical significance
3 Shape	10	95.5	29.19	NS (p=0.47)
GC	10	86.5	25.60	

TABLE 7 Descriptive statistics of cement thickness measured in µm at cervical margin B.

Scanner	Ν	average	Standard deviation	Statistical significance
3Shape	10	98.5	23.81	NS (p=0.25)
GC	10	85.5	25.43	

TABLE 8 Descriptive statistics of cement thickness measured in µm at axial wall A.

Scanner	Ν	average	Standard deviation	Statistical significance
3Shape	10	69	16.12	NS (p=0.56)
GC	10	65	14.33	

TABLE 9 Descriptive statistics of cement thickness measured in µm at axial wall B.

Scanner	Ν	average	Standard deviation	Statistical significance
3Shape	10	74.5	12.79	NS (p=0.71)
GC	10	72.5	11.11	

Scanner	Ν	average	Standard deviation	Statistical significance
3Shape	10	162	34.33	NS (p=0.035)
GC	10	190.5	19.64	

TABLE 10 Descriptive statistics of cement thickness measured in µm at occlusal wall.

Only in the occlusal wall, cement thickness values were statistically significantly higher in GC scanner than in 3shape scanner (p=0.035). No statistically significant difference was found in the other sections (p>0.05).

DISCUSSION

The purpose of this in vitro study was to evaluate the performance of two intraoral scanners for the realization of lithium disilicate complete crowns and to determine if there were statistically significant differences between the two devices. The use of a lab scan impression as reference was fundamental to evaluate the difference in the precision of the two devices because it can be considered as the gold standard in terms of precision.(17, 18) The impressions obtained with the two devices were separately superimposed on those of the lab scan and trough the software (Aadva GC 2.1.2 Dental DB) it was possible to highlight the differences, i.e. discrepancy, using a color scale, from blue to red, along all the surface of the impressions and not only in standardized points. The red areas for each abutment, where discrepancy was between 0.08 and 0.1 mm, were calculated and analyzed. In this way the precision of the two scanners was analyzed separately and then compared and no statistically significant differences were found between them.

Then, cement thickness was evaluated in 5 points along the surface and these measures are a direct indicator of the precision of the restorations created with a complete digital workflow from the two tested devices. The cement thickness along the surface of the abutments does not have standardized value, since most of the data in literature refer to cement thickness at the margin, which is usually set under 120 μ m, as McLean described.(19) But it must be taken into consideration that the internal fit is also an important criterion and has a direct effect on the seating of the crown and consequently on the marginal fit, so it should be considered as a primary factor for the good outcome of a fixed restoration. Indeed, 25-um-thick die spacer has been shown to improve the seating of a crown and increase the retention of the restoration by 25%.(20) In another study, increasing cement thickness was shown to decrease the fracture resistance of the ceramic restorations because of the greater deformation of the porcelain into the cement layer and the decreased thickness of the restorations.(21) However, the result of this study showed that the gap at the margins was under a clinical acceptability.(21-23)

Trios 3 (3Shape) scanner is a well-known and clinically accepted scanner and often used as reference when new scanners are tested, whereas Aadva is a new device just launched in the market: the comparison between them showed similar clinical performances. It can be reported that, although it was not specifically investigated in this study, the scanner speed of Trios 3 was about 20% shorter than Aadva.

From this in vitro study no statistically significant difference was found between the cement thickness of the two tested devices apart from the occlusal wall where the Aadva crowns showed ticker layers of cement than 3Shape ones. Both the tested devices showed good results in this in vitro study, but further studies should be carried out to evaluate the performance of the devices in intraoral conditions because many clinical factors can affect the precision such as patient and hand movements during scanning as well as the presence of saliva and reflections from tooth and adjacent structures.(21-27)

CONCLUSIONS

The two IOS systems tested showed comparable levels of precision in impression making for lithium disilicate complete coverage crowns regarding internal fit. Further studies are needed to validate the accuracy of these scanners in clinical conditions.

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2.2 Comparison of marginal fit and sealing ability of luted lithium disilicate crowns fabricated with CAD/CAM technology using two different intraoral scanners.

ABSTRACT

The aim of this *in vitro* study was to compare marginal fit discrepancy of lithium disilicate single crowns fabricated with computer-aided design and computer-aided manufacturing (CAD/CAM) technology using two digital impression systems. 20 molars were prepared for the placement of lithium disilicate single crowns with vertical margins. Teeth were scanned using a model scanner, in order to create master scans. Then two intraoral scanners (IOS) were used to take impressions of all the 20 prepared teeth: Trios (3 Shape, Copenhagen, Denmark) and Aadva (GC, Tokyo, Japan), so that abutments were scanned with both devices. Then 40 lithium disilicate crowns were fabricated with CAD/CAM technology: each abutment had two crowns made with the two IOS. Then, 20 crowns (10 randomly selected from each IOS group) were luted to the 20 prepared teeth. The crowns were tested for marginal leakage by means of aluminum nitrate solution. Then, teeth were embedded in self-curing transparent resin and cut into 1 mm thick slices by means of a low speed, precision cutting machine (Buehler Isomet) using a diamond blade. The slices of each tooth were observed under optical microscope to evaluate the amount of leakage, if any. Then, the slices were sputter coated with gold and observed under scanning electron microscope (SEM) to evaluate the thickness of the cement at the margins. No statistically significant differences were found, neither regarding the nanoleakage of the crowns made with the two tested IOS nor regarding cement thickness. Measurements of cement thickness were on average within the acceptable limits considered. Both IOS tested showed good performances and, from the results of this in vitro study, can be considered useful for clinical application.

INTRODUCTION

For many years traditional impressions have been performed in everyday practice to fabricate complete coverage crowns with great results,(1) but lately many technological advances upgraded the performance of intraoral scanners. Nowadays, the level of optical impressions is as accurate as or even better than the traditional ones for the fabrication of fixed restorations,(2) especially when working with supragingival margins.(3,4) Key factors for long-term clinical success of complete crowns are function preservation, biocompatibility, marginal and internal fit and fracture resistance. Marginal fit is one of the main factors in the success of the restoration because any discrepancy

leads to marginal gap and, subsequently, to microleakage, cement dissolution by oral fluids, and biofilm accumulation, with consequences such as caries or endodontic and periodontal problems.(5,6,7) The maximum width of the marginal gap has not been universally set with precision; many studies consider acceptable gaps until 200 µm, but fixed restorations with marginal discrepancies of less than 120 µm are considered more likely to be successful.(8) Anyway, the marginal gap should be as small as possible. In traditional fixed prosthodontics, polyether and polyvinyl siloxane are the most used materials for the definitive impression of the prepared abutment, from which the gypsum model is made for the fabrication of the restoration. The final result is strongly affected by dimensional changes of impression materials and gypsum due to variation in temperature, time elapsed between impression taking and pouring, surface wettability of the gypsum product, and disinfection procedures.(9,10) All these possible liabilities in the traditional procedure are eliminated in the digital one. The introduction of digital impressions by means of intraoral scanners (IOS) has thoroughly changed the workflow because patients' anatomy is directly acquired and transformed in a .stl file that can be sent to the lab in a few minutes. In the digital workflow, the technicians work directly on the .stl file (CAM, computer-aided design step) and, once the digital project is ultimate, they send the project to the CAM (computer-aided manufacturing) machine so that the final restoration is milled.

Advances in both CAD-CAM technology and in the new materials used, such as zirconia and lithium disilicate, have led to the production of more accurate fixed milled restorations.(11-13) The use of IOS, beside producing good restorations, has many other advantages, such as: less time-consuming impression taking and transportation to the lab, real time visualization, easy and selective repeatability, no need to disinfect dental impressions and no wear of the model.(14,15) Currently, many different scanners are on the market, so the purpose of this *in vitro* study was to evaluate the marginal fit of crowns made from impressions taken by two different IOSs. The aim of the study was in fact to compare lithium disilicate full crowns made by using two different devices, in terms of marginal fit and sealing ability.

The null hypotheses tested were:

1)marginal precision and sealing ability are statistically different between the two groups of lithium disilicate crowns;

2) marginal cement thickness of the two groups of lithium disilicate crowns shows statistically significant differences.

MATERIALS AND METHODS

A sample of 20 intact human molars, extracted for therapeutic reasons and stored in saline solution, were prepared with appropriate tooth reduction for a complete crown and a vertical finishing line. The abutments were then included in 20 customized supports made of putty polyvinyl siloxane and scanned with a lab scan for control. All 20 teeth were scanned again with the two IOSs and 40 digital impressions were obtained: 20 using Trios (3Shape, Copenhagen, Denmark) and 20 using Aadva (GC, Tokyo, Japan) according to the manufacturer's protocols. The 40 .stl files obtained were then sent electronically to the technician that performed the CAD phase and then to a centralized milling center for the fabrication of 40 complete lithium disilicate crowns. From the 40 lithium disilicate crowns produced (20 from Trios 3 Basic 3 and 20 from Aadva), only 20, 10 from each group, were randomly selected to be luted to the abutments as follows. - Group 1: Abutments 3, 8, 10, 12, 14, 15, 16, 17, 19, 20 were restored with Trios crowns.

restored with Aadva crowns.

For luting the lithium disilicate crowns the following adhesive protocol was used: 9% hydrofluoric acid in the internal part of the crown, wash, dry and primer with silane, 37% orthophosphoric acid on the abutment, wash, dry, adhesive, polymerization. The cement was placed in the internal part of the crowns, which were then seated on the abutments and light-cured from all sides. Samples underwent ammoniacal silver nitrate microleakage procedure in order to evaluate microleakage at the crown's margins. The teeth were covered with red nail polish on all the surface except the margins between the crown and the abutment. Then, they were immersed in an ammoniacal silver nitrate solution diluted with distilled water (ratio 1:4) and left there for 24 hours. After that, teeth were rinsed thrice in tap water for 10 minutes and then removed the nail polish was removed. Teeth were immersed in a photo-developer solution diluted with distilled water (1:10) for 8 hours and then rinsed thrice in tap water for 10 minutes each time. The teeth were embedded in transparent self-curing acrylic resin and then sliced with a low-speed diamond saw (Buehler Isomet) under watercooling, in order to obtain 1 mm thick slices cut along their long axis and perpendicularly to the proximal margins. The observation of the margins was performed on every section. Marginal microleakage was carefully evaluated with an optical microscope and scored according to the following grade scale:

0: no microleakage;

1:0% to 20% of gingival floor interface showing nanoleakage;

2: 20% to 40% of gingival floor interface showing nanoleakage;

3: 40% to 60% of gingival floor interface showing nanoleakage;

4: 60% to 80% of gingival floor interface showing nanoleakage;

5: 80% to 100% of gingival floor interface showing nanoleakage.

The scores of the microleakage test of crowns on dentin and enamel were analyzed. Since the data did not pass the Shapiro-Wilk's test (p<0,05), the Mann-Whitney U test was performed. In all tests the level of statistical significance was set at p<0,05.

Wilcoxon signed-rank test was performed to assess the absence of clinically significant differences between the scores of microleakage registered on dentin and on enamel under the crowns made from the digital impressions performed with the same scanner.

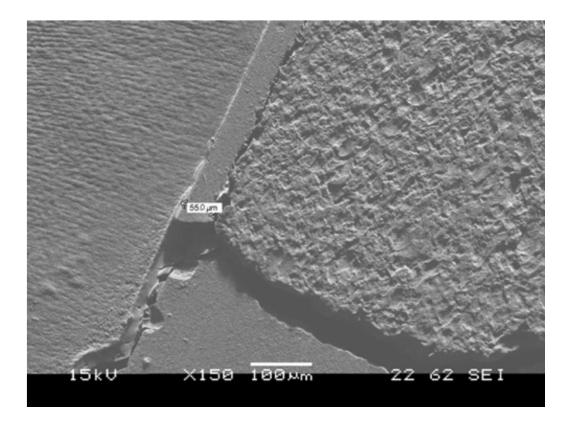
After the observation under optical microscope (Fig. 1) samples were processed for SEM analysis (Fig. 2) as follow: first, they were etched with 37% orthophosphoric acid, washed and dried, then they underwent vacuum sputter coating with gold. The samples were then observed, once again, under electronical microscope in order to evaluate margins at higher magnification and measure cement thickness in two sites. Cement thickness was analyzed with Student's t test, after validating the assumptions of normality (Shapiro-Wilk's test, p>0.05) and variance (Levene's test, p>0.05) homogeneity in the two groups.

FIGURE 1. Optical microscope images of crowns margins.





FIGURE 2. SEM image of cement thickness measurement.



RESULTS

The results of the infiltration at the margins in enamel and dentin are reported in Table 1. TABLE 1. Score of nanoleakage of each tooth.

Group 2: Crown GC	Slice number	Enamel	Dentin
1	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
	7	0	0
	8	0	3
2	1	0	2
	2	0	2

	3	0	0
	4	0	0
	5	0	0
	6	0	2
4	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
5	1	0	0
	2	0	0
	3	0	2
	4	0	0
	5	0	0
	6	0	0
6	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
7	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
9	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
11	1	0	0
	2	0	0

	3	0	0
	4	0	0
	5	0	0
	6	0	0
13	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
18	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
Average		0	0,177

Group 1: 3Shape	Slice number	Enamel	Dentin
3	1	0	1
	2	0	0
	3	0	0
	4	0	0
	5	0	0
8	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
10	1	0	0
	2	0	0
	3	0	0

	4	0	0	
	5	0	0	
	6	0	0	
12	1	0	0	
	2	0	0	
	3	0	0	
	4	0	0	
	5	0	0	
	6	0	0	
14	1	0	0	
	2	0	0	
	3	0	3	
	4	0	0	
	5	0	0	
	6	0	0	
15	1	0	0	
	2	0	0	
	3	0	0	
	4	0	0	
	5	0	0	
	6	0	0	
16	1	0	0	
	2	0	0	
	3	0	0	
	4	0	0	
	5	0	0	
	6	0	0	
17	1	0	0	
	2	0	0	
	3	0	0	
	4	0	0	
	5	0	0	
	6	0	0	

19	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	0	0
	6	0	0
20	1	0	0
	2	0	0
	3	0	4
	4	0	0
	5	0	0
	6	0	0
Average		0	0,135

Cement thickness of both groups is reported in Tables 2 and 3. The Aadva group showed lower cement thickness than the 3Shape group at the cervical margins, although this was not statistically significant.

	Cervical margin A	Cervical margin B
1	110	90
2	55	75
4	60	55
5	75	65
6	55	70
7	110	90
9	100	120
11	125	135
13	100	90
18	75	65
Average	86.5	85.5

TABLE 2. Cement thickness of Aadva IOS GC

TABLE 3. Cement thickness of Trios 3, 3Shape

	Cervical margin A	Cervical margin B
3	55	65
8	70	75
10	55	70
12	75	105
14	120	130
15	135	95
16	115	90
17	105	120
19	105	105
20	120	130
Average	95.5	98.5

The Wilcoxon signed-rank test was applied to the microleakage scores. In enamel, the scores were 0 under all crowns.

Table 4 reports the scores of microleakage recorded on dentin. The Mann-Whitney test did not find any statistically significant differences between the performance of the two IOSs as regards dentin infiltration (p=0,527).

Table 5 reports microleakage scores on dentin and enamel under the crowns made from the impressions taken with Aadva (GC).

Table 6 reports microleakage scores on dentin and enamel under the crowns made from the impressions taken with Trios 3Shape.

The Wilcoxon signed-rank test did not find any statistically significant differences between the microleakage scores recorded on dentin and enamel, neither under the crowns made from Aadva (p=0,063) nor under the crowns made from Trios (p=0,25).

Tables 7 and 8 report the descriptive statistics of cement thickness measured in microns and the statistical significance of the differences between the two experimental groups in this variable.

TABLE 4. Scores of microleakage registered on dentin.

SCANNER	Ν	Median	Interquartile range
GC IOS	62	0	0-0
3Shape	59	0	0-0

TABLE 5. Microleakage scores on dentin and enamel under crowns made from the impression performed with Experimental Aadva.

GC IOS	Ν	Median	Interquartile range
Enamel	62	0	0-0
Dentin	62	0	0-0

TABLE 6. Microleakage scores on dentin and enamel under crowns made from the impression performed with Trios.

3Shape	Ν	Median	Interquartile range
Enamel	59	0	0-0
Dentin	59	0	0-0

TABLE 7. Descriptive statistics of cement thickness measured in µm at cervical margin A.

SCANNER	Ν	Median	Interquartile range	Statistical significance
GC IOS	10	86.5	25.60	NS (p=0.47)
3Shape	10	95.5	29.19	

SCANNER	Ν	Median	Interquartile range	Statistical significance
GC IOS	10	85.5	25.43	NS (p=0.25)
3Shape	10	98.5	23.81	

TABLE 8. Descriptive statistics of cement thickness measured in µm at cervical margin B.

NS=statistically not significant difference, *=statistically significant difference

DISCUSSION

According to the results of this study the null hypothesis that statistically significant differences would be found in the marginal fit of lithium disilicate crowns fabricated with the two IOS is rejected. In this study, the fit of crowns was assessed by means of microleakage of aluminum nitrate solution through the margins between the restoration and the abutment and on cement thickness at the margins measured at SEM.

It is necessary to consider that marginal fit depends on different factors, among which the fabrication process from the preparation design to the cementation methods.(16) Therefore, the differences in scanning precision, or CAD software may also affect fit accuracy.(17) Marginal fit discrepancies, due to an imprecise impression of the abutment, can only be filled with cement, which is susceptible to dissolution.(18) For this reason, the precision of the intraoral scanner in the impression of the abutment is fundamental. Analysis of the results of this study suggests that the marginal fit of lithium disilicate crowns fabricated with the fully digital method with the two IOSs are comparable between them and in line with the fit parameters set for crowns made with the conventional method. In fact, no statistically significant differences were found between cement thickness of the two groups of crowns.

The ability to directly visualize and measure marginal discrepancy by means of SEM photography provided accuracy and reproducibility and the possibility to see imperfections of the restoration at a high resolution have been used only in a few other studies. Furthermore, the marginal fit was indirectly evaluated by means of an infiltration procedure of the cement and observing microleakage under the crowns. As stated by Pioch the term "nanoleakage" was introduced to describe a specific type of leakage within the dentin margin of the restoration.(19) Consequently, the sealing ability and resistance to the varying stresses of luting agents used to cement the crown

are extremely important and the thickness of cement exposed to the oral fluids should be the lowest possible.(20)

It is commonly believed that increased adaptation of the crown leads to lower leakage, as it may lead to an increase in the cement dissolution, with a potential for leakage.(17)

From the results of the present study no statistically significant difference was found between the infiltration scores of the two groups of crowns made with the two IOSs. Both tested devices showed good performances in this in vitro study, but further studies should be carried out to evaluate the performance of the devices in intraoral conditions, because many clinical factors can affect the precision such as patient and hand movements during scanning as well as the presence of saliva and reflections from tooth and adjacent structures.(21-27)

CONCLUSIONS

The two tested intraoral scanner systems showed comparable levels of precision in the impressions taken for lithium disilicate complete coverage crowns regarding marginal fit. Further studies are needed to validate the accuracy of these scanners under clinical conditions.

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3. Chapter 3: Intraoral scanners and crowns margins

3.1 Accuracy of Four Intra-Oral Scanners in Subgingival Vertical Preparation: An In Vitro 3-Dimensional Comparative Analysis

ABSTRACT

One of the most critical aspects in intraoral impression is the detection of the finish line, particularly in the case of subgingival preparations. The aim of this in vitro study was to evaluate the accuracy among four different Intra Oral Scanners (IOSs) in scanning a subgingival vertical margins preparation (VP). A reference maxillary typodont (MT) was fabricated with a VP for full crown on #16 and #21. The MT was scanned with a laboratory scanner (Aadva lab scanner, GC, Tokyo, Japan) to obtain a digital MT (dMT) in .stl format file. A group of 40 digital casts (dIOC) were obtained by scanning the MT 10 times with four different IOSs: Trios 3, 3Shape A/S; I700, Medit; Vivascan, Ivoclar; and Experimental IOS, GC. All the obtained dIOCs were imported into an inspection software program (Geomagic Control X; 3D SYSTEMS) to be superimposed to the dMT in order to calculate trueness. Therefore, in order to calculate precision, all the scans of the same scanner group were superimposed onto the cast that obtained the best result of trueness. The results were collected as the root mean square value (RMS) on the #16 and #21 abutment surfaces and on a marginal area positioned 1 mm above and below the gingival margin. A nonparametric analysis Kruskal-Wallis test was performed to compare the RMS values obtained in the different iOS groups for trueness and precision. Statistical significance was set at 0.05. For the trueness on the #16 abutment, the Vivascan reported statistically lower values, while on the #21 abutment, Vivascan (56.0 ± 12.1) and Experimental IOS, GC (59.2 ± 2.7) performed statistically better than the others. Regarding precision, Experimental IOS, GC were significantly better than the others on #16 (10.7 \pm 2.1) and in the #21 area Experimental, GC, and Trios 3 performed statistically better (16.9 ± 13.8) ; 18.0 ± 2.7). At the subgingival marginal level for both #16 and #21, all the IOS reported reduced accuracy compared to clinical acceptance.

INTRODUCTION

The use of digital technology in dentistry has been increased in recent years ,(1) thanks to different computer-aided design and computer-aided manufacturing (CAD-CAM) systems being used to

fabricate different types of prostheses (2) and to intraoral scanners (IOSs) that allow to obtain a full digital workflow from the impression to the delivery.

In a completely digital workflow, an accurate IOS is an essential aspect to ensure long term results, since the fitting of the future restoration is largely depending on the quality of the IOS.(3) Recently the IOS clinically acceptable results were shown on the fabrication of crowns and fixed partial dentures (FPDs),(3-5) with higher time efficiency and better patient acceptance compared with those of conventional impression methods.(6,7) As reported in the glossary of digital terms [8], the accuracy of a digital scanner is the closeness of agreement between a measured result and a reference value. It is described by trueness and precision. Trueness is the closeness between the test object and the reference object, whereas precision is the variability of repeated measurements of the object [9,10]. Differences in accuracy have reported between IOSs and laboratory scanners, (11) and among different IOSs, (12,13) Additionally, the accuracy of a IOS can be affected by clinical circumstances as scanning protocol, (14) presence of blood or saliva, (15) limited spacing between abutments and adjacent teeth (16), and edentulous span length. (17) One of the most critical steps during impression taking, both conventional and digital, is detecting the finish line, in particular subgingival tooth margins. For both traditional or digital impression technique the detection of the finish line relies on a clean, healthy gingival sulcus, proper soft tissue displacement, and clear visibility of the prepared tooth anatomy. However, the preparation of an abutment for a digital impression must consider limitations due to the digital impression device. (18) To date only fews studies (15, 19–22) evaluated the reliability of intraoral scanners in detecting subgingival vertical preparations (VP). So, the aim of this in vitro study was to evaluate the trueness and precision of four IOS devices (Trios 3, 3Shape A/S), (Medit I700), (Vivascan, Ivoclar) and (Experimental IOS, GC) used in standardized conditions, on complete crowns abutments with subgingival VP finishing line with particular attention to the subgingival surface of the preparation. The following null hypothess were tested: 1) there are no differences in term of trueness and precision among the different IOSs for the abutment surface 2) there are no differences between the tested IOSs in term of accuracy at the subgingival marginal area.

MATERIALS AND METHODS

A reference maxillary typodont (MT) mounted on a simulator phantom head, was fabricated by performing a vertical preparation for full coverage on resin abutments on maxillary right first molar #16 and left first incisor #21. Teeth preparations were performed with the following protocol: mesio-distal preparation with flame bur 012 (Komet, Lemgo, Germany) preparation of the occlusal

surface following the angle of the cusps using a conical burr (Komet, Lemgo, Germany); and axial reduction above the buccal and palatal cemento-enamel junction with the 012C flame diamond burr. Thus, a circumferential tooth reduction was obtained using a flame bur 012C vertically below the cemento-enamel junction until the preparation is rectified with the axial plane. In order to standardize the scanning condition, the preparation was performed at least 2 mm around the gingival margin to ensure the overcome clinical limit and was confirmed with a periodontal probe (CP 15 UNC; HU-Friedy, CHI, USA). The final MT model is shown in Figure 1.

FIGURE 1: MT model



The MT was scanned with a laboratory scanner (Aadva lab scanner, GC, Tokyo, Japan) to obtain a digital maxillary typodont (dMT) in standard tessellation language .stl format. Subsequently, 40 digital casts (dIOC) were obtained by scanning the MT 10 times by each of the four different IOSs (Trios 3, 3Shape A/S), (I700, Medit), (Vivascan, Ivoclar), (Experimental IOS, GC). The scanning procedure was conducted starting from the right maxillary quadrant and ending at the left one and then continuing on the palatal side and finally on the palatal vault with a clockwise movement. All the scans were done under the same light conditions and by the same operator with an interval of 10 minutes to rest and allow the IOS to cool. All the excess areas were removed by using CAD software (Meshmixer; Autodesk, San Rafael, USA) so that the acquired test models were standardized and ready for superimposition as reported in Figure 2. FIGURE 2: dMT after been standardized with Meshmixer.



The two groups of .stl files dMT and dIOC were imported into an inspection software program (Geomagic Control X; 3D SYSTEMS) to be superimposed, indicating the dMT "as reference data" in the software program, to calculate trueness. The dMT .stl file was superimposed with each dIOC .stl file in the software program by activating the function "initial alignment" and then the function "best-fit alignment," which aligned the 2 digital casts with a minimal distance between the superimposed surfaces [23]. 3D analysis was performed on the prepared teeth #16 and #21 (all regions above the finish line of abutment), and marginal region (the region up to 1,5 mm on the gingival margin) of the abutment.

The correspondence between dMT and dIOC was evaluated by using the 3D comparison function. The root mean square value (RMS) was calculated based on all cloud points of dMT by using the following formula:

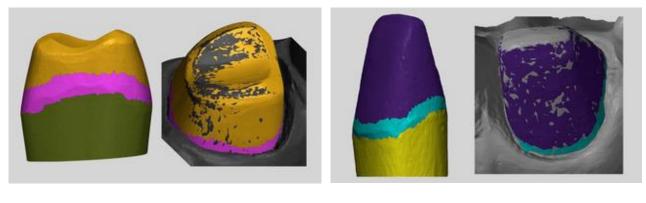
$RMS = \frac{1}{\sqrt{n}} \cdot \sqrt{\sum_{i=1}^{n} (X_{1,i} - X_{2,i})^2},$

where X1,i indicates a measurement point at ith in dMT and X2,i indicates a measurement point at ith in dIOC. n is the number of all points evaluated. Therefore, the RMS value is the absolute average distance of all cloud points and means the degree of agreement between dMT and dIOC, so this value was used to evaluate the trueness.

For each experimental group, the trueness was calculated taking the RMS value resulting from the superimposition of each dIOC .stl and the dMT .stl. The precision was evaluated as the RMS values recorded after the superimposition between each dIOC and the cast that recorded the best result of trueness in the same group. Therefore, all the scans from the same scanner group were superimposed onto this selected cast, whose trueness corresponded to the actual reference value for precision.

In order to evaluate the difference in subgingival marginal area, it was selected the single prepared abutments models for 16 and 21 as reported in Figure 3. The 3D comparison was performed as previously reported after the alignment of the abutment model with the 10 different scans obtained per each group.

FIGURE 3: (a) marginal selection area on #16; (b) marginal section area con #21.



(a)

(b)

All RMS data were statistically analyzed to evaluate trueness and precision. The homogeneity and normality of distributions were tested by the Kolmogorov-Smirnov. The nonparametric Kruskal-Wallis test was performed to compare the trueness and precision differences among the scanner groups ($\alpha = 0.05$) All statistical analyses were performed by using a statistical software program (IBM SPSS Statistics, v22.0; IBM Corp).

RESULTS

The numbers of images per scan varied between 743 and 1126, and the scanning time was between 1 and 2 minutes.

RMS evaluations

The mean RMS values and standard deviations of each group regarding the trueness and precision on the prepared abutments were reported in Table 1.

	Trueness #16	Trueness #21	Precision #16	Precision #21
	[µm]	[µm]	[µm]	[µm]
Trios 3	60.2 ± 4.9^{a}	68.7±4.0 ^b	31.7± 13.1 bc	18.0 ± 2.7 ^{ab}
I700	58.0±8.9 ^a	83.3± 5.6 ^c	15.8 ± 2.7 ^b	29.8 ± 3.7 ^b
Vivascan	69.6±6.9 ^b	56.0 ± 1.21^{a}	41.4 ± 20.2 ^c	49.9 ± 19.6 ^c
Experimental IOS, GC	55.4±5.6 ^a	59.2 ± 2.7 ^a	10.7 ± 2.1^{a}	16.9±1.3 ^a

TABLE 1: RMS Mean values and standard deviations of each scanner obtained for trueness and precision in 16 and 21 abutments.

Statistical significative values are reported with different letters a,b or c (P<0,05).

On #16 abutment, Experimental IOS, GC performed the best trueness result (55.4±5.6µm), but not statistically significant differences were found in comparison to the other tested groups except with Vivascan (p= 0.003) that performed statistically worse than the others. On #21 abutment, Vivascan (56.0 ±12.1µm) and Experimental IOS, GC (59.2±2.7µm) performed statistically better than the other two devices for trueness. Regarding precision, Experimental IOS, GC (10.7 ± 2.1µm) showed statistically better results than the other groups on the molar #16, while on the incisor abutment #21 the ones that reported statistically better results were Experimental IOS, GC (16.9±13.8µm) and Trios 3 (29.8±3.7µm).

Accuracy at the subgingival marginal level

The RMS mean values and standard deviations of each scanner at the subgingival marginal level of the prepared abutments are reported in the table 2.

TABLE 2: Mean value and standard deviation of the accuracy of the different IOSs at the marginal level.

	Marginal #16 [µm]	Marginal #21 [µm]
Trios 3	166.0 ± 0.34^{b}	147.4 ± 2.18^{a}
1700	96.3 ± 0.13^{a}	154.2 ± 1.89^{a}
Vivascan	141.2 ± 2.20^{b}	170.0 ± 1.33 ^b
Experimental IOS, GC	145.2 ± 1.87 ^b	135.7 ± 0.825 ^a

Statistical significative values are reported with different letters a,b or c (P<0,05).

1700 reported the highest accuracy at subgingival marginal level on the $\#16 (96.3 \pm 0.13)$. The 1700 and Experimental IOS, GC scanners obtained statistically difference and better results than Trios 3 and Vivascan at marginal level for the 21.

The comparisons between trueness on 16 and 21 and their respectively subgingival marginal area reported a statistically difference in all the IOS groups.

Color map evaluations

A color map was created to visualize the displacement between the superimposed IOS to MT for the whole abutment area as shown in Figure 4 and for the sub gingival margin as shown in Figure 5. The color scale used to highlight the discrepancies is from blue to red respectively from from -100 microns to 100 microns of discrepancy between the two superimposed files. The red-orange areas highlighted discrepancies between 0.5 μ m and 1 mm, while the green areas are the ones perfectly superimposed where the discrepancy is 0 μ m. The yellow or light blu areas are representing minor discrepancies of +/- 0.2 μ m.

FIGURE 4: 3D trueness analysis of molar and incisor made by different IOSs.

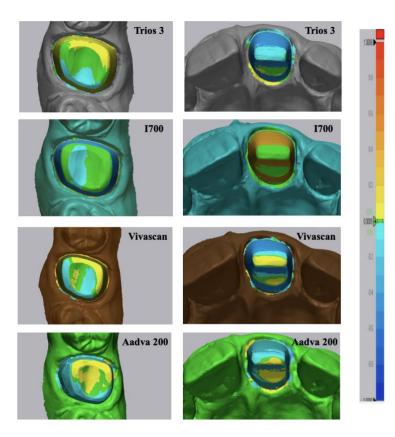
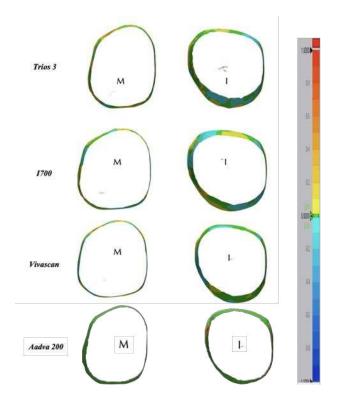


FIGURE 5: 3D analysis on the sub-gingival finish line



DISCUSSION

In the digital workflow, the accuracy of the cast obtained by IOS becomes fundamental for long term results (5) in order to achieve good marginal and internal fit of the restoration.(24,25) Internal fit of the restoration, if incongruous, can lead to precontacts between the restoration's material and some areas of the abutment, a thick thickness of cement along the surface and ultimately an exposition of cement at the margin. Marginal fit is one of the main factors in the success of the restoration because any discrepancy leads to marginal gap and, subsequently, to possible microleakage, cement dissolution by oral fluids, and biofilm accumulation, with consequences such as caries or endodontic and periodontal problems.(26) The maximum width of the marginal gap has not been universally set with precision; many studies consider acceptable clinical gaps until 200 μ m, but fixed restorations with marginal discrepancies of less than 120 μ m are considered more likely to be successful.(27) It should be considered that in a clinical environment it would be difficult to translate the μ m measured in in vitro study and for this reason a universally set clinically acceptance level is difficult to be set; anyway it should be as low as possible.

In a previous in vitro study Verniani et all. (28) evaluated the marginal fit of crowns fabricated with a completely digital workflow of vertical preparation. It was reported that the obtained crowns had good adaptation to the abutment independently from the two tested iOS, however it was not evaluated the accuracy at the subgingival finish line.

To date only few studies have evaluated the accuracy of IOSs depending on the finishing line location and the difficulties in acquiring subgingival margins, and they compared only few devices. (19–22)

Due to the lack of evidence in the evaluation of the IOS behaviors in vertical preparation, the aim of the present study was to assess the accuracy of different IOSs on complete abutment surface and on sub gingival area in vertical prepared abutments. The evaluated IOSs devices reported statistically different results for trueness and precision for both #16 and #21 thus the null hypotheses were rejected.

Regarding the level of accuracy of complete abutments, all the reported values were largely lower than 100 µm, that was indicated in previous clinical trials studies as the clinically acceptable margins and consequently the recommended scan accuracy.(29,30) The result of this study suggests that while for the trueness in the molar area no statistically significant difference was shown between Experimental IOS, GC, Medit I700 or Trios 3; Vivascan performed statistically

worse. When the incisor abutment was evaluated, the Vivascan and the Experimental IOS, GC showed statistically significative better results compared to the other tested intraoral scanner. It can be supposed that the proximity of the molar abutment to the adjacent teeth in the posterior area, can acts as a confounding factor that can modify the performances of the IOSs. (16) On the other hand, in the incisor area, thanks to the increased interproximal space among the abutment and adjacent the teeth, the effect of this confounding factor can be reduced , thus some statistical differences were found in the RMS obtained valued.

Also, in both #16 and #21 abutment, interproximal margins were significantly affected in the presence of adjacent teeth and a lower accuracy resulted respect to the vestibular and palatal marginal site. This is still referable to limited space between the scanned surface and the adjacent tooth as described by Keeling et all. (16)

Regarding precision Experimental IOS, GC reported statistically lower results than the others IOS devices in both molar and incisor abutments revealing the closure scans in between each the same group, thus resulting as the most repeatable reliable IOSs. Instead Vivascan reported the biggest standard deviations or precision.

All our data about sub gingival marginal region reported increased values of trueness and precision compared to full abutment. The mean values for trueness and precision are all above the level of clinical acceptability according to Shim et all. (30) except for i700 on marginal M.

As it can be evaluated in the color map images in Figure 4 and Figure 5, the prevalence of cold colors at marginal level revealed as the IOS abutment surface did not penetrate in the reference scan surface. Thus, it seems that the IOS was not able to record the true abutment surface into the sulcus when, at marginal level, it was closer to the tissue surface. A possible explanation of this finding is related to the continuous surface generated in the software by "joining the dots" according to the "stitching" algorithm.

This behavior of IOS was confirmed by recent papers. Son et al. (21) reported that the trueness of the subgingival marginal region at the location of the subgingival finish line (0.5-mm below the level of the gingival) was the worst. In another study, (20) the two IOSs tested showed clinically acceptable scan trueness at a depth of up to 0.25-mm of subgingival finish line without gingival displacement cord but showed clinically acceptable scan trueness at a depth of up to 1-mm when the gingival displacement cord was used. Additionally, they found out that with the increase of the subgingival finish line depth without gingival displacement cord, the surface area of the abutment decreased but they limited the study only to two different types of intraoral scanners. Our data confirm also the results obtained by Ferrari Cagidiaco et all., (19) that digital impression is not recommended when crowns' margins are positioned deep (1.5–2 mm) into the sulcus.

However further studies could be conducted in order to understand what the vertical limit for each IOSs is to obtain an acceptable scan in terms of accuracy at marginal level.

Additionally, the present study has some limitations like the absence of saliva, blood, limited mouth opening and movements of the patient, (31) those factors could be considered in an in vivo experimental design.

Also, it must consider that three devices were using a software already available, while the Experimental IOS, GC was an experimental software not available into the market yet.

CONCLUSIONS

Based on the findings of this in vitro study, the following conclusions can be drawn:

- 1) The trueness deviations of the analyzed scanners were significant different in the full abutment surface of molar and incisor.
- At subgingival marginal level the accuracy results were not clinically acceptable for all the IOS probably due to the "joining the dots" effect.
- 3) More studies are required to validate the behavior of IOS in vertical preparations.

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3.2 Accuracy evaluation of digital impressions on horizontal finish line designs

ABSTRACT

In the last years, intraoral scanners (IOSs) have gained success in prosthodontics. This study aimed to evaluate the accuracy of digital impressions performed with two different intraoral scanners on subgingival chamfer and shoulder prepared teeth considering all the abutment surface and the marginal level. Two upper arch models were produced with elements #16 and #21 receiving a chamfer and a shoulder preparation design. Each model was scanned 10 times with two IOSs: Medit i700 (Medit Corp, Seongbukgu, South Korea) and TRIOS 3 (3Shape, Copenhagen, Denmark). The trueness on the prepared abutments was measured using Geomagic Control X, by superimposition between the scans performed with the IOSs and the scans performed with a laboratory scanner (Aadva Lab Scan, GC Corporation, Tokyo, Japan), and expressed as RMS deviation values and as a color-coded map. Precision was measured by superimposing the scans of the IOSs showing the highest trueness with the other IOSs' scans. The trueness considering the preparation margin alone was measured as well. The IOSs under study demonstrated a high accuracy, with comparable trueness on the prepared abutments and statistically significant differences in precision. Medit i700 demonstrated the highest precision. At the marginal level, statistically significant differences in trueness were observed between the two IOSs with an overall low accuracy. Medit i700 and TRIOS 3 provided an acceptable in vitro accuracy in the scanning of abutments with horizontal subgingival preparations, both on incisors and molars. However, none of the scanners used provided an acceptable accuracy when only the margin was evaluated. This suggests

INTRODUCTION

In the last years, dentistry has evolved towards digital methods thanks to the introduction of intraoral scanners (IOSs) enabling a complete digital workflow(1). IOSs have gained success in daily practice due to many associated advantages. First of all, IOSs are well-received by the patient as they reduce discomfort in intraoral impression capturing with respect to conventional impressions(2,3). They also enable faster clinical procedures (4,5), improve communication with the lab technician, clinicians and patients (6) and eliminate errors related to the dimensional instability of impression materials. (2)

an incorrect margin reproduction with a possible alteration in the adaptation of the prosthesis.

The latest scientific evidence has focused on the evaluation of the accuracy of IOSs and according to many recent in vivo and in vitro studies, these devices provide clinically acceptable accuracy, comparable to that of conventional impressions.(3,7,8) However, due to the clinical importance of impression accuracy in prosthodontics and due to many clinical factors, that could affect IOS performance, further investigations are still needed. (9)

The performance of both conventional and digital impressions is scientifically termed "accuracy". According to ISO-5725, (10) accuracy is described by two parameters, namely "trueness" and "precision". Trueness represents the ability of a device to produce results close to the reference value, therefore close to the truth. Precision instead describes the repeatability of data when more tests are performed with the same device.

To be accurate and reproduce reality, an impression must have the highest trueness and precision possible. However, precision and trueness change from one IOS to another based on the technology used but they could also be influenced by intraoral clinical factors, which vary from patient to patient. The production of an accurate digital impression is of paramount importance to obtain a correct internal and marginal fit of the prosthetic device on the prepared tooth. In particular, the marginal fit is fundamental for the long- term success of the prosthetic restoration, which must be seated in such a way as to correctly seal all the margins of the preparation. Marginal gaps will eventually lead to marginal infiltration, cement dissolution by oral cavity agents, plaque accumulation and consequently caries and periodontal problems, leading to a poor prognosis for the involved tooth. (11)

The adaptation of fixed prostheses has been assessed in many studies, but we don't have a specific scientifically proven maximum value for the marginal gap between crown and abutment. Therefore, many authors still use as reference a clinically acceptable gap value up to 120 μ m, which is the threshold set by McLean (1971). (12,13)

According to the latest literature, the new IOSs on the market have demonstrated a clinically acceptable accuracy on both vertical (14) and horizontal (15) finish line designs, independently from their abutment geometry.(16) A relevant issue is related to the position of the preparation margin with respect to the gingival margin: supragingival, iuxtagingival or subgingival. In fact, it has been demonstrated that there is some difficulty in the reproduction of the finish line by IOSs when this is localized deeply in the gingival sulcus. According to some in vitro studies, deep preparations into the sulcus are not recommended to be scanned (17) and a supragingival finish line design is better reproduced by IOSs than a subgingival one.(18) This occurs in association with clinically relevant confounding factors that affect the performance of IOSs by hampering the light

beam from reaching the preparation margin, such as the presence of adjacent teeth in close proximity or the marginal gingiva itself. (9)

However, current literature is lacking regarding the accuracy of IOSs on teeth with horizontal preparations that are subgingivally positioned. In the present study, the accuracy of two IOSs was compared: TRIOS 3 (Trios 3, 3Shape A/S) and i700 (I700, Medit corp.). These IOSs work through different scanning technologies, namely confocal microscopy and video technology for TRIOS 3 (2,19) and triangulation and video technology for Medit i700. (20,21) This difference could affect the performance of the tested IOSs and could reflect in the results obtained. The purpose of this in vitro study was to evaluate the accuracy of digital impressions (DIs) performed with two different intraoral scanners on subgingival chamfer (C) and shoulder (S) finish line designs considering all the abutment surface and the marginal level. The null hypothesis is: There is no statistically significant difference in the accuracy of DIs obtained with the two IOSs on subgingival horizontal finish line designs.

MATERIALS AND METHODS

Two upper right molars and two left central incisors in resin- based material, were prepared with horizontal finish line designs and positioned in an upper arch typodont model with alveolar removable teeth. One molar and one incisor were selected for a 0.8 mm chamfer (C) preparation with a 2 mm chamfer bur. The remaining two teeth, were prepared with a 1 mm shoulder (S) with a 2 mm cylindrical bur. The margin preparation was positioned 1 mm subgingivally in both preparation types. The occlusal and axial reductions were approximately 1.5 mm for both designs. The two sets of teeth prepared with chamfer and shoulder were placed separately in an upper arch typodont model, thus two models scenarios were produced in two different moments: a full-arch with elements #16 and #21 prepared with chamfer finish line (Model C) and a full-arch with elements #16 and #21 prepared with shoulder finish line (Model S) as shown in Figure 1. FIGURE 1: model S with elements 16 with shoulder finish line.



The model C and model S were scanned 10 times each with two different IOSs: TRIOS 3 (3Shape, Copenhagen, Denmark) and Medit i700 (Medit Corp, Seongbukgu, South Korea). The scanning strategy followed the same recommendations, starting from the occlusal surface of the second molar up to the contralateral one, then scanning all along the buccal surface and then moving palatally. The scans have been performed by the same operator (E. F.). The typodont was handheld while scanned and the environmental conditions have been kept constant, performing the scans in a mildly lit room at a comparable temperature. A total of n = 40 DIs were obtained with IOSs on Model C (n = 20) and Model S (n = 20). All the produced DIs and the reference scans were exported in Standard Tessellation Language (STL) file format.

Two reference files, ref-S and ref-C were obtained by scanning the two models (Model S and Model C) with a laboratory scanner: Aadva Lab Scan (GC Corporation, Tokyo, Japan) and used as controls as Shown in Figure 2. Each reference file was produced only after performing all the scans with the two IOSs under study for the corresponding model, in order not to create variations related to the removal and reinsertion of the prepared teeth.

FIGURE 2: ref-S scanned with Aadva lab scanner.



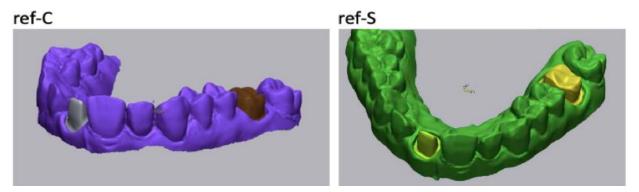
Ref-C and ref-S were then imported in Meshmixer (v3.5.474, Autodesk Inc, San Rafael, CA, USA), in order to cut the palate and make an even line on the vestibular aspect of the models to facilitate subsequent alignment with the IOS scans. The STL files obtained from the IOS were then superimposed to the reference scans by using an evaluation software: Geomagic Control X (v.2018.0.1, 3D Systems, Rock Hill, SC, USA). The accuracy of each DI was evaluated by calculating trueness and precision, based on ISO 5725 10, which defines accuracy as a combination of these two parameters.

The alignment between the reference STL file and the STL under study was performed with an "initial alignment" followed by a "best-fit alignment". Once aligned, the files were compared with the "3D compare" function.

For the trueness, all the IOS STL files (n = 20) related to Model C were compared with the ref-C STL file. The same has been done with all the IOS STL files (n = 20) of Model S with ref-S STL file. For each scan superimposition the "best-fit alignment" and "3D compare" were performed separately on the full abutments of elements #16 and #21. This has been made by selecting the area of the abutment up until the preparation margin on the reference STL files by using the "region" function before alignment (Fig. 3).

A total of n=10x2x4=80 values of trueness were obtained.

FIGURE 3. The STL files of ref-C and ref-S after region selection on the two prepared teeth.

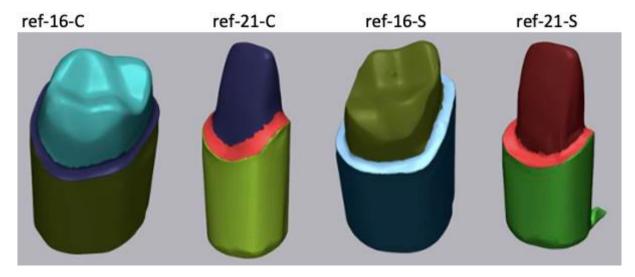


The results were expressed as Root Mean Square (RMS) values, indicating the deviation between the two models, and visualized as a color-coded map. The tolerance range in the color-coded scale was established between + 100 and - 100 μ m of discrepancy. A high trueness reflected a high level of 3D matching of the superimposed structures and resulted in a low RMS and highlithed in green color.

For precision, instead of using the ref-C and ref-S files, the scan that obtained the highest trueness in each subgroup was used as a reference for the superimpositions of the related abutment. Also, the preparation margin areas were analyzed for each abutment type. Single elements #16 and #21 with chamfer and shoulder preparation were removed from the typodont and scanned with Aadva Lab Scan. This resulted in the creation of 4 reference models: ref-16-C, ref-21-C, ref- 16-S and ref-21-S, to which each scan was compared.

The reference scans were imported on Geomagic Control X as STL files and the margin alone was selected with the "region" function on each reference model (Fig. 4). Then, with the "transform alignment" function each reference model was aligned to the same full-arch IOS STL files that were used for trueness and precision. In each superimposition, after "best-fit alignment", the "3D compare" function was activated only on the selected margin.

FIGURE 4. The 4 reference STL files after region selection on the preparation margin.



The results of the marginal trueness were expressed as RMS values and described with a colorcoded map. The data obtained were divided in the same groups and subgroups as previously reported.

Another marginal analysis was performed by visualizing a bucco-palatal cross-section of the two prepared teeth #16 and #21 for each type of preparation with each scanner, after "transform alignment" and "best-fit alignment", by means of the "2D compare" function.

Statistical Analysis was performed with SPSS Statistics software Version (26) (IBM, Armonk, NY, USA).

One sample Kolmogorov-Smirnov test was performed to evaluate the normality distribution of the accuracy values per each group.

Independent samples T-test was performed for normally distributed sample groups. Mann-Whitney U test for independent samples was applied to non-normally distributed sample groups. The statistical significance level was accepted as p < 0.05.

RESULTS

Table 1 reported the RMS values in μ m for the mean trueness of all scanners on each preparation type. Different low-case letters indicate statistically significant differences (p < 0.05) between the two scanners on each preparation type.

TABLE 1: mean trueness in RMS (μ m), standard deviation (SD) and level of significance for the full abutment analysis on molars (#16) and incisors (#21) with chamfer (C) and shoulder (S) preparations.

	#16 Chamfer	#21 Chamfer	#16 Shoulder	#21 Shoulder
TRIOS 3	19,1 ± 2,6 ª	27,6 ± 5 ª	18,9 ± 2,6 ª	$30,3 \pm 4,4$ ^a
Medit i700	18,5 ± 2,1 ª	$25,1 \pm 2,6^{a}$	19,8 ± 5 ª	36,1 ± 4,5 ^b

No statistically significant difference was observed between TRIOS 3 and Medit i700 regarding the trueness of molar and incisor chamfer preparations and of molar shoulder preparation. A statistically significant difference was shown in the trueness on incisor shoulder preparation. In the incisor shoulder preparation, TRIOS 3 ($30.3 \pm 4.41 \mu m$) performed statistically better than

Medit I700.

TABLE 2 : RMS values in μ m for the mean precision of all scanners on each preparation type. Different low case letters indicate statistically significant differences (p < 0,05) between the two scanners on each preparation type.

	#16 Chamfer	#21 Chamfer	#16 Shoulder	#21 Shoulder
TRIOS 3	9 ± 1 ª	11,7 ± 0,8 ^b	$9,4 \pm 0,7$ ^b	10,6 ± 0,6 ^b
Medit i700	8,9 ± 1,3 ª	9,5 ± 0,8 ª	6,9 ± 1,1 ª	$8,5 \pm 0,8^{a}$

No statistically significant differences were observed between TRIOS 3 and I700 Medit regarding the precision of molar chamfer preparation. Instead, for incisor chamfer, molar shoulder and incisor shoulder preparations there was a statistically significant difference: Medit I700 performed statistically better on Incisor prepared with chamfer or shoulder, while Trios 3 performed statistically better on molar prepared with shoulder.

Marginal analysis

Table 3 displays the RMS values in mm for the mean trueness of all scanners on each preparation type at the marginal level . Different low case letters indicate statistically significant differences (p < 0.05) between the two scanners on each preparation type

TABLE 3:

	Marginal trueness #16 C	Marginal trueness #21 C	Marginal trueness #16 S	Marginal trueness #21 S
TRIOS 3	542,6 ± 10 ª	$360,1 \pm 16^{a}$	530 ± 5,4 ^b	267 ± 8,3 ^b
Medit i700	$543,8 \pm 7,3^{a}$	375,6 ± 7 ^b	505 ± 5,4 ª	178 ± 35 ^a

Statistically significant differences were observed among the IOSs under study on all preparations except for molar chamfer preparation.

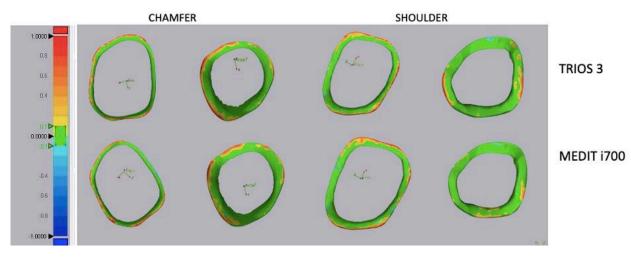
TRIOS 3 (360.1 \pm 15.91 μ m)performed statistically better on incisor chamfer preparation compared to Medit I700.

At the marginal level, Medit I700 performed statistically better than TRIOS 3 for molar shoulder preparation ($505 \pm 5.4 \mu m$) and for incisor shoulder preparation ($178.1 \pm 35 \mu m$).

Figure 5 shows the color-coded map representing the marginal trueness of TRIOS 3 and Medit i700 for both molars and incisors with chamfer and shoulder preparations. The images are taken from the superimposition reporting the highest value of trueness among the scans on each preparation. The tolerance range was set at \pm 100 μ m.

The colors reflect the RMS values described in Table 3 and allow the visualization of the areas with a higher discrepancy (red areas). We can identify areas colored in yellow and red mainly at the most external aspect of the marginal finish line, where the prosthetic crown should close in order not to leave marginal gaps. Yellow and red areas represent positive deviation values over 100 μ m (range of tolerance) with respect to the reference model. The values obtained are overall higher than the ones recorded for the full abutment analysis in Table 1.

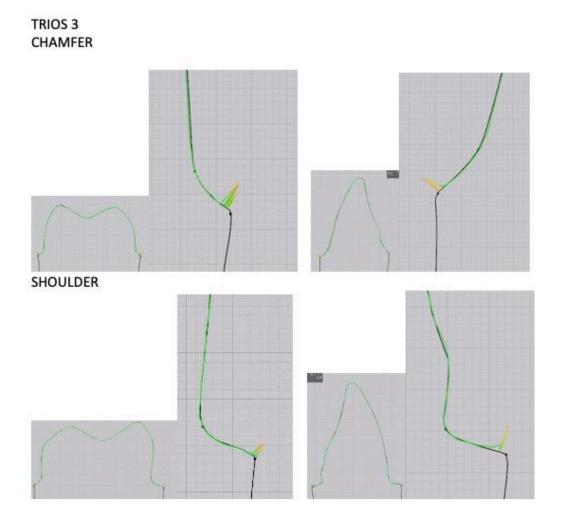
FIGURE 5. Color-coded map of the marginal trueness on molars and incisors with chamfer and shoulder preparations.



The 2D compare analysis performed on the cross-sections showed a difference in the reproduction of the marginal finish line between the superimpositions of IOSs' scans with ref-C and ref-S scans (full abutment analysis) and the superimpositions with the reference single abutments (ref- 16-C, ref-21-C, ref-16-S and ref-21-S) (marginal analysis). Figure 6 shows the 2D compare analysis of the cross-sections performed during the marginal trueness evaluation for the two IOSs compared to the reference single abutments (ref- 16-C, ref-21-C, ref-16-S and ref-21-C, ref-16-S and ref-21-C, ref-16-S and ref-21-S). The section is buccopalatal on both incisors and molars.

All comparisons show a deviation of the margin scanned with the IOSs with respect to the reference scan. This discrepancy reflects the RMS values observed in Table 3, which result way higher than the full abutment comparisons.

FIGURE 6. 2D compare analysis on molars and incisors (chamfer and shoulder) scanned with TRIOS3.



DISCUSSION

The aim of this in vitro study was to analyze the accuracy of TRIOS 3 and Medit i700 on subgingival horizontal preparations.

Regarding the trueness, in the full abutment analysis the null hypothesis (H0), stating that there was no statistically significant difference in the accuracy between the scans made with the IOSs under study on teeth with subgingival horizontal preparations, was accepted except for one group. As reported in Table 1, the trueness of TRIOS 3 and Medit i700 demonstrated no statistically significant difference in reproducing both molars and incisors with chamfer preparations and molars with shoulder preparation, demonstrating a clinically acceptable accuracy. (12,13) Only the trueness of incisor with shoulder preparation showed a statistically significant difference between the two scanners. The highest trueness for TRIOS 3 was reported for molar preparations: $19.1 \pm 2.63 \mu m$ (chamfer); $19.9 \pm 2.56 \ \mu m$ (shoulder). Also for Medit i700 the highest trueness was reported for molars: $18.5 \pm 2.12 \ \mu m$ (chamfer); $19.8 \pm 5.01 \ \mu m$ (shoulder). However, Medit i700 and TRIOS 3 showed a clinically

acceptable accuracy for incisors with both preparation types, way below the maximum tolerated value of $100 \ \mu m$.

As reported in Table 2, both IOSs showed a comparable precision on molar tooth with chamfer preparation. This is the only case in which the null hypothesis (H0) was accepted. For the other three preparation types the null hypothesis (H0) was rejected, with Medit i700 showing the highest precision. In brief, TRIOS 3 and Medit i700 showed high trueness on all abutment preparations, with Medit i700 being the most precise on all abutments apart from the molar tooth with chamfer preparation, on which it is comparable to the other IOS. The high accuracy of Medit i700 and TRIOS 3 on horizontal preparations is supported by the recent literature. Falih et al. performed an in vitro study in which they compared the trueness, precision of eight intraoral scanners on a maxillary arch with the right molar prepared with shoulder, chamfer and vertical supragingival finish line designs. Medit i700 demonstrated the highest trueness and precision on all preparation types. The mean value (RMS) obtained for trueness on chamfer preparation was $12 \pm 1 \mu m$, the one for shoulder preparation was $16 \pm 1 \mu m$. For precision, the values obtained were respectively $9 \pm 2 \mu m$ and $6 \pm 1 \mu m$. (22) The deviation values for Medit i700 shown in the present study for preparations on molars are a little bit higher than this but comparable, while the values of precision are the same. The increased discrepancy showed in our study is most likely associated with the position of the preparation margin with respect to the gingiva, which constitutes per se a confounding factor able to affect the overall performance of the IOS. Comparable values of trueness and precision were obtained by Medit i700 on supragingival chamfer preparations for short-span fixed dental prostheses by Jivanescu et al. with a trueness of $25.55 \pm 1.85 \,\mu\text{m}$ and a precision of $9.1 \pm 3.8 \,\mu\text{m}.(23)$

A study with a protocol similar to the present one has been carried out by Zarone et al., comparing the accuracy of Medit i700 on a model with a molar prepared with chamfer preparation positioned 1 and 2 mm below the gingival margin. The mean trueness and precision obtained on 1 mm subgingival preparation were respectively $41.1 \pm 0.57 \mu m$ and $27.4 \pm 1.52 \mu m$, which are RMS values comparatively higher than the ones obtained in this study. An interesting aspect of the study by Zarone et al. is that chamfer preparation with a 2 mm deep subgingival margin showed better results in terms of trueness and precision.(24)

The study by Bernauer et al. analyzing the accuracy of different scanners on the chamfer, shoulder and tangential preparation designs showed high accuracy for TRIOS 3 on a chamfer preparation of 0.8 mm epigingivally located (trueness: $42 \pm 5 \mu m$ on incisors and $39 \pm 4 \mu m$ on molars) and on shoulder preparation (trueness: $48 \pm 5 \mu m$ on incisors and $34 \pm 4 \mu m$ on molars). These values are higher compared to the present study. However, similarly to our study, a lower trueness is registered for incisors compared to molars with horizontal preparations.(18)

The marginal analysis in Table 3 displayed statistically significant differences in trueness among the two scanners on incisors with chamfer preparation and molars and incisors with shoulder preparation. The null hypothesis (H0) was rejected. Instead, on molars with chamfer preparation the null hypothesis (H0) was accepted.

None of the scanners demonstrated a clinically acceptable accuracy on the marginal finish line, with RMS values way higher than the $\pm 100 \,\mu m$ threshold of deviation.

Conversely to the results obtained on full abutments, incisors with both chamfer and shoulder preparations demonstrated a higher trueness with respect to molars with both preparations. In Figure 5, the distribution of the discrepancy from the reference single abutment scan is described. The areas of maximum deviation accumulate along the most external portion of the margin, where the prosthetic crown should seal leaving a marginal discrepancy of $< 120 \mu m$. The lowest values of deviation were seen for the incisor with shoulder preparation for both scanners.

Similar data regarding the marginal trueness were obtained in the study by Son et al., that analyzed the accuracy of two intraoral scanners (Medit i500 and CS3600) on molars with chamfer preparations positioned at different gingival depths. The reported mean marginal trueness on 1 mm subgingival preparations was $228.2 \pm 6.7 \mu m$ (CS3600) and $255.6 \pm 8 \mu m$ (Medit i500), comparable to the results of the present study. In the study by Son et al. the same evaluation has been performed with or without gingival displacement cords, showing an improvement of scanning trueness of about 90% with their use. This suggests that for subgingival finish line designs gingival displacement cords could improve the clinical results. (25)

Nedelcu et al. also evaluated the accuracy of IOSs on subgingival horizontal finish line designs, demonstrating higher positive deviation values in the marginal region of subgingival finish lines. It was pointed out that this deviation may produce short margins and poor marginal fit of the prosthesis. (26)

In the current study the analysis went deeper in the understanding of this increased marginal discrepancy by performing a 2D analysis on the cross-sections of all prepared teeth for both IOSs. Figure 6 demonstrated a deviation from the reference single abutment scan on the most external portion of the marginal finish line, which is closer to the gingival margin.

This deviation is probably related to the ability of the IOSs to only detect directly visible regions, which constitutes a limiting factor for the reproduction of subgingival margins as the gingiva

hampers the light beam to reach the most apical portions. Moreover, IOSs software creates a compensation at the level of the sharp and low point clouds acquisition regions. This leads to the creation of connections and gaps correction between close outermost points when scanning the sharp edges of the finish line, resulting in a junction between the margin of the preparation and the gingival margin. (25,27) This "bridge effect" is well described by Keeling et al. in a study analyzing the effect of clinical factors, namely the presence of adjacent teeth, proximity to gingiva and impairment of wand positioning in the oral cavity, on IOSs' accuracy (9). All these factors, hampering the visibility of the prepared abutments, significantly affected the sharpness of the marginal finish lines. In particular, preparation margins in close proximity to adjacent teeth demonstrated bulging or bridging with the latter, as a compensation produced by the IOS's software.

If, on one side, the findings of the current study confirm the high level of accuracy provided by TRIOS 3 and Medit i700 as described in the literature, they also raise questions about the actual marginal fit and subsequent clinical performance of prosthetic restorations obtained with the use of IOSs on subgingival preparations. Clinical studies on comparable clinical conditions with adequate follow-up time are necessary. Although this in vitro study tried to reproduce the clinical conditions at the single arch level in terms of teeth and soft tissues relationship, many other obstacles to scanning are found in the oral cavity. In particular, the difficulty of access in the circumscribed oral cavity, the presence of saliva and the possible occurrence of blood, are all factors that could affect IOSs' accuracy and which should be further addressed in clinical studies. Moreover, additional research is needed to evaluate the effects of gingival retraction on the accuracy of IOSs.

CONCLUSIONS

Within the limitations of the present study, we can conclude that:

- 1. Medit i700 and TRIOS 3 provide a clinically acceptable accuracy in the scanning of abutments with horizontal subgingival preparations, both on incisors and molars.
- 2. Medit i700 demonstrated overall the highest precision. However, none of the scanners used in this study provides a clinically acceptable accuracy when only the trueness of the marginal finish line design is analyzed. The discrepancy observed suggests an incorrect margin reproduction with a possible alteration in the adaptation of the prosthesis.

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4. Chapter 4: Digital workflow in vivo studies

4.1 A randomized controlled clinical trial on press and block lithium disilicate partial crowns: a four-years recall

ABSTRACT

To evaluate clinical performances of two lithium disilicate systems (Initial LiSi press vs Initial LiSi Block, GC Co., Tokyo, Japan) using modified United States Public Health Service (USPHS) evaluation criteria and survival rates after 4 years of clinical service.

Partial adhesive crowns on natural abutment posterior teeth were made on sixty patients. Patients were randomly divided into two groups: Group 1 Initial LiSi press and Group 2 Initial LiSi Block. Fabrication of partial crowns was made with full analog and digital workflow in Group 1 and 2 respectively. The restorations were followed-up for 1 and 4 years, and the modified USPHS evaluation was performed at baseline and each recall together with periodontal evaluation. Contingency tables to assess for significant differences of success over time in each group and time-dependent Cox regression to test for differences between the two groups were used and the level of significance was set at p<0.05.

Regarding modified USPHS scores, all evaluated parameters showed Alpha or Bravo and no Charlie was recorded. No statistically significant difference emerged between the two groups in any of the assessed variables (p>0.05). No statistically significant difference between scores recorded at the baseline and each recall. All modified USPHS scores were compatible with the outcome of clinical success and no one restoration was replaced or repaired, and the survival rate was 100% after 4 years of clinical service. No difference was found between traditional and digital workflow to fabricate the crowns. The two lithium disilicate materials showed similar results after 4 years of clinical service. The crowns realized with the two tested lithium disilicate materials with analog and digital workflows showed 100% survival after 4 years of clinical service and no statistically significative differences in modified USPHS scores.

INTRODUCTION

The mechanical and optical properties of lithium disilicate (LD) enable stiffer, more aesthetic, full and partial anterior and posterior crowns than other silicate ceramics. (1-4) Therefore, LD is a well-accepted prosthodontic material by both dentists and dental technicians. (5-9)

LD is offered into the market in two different formulations, press and blocks. The two LD have different formulations and differ in their composition, giving them similar, but not identical, mechanical, and optical properties. In fact, while for the press LD the final restoration is realized pressing the material at high temperature into the final shape in the laboratory, for the blocks LD the final piece is obtained with a subtractive procedure from a block of material. Blocks LD can be milled also chairside, reducing time and costs. Consequently, LD press and blocks do have different characteristics that will reflects also directly on accuracy of margins and occluso-axial angles. ^{11,12} Between the two types, press LD formulation has shown superior mechanical properties compared to block LD formulation. (13, 14)

In vitro studies have been widely used as a screening method among similar LD materials, (14-18) but randomized controlled trials [RCT] are needed to provide reliable clinical evidence.(19) The 'press' LD formulation was the first launched into the market and some RCTs are available on it. (19-28) Retrospective studies on posterior crowns up to 6 and 12 years showed overall survival rates of 95.46% and 97.93% showing bulk fractures of failed teeth. (20-21) Similar results were reported in other two retrospective studies, with a survival rate between 81.9% and 96.1% for a time frame between 9 and 15 years of clinical service (22-23) and in a 10-year prospective study the survival rate was 83.4%. (24) By contrast, fewer clinical studies are available for these 'blocks' formulation.(29) The first LD was launched in 2005 as IPS e-max Press (Ivoclar Vivadent AG) and recent reports show the material to be reliable for long term clinical use. (23,30-32)

Recently, a new LD material was introduced into the market as Initial LiSi Press (GC Co., Tokyo, Japan). It showed good mechanical properties (33,34) and excellent clinical results were reported after 3 years of clinical service, when adhesive partial pressed crowns (27) and full pressed crowns were made and luted on posterior teeth. (28,29) However, while promising results on medium- and long-term clinical trials are available for the Initial LiSi Press type, (27-32) only one short term RCT is available on Initial LiSi blocks. (29)

The clinical evaluation of single crowns can be performed using different scoring systems and the description of failure has been different among some clinical reports.(35-37) Malament et al., considered 'failure' the fracture of the partial crown so that the restoration had to be remade. (24) Other authors proposed to consider 'failure' also chipping in esthetic area and debonding of the crown. (35,36)

In a very recent article, a short term RCT on Initial LiSi Blocks versus Initial LiSi Press was reported and after one year of clinical service a 100% success was recorded of both LD press and block partial crowns. The aim of this medium-term randomized clinical study (RCT) was to evaluate the clinical outcomes of two LD materials, press and block (Initial LiSi Press and Initial LiSi Block; GC Co., Tokyo, Japan) after 4 years of clinical service.

The null hypothesis was that there is no difference between the two LD formulations at 4-year followup.

MATERIALS AND METHODS

Sixty patients were recruited between July 2018 and October 2018 in the Prosthodontics department University of Siena (Siena, Italy). All patients were informed about the scope of the trial and provided their written consent. The study protocol was approved by Ethical Committee (clinicaltrial.gov # NCT 01835821; protocol code PR001; date of approval 21 May 2018). Also, the clinical treatment was performed in accordance with the ethical standards of the Institutional and National Research Committee and with the Declaration of Helsinki of 1964 and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines. Patients were recruited according to the following inclusion and exclusion criteria:

Inclusion criteria. Periodontally healthy or successfully treated adult patients (Bop<10%) (18+ years) in need of an overlay or onlay partial crown (one restoration each) on a posterior tooth.

Exclusion criteria: Not adult age (< 18 years), pregnancy, disabilities, systemic disease or severe medical complications, lack of compliance, language barriers, allergic history concerning methacrylate, xerostomia, previous prosthodontic restorations of abutment teeth, severe and/or chronic periodontitis, heavy occlusal contacts or history of bruxism, rampant caries, plaque index higher than 20, bleeding on probing higher than 10%. Residual dentin thickness < 0.5mm between the bottom of the cavity and the pulp.

There were 35 females and 25 males with a mean age of 34 (± 7.5) years (range 18 to 42). Twentynine premolars and 31 molars were selected.

After being recruited, all patients underwent professional oral hygiene instruction and prophylaxis to achieve optimal plaque control and gingival health. Periodontal probing depth (PPD), bleeding on probing (BoP) and full-mouth plaque index (PI) were recorded for each patient. (37,38)

Clinical procedures

In order to standardize the clinical procedures, the same trained prosthodontist (M.F.) performed the clinical treatments. Intraoral radiographs were taken before starting the treatment using an individual X-ray tray specifically fabricated for each abutment tooth, to standardize radiographic examinations

and have the possibility to make the radiograph in the same position at future recalls. After anesthesia, rubber dam was placed, all carious lesions and any restorative material were removed.

Abutments were prepared at the margins with a chamfer finish line. To prepare the abutments diamond burs mounted on a high-speed handpiece were used. Cavity's design was made accordingly the presence of caries and pre-existing restorations. Manufacturers preparation guidelines were followed throughout. Teeth with a Residual dentin thickness (RDT) lower than 0.5 mm between the bottom of the cavity and the pulp were excluded from the study. Margin thicknesses was between 0.5-1 mm and 1.0-1.5 mm of occlusal clearance. As much as possible margins were kept into enamel (i.e. more than 50%) and placed equi- or supra-gingivally; only interproximal boxes had cervical margins below the cementum-enamel junction. In order to be included into the study, cusps were covered and teeth must be vital.

The abutments' dentin received an immediate dentine sealing with the application of a universal bonding agent (G-Premio Bond, GC Co., Tokyo, Japan) and then a thin layer of flowable composite (Genial Flow, GC Co., Tokyo, Japan). Undercuts were filled by flowable composite to realize a uniform cavity. The abutments, after being prepared, were finished and polished with a rubber point under copious water spray, and finally impressions were made.

Randomization, allocation concealment and masking of examiners The sixty recruited sample teeth were randomly divided in one of the two experimental groups (n=30), accordingly with the material used for the final restoration.

- Group 1: Initial LiSi Press (GC Co, Tokyo, Japan).
- Group 2: Initial LiSi Block (GC Co., Tokyo, Japan).

Details of the teeth included in the study are reported in Table 1.

	Molars	Premolars	Molars	Premolars	Number of	Number	Old Restoration
	upper	upper	lower	lower	cusps	of	or new
						surfaces	restoration
Group 1	8	7	7	8	All (26), 3 (4)	4 (26, 3 (3)	OR 24/NR 6
Group 2	7	8	7	8	All (27, 3 (3)	4 (27, 3 (3)	OR 23/NR 7

Treatment assignment was noted in the registration and the treatment assignment form was kept by the study. Allocation concealment was performed by using opaque, sealed and sequentially numbered envelopes. The statistician made the allocation sequence by means of a computer-generated random list and instructed a different subject to assign a sealed envelope containing the type of LD material to be used. The opaque envelope was opened immediately before material selection and communicated to the operator after each tooth preparation was completed right before the impression taking.

The final impressions of Group 1 were performed using an elastomeric material (Exa'lence, GC Co., Tokyo, Japan), and then the impression was poured in Type IV (FujiRock, GC Co., Tokyo, Japan). The final restorations were made strictly following the manufacturers' instructions.

Final impressions of Group 2 were made using an intraoral scanner (Aadva iOS, GC Co., Tokyo, Japan) realizing a digital model so that the crowns were digitally waxed-up and then shaped from Initial LiSi blocks in a milling machine (n4 Plus, Vhf AG, Ammerbuch, Germany).

All abutments received a temporary crown made in self-curing acrylic resin and cemented with noneugenol temporary cement to protect the prepared teeth. LD final restorations were delivered after one week and luted following manufacturers' instructions after their try-in. The final restorations made by both traditional and digital workflow needed only small adjustments and no piece was remade. The intaglio surface of each restoration was etched with 10% hydrofluoric acid for 1 minute, silanized with G-Multi Primer (GC Co., Tokyo, Japan) and then luted using LinkForce (GC Co., Tokyo, Japan) in both groups rubber dam was placed in all cases to perform luting steps.

All patients were enrolled in an oral hygiene program in which recalls were planned every 6 months. A clinical examination was performed immediately after the seating of crowns (baseline), as well as after 6 and 12, 24, 36 and 48 months of clinical service. Modified USPHS scores was assessed and recorded ,as reported in Table 2, at baseline and at the 1- and 4-years follow-up also taking a standardized intraoral radiograph using a customized x-ray tray for each restoration. ³⁵At the 4-years recall, two examiners (E.F.C. and G.V.) after being calibrated, blinded evaluated all the patients and assessment was taken by consensus.

Table 2. Criteria of the Modified United States Public Health Service Method.

Topics	Score	Criteria		
	Alpha	Margin continuity(without prominence or crack)		
Marginal adaptation (MARA)	Bravo	Little discontinuity detectable by explorer, but it does not require replacement		
	Charlie	Prominence or crack; require replacement		
Color Alteration	Alpha	No color alteration close to the tooth structure		
(COA)	Bravo	Little color alteration, clinically acceptable		
	Charlie	Esthetically unacceptable		
Marginal	Alpha	No marginal discoloration		
Discoloration	Bravo	Marginal discoloration		
(MARD)	Charlie	Deep discoloration		
	Alpha	No fracture		
Restoration Fracture (RESF)	Bravo	Small fracture fragments (1/4 of the restoration)		
	Charlie	Severe fracture (3/4 of the restoration)		
	Alpha	No tooth fracture		
Tooth Fracture (TFRA)	Bravo	Small fracture fragments of tooth fracture (1/4)		
	Charlie	Severe tooth fracture $(1/2)$		
Restoration wear	Alpha	No wear		
(RESW)	Bravo	Wear		
Antagonist Tooth	Alpha	No wear		
Wear (ANTW)	Bravo	Wear		
Caries Presence	Alpha	Absent		
(CARP)	Charlie	Present		
Postoperative	Alpha	Absent		
Sensitivity (POSTS)	Charlie	Present		

Also, periodontal parameters as Bleeding on Probing (BoP) and Plaque Index (PI) and Stain and Gap at Margins were recorded as well at each recall.

In order to clinically classify each single crown, it was considered "Success" when it did not show any biological (such as pulpal or periodontal problems) or technical complication (such as debonding, chipping or fractures of the restorations) at the last recall, and "Survival" when it was still in place at the last recall but with a biological or technical complication that needed to be treated, but without the need to remake the crown; if the restoration was lost at last recall or, because of mechanical or biological complications, needed to be replaced, it was classified as "Failure".(28)

Statistical analysis

Contingency tables to assess for significant differences of success over time in each group and timedependent Cox regression to test for differences between the two groups were used and the level of significance was set at p<0.05. The Mann-Whitney 'U' test was used and the level of significance was set at p<0.05 to analyze the periodontal parameters.

The statistical analysis was calculated by dedicated software (PASW Statistics 18, IBM, Armonk, NY, USA).

RESULTS

The patients' recall rate was 100%. Also, each recall, survival rates were 100%, since no major technical or biological complications were observed.

At 1-year follow-up, clinical examination of periodontal parameters showed the following mean scores for Groups 1 and 2 respectively: 17.5 ± 2.5 (range: 15-20) and 17.0 ± 1.0 (range: 15-19) for PI; 2.9±0.5 mm (range: 1-4) and 2.8±0.5 mm (range: 1-4) for PPD; 16.1±0.5 mm (range: 17-24) and 16.8±1.2 (range: 16-21) for BoP (Table 3b).

At 4-year recall the clinical parameters showed the following scores for Groups 1 and 2 respectively: 18.5±2.5 (range: 15-20) and 18.0±1.0 (range: 15-19) for PI; 3.0±1.5 mm (range: 1-4) and 2.8±1.5 mm (range: 1-4) for PPD; 16±1.5 mm (range: 17-24) and 16.5±2.5 (range: 16-21) for BoP (Table 3c).

No statistically significant differences were found between the two Groups at baseline, 1-year and 4-year follow-up.

Tables 3a-c. Periodontal parameters. No statistically significant differences were found at the baseline, 1- and 4-year recall between the two groups.

Legend: PI: plaque index; PPD: Periodontal probing depth; BoP: Bleeding on probing.

Table 3a: Baseline

	PI	PPD	ВоР
Group 1 (Initial LiSi Press)	17.5±2.5 ^a	2.9±0.5 mm ^a	16.1±0.5 ^a
Group 2 (Initial LiSi Block)	17.0±1 ^a	2.8±0.5 mm ^a	16.0±1.2 ª

Table 3b: 1-year recall

	PI	PPD	BoP
Group 1 (Initial LiSi Press)	17.5±2.5 ª	2.9±0.5 mm ^a	16.1±0.5 ^a
Group 2 (Initial LiSi Block)	17.0±1 ^a	2.8±0.5 mm ^a	16.8±1.2 ª

Table 3c: 4-year recall

	PI	PPD	BoP
Group 1 (Initial LiSi Press)	18.5±2.5 ª	3.0±1.5 mm ^a	16.0±1.5 °
Group 2 (Initial LiSi Block)	18.0±1 ^a	2.8±1.5 mm ^a	16.5±2.5 ª

Tables 4a-b: Contingency tables for Lisi press (a) and Lisi Blocks (b).

Topics	Time 0			Time 1		Time 4		Sig.		
Topics	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	Sig.
Marginal										
adaptation	30	/	/	29	1	/	28	2	/	.770
(MARA)										
Color										
Alteration	30	/	/	30	/	/	28	2	/	.326
(COA)										
Marginal										
Discoloration	30	/	/	29	1	/	27	3	/	.318
(MARD)										
Restoration										
Fracture	30	/	/	29	1	/	28	2	/	.770
(RESF)										
Tooth										
Fracture	30	/	/	30	/	/	30	/	/	N.A.
(TFRA)										
Restoration										
wear	30	/	/	30	/	/	29	1	/	.1000
(RESW)										
Antagonist										
Tooth Wear	30	/	/	30	/	/	29	1	/	1.000
(ANTW)										
Caries										
Presence	30	/	/	30	/	/	30	/	/	N.A.
(CARP)										
Postoperative										
Sensitivity	30	/	/	30	/	/	30	/	/	N.A.
(POSTS)										

Table 4a: Modified USPHS scores for Lisi Press and significance of differences over time points.

Topics Time 0		Time 1	Time 1			Time 4				
	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie	
Marginal										
adaptation	30	/	/	29	1	/	27	3	/	.318
(MARA)										
Color										
Alteration	30	/	/	29	1	/	27	3	/	.318
(COA)										
Marginal										
Discoloration	30	/	/	29	1	/	27	3	/	.318
(MARD)										
Restoration										
Fracture	30	/	/	29	1	/	27	3	/	.318
(RESF)										
Tooth										
Fracture	30	/	/	30	/	/	30	/	/	N.A.
(TFRA)										
Restoration										
wear	30	/	/	29	1	/	27	3	/	.318
(RESW)										
Antagonist										
Tooth Wear	30	/	/	29	1	/	27	3	/	.318
(ANTW)										
Caries										
Presence	30	/	/	30	/	/	30	/	/	N.A.
(CARP)										
Postoperative										
Sensitivity	30	/	/	30	/	/	30	/	/	N.A.
(POSTS)										

Table 4b: Modified USPHS scores for Lisi Blocks and significance of differences over time points.

No Charlie score was recorded at 4-year recall. At 1-year recall, only 1 restoration showed Bravo score for MARA, COA, MARD, RESF, RESW and ANTW, while at 4-year recall for the same clinical parameters between 2 and 4 restorations scored Bravo.

No statistically significant differences were found between the experimental groups in any of the assessed variables (p>0.05) and among baseline and the two recalls. No statistically significative difference was found with time-dependent Cox-regression analysis for Alpha as shown in Table 5.

Table 5: Time-dependent Cox Regression analysis. No statistically significative difference was found between the two different groups.

,10ups.	
Topics	Sig. (Cox
Topics	Regression)
Marginal	.939 (NS)
adaptation	
(MARA)	
Color	.879 (NS)
Alteration	
(COA)	
Marginal	.1000 (NS)
Discoloration	
(MARD)	
Restoration	.939 (NS)
Fracture	
(RESF)	
Tooth	.1000 (NS)
Fracture	
(TFRA)	
Restoration	.762 (NS)
wear	
(RESW)	
Antagonist	.763 (NS)
Tooth Wear	
(ANTW)	
Caries	.1000 (NS)
Presence	
(CARP)	
Postoperative	.1000 (NS)
Sensitivity	
(POSTS)	

DISCUSSION

This RCT at one year recall was the first that reported clinical performances of partial single units made with two different Lithium Disilicate formulations (press and block) and the present report extended the recall at 4 years.

Published studies on lithium disilicate crowns were mainly conducted retrospectively. Several retrospective studies on lithium disilicate partial crowns up to 6 and 12 years showed a survival rate up to 95%,(20-21) whilst other two trials a survival rate between 81.9% and 96.1% for a time frame between 9% and 15%. (22-24) All these studies were performed with traditional workflow and press formulation of the material.

The present study was conducted prospectively and showed a success with a consequently survival rate of 100% and it is one of the first published on lithium disilicate block formulation. At Baseline all restorations scored Alpha for all parameters then at 1-year and 4-years recalls the same modified USPHS parameters were revaluated in order to follow the behavior of lithium disilicate partial crowns in both formulations (Table 4a-b).

Consequently, the tested null hypothesis that there is no difference between the two LD formulations at 4-year follow-up was accepted; in fact no statistically significant differences were found at baseline, 1-year and 4-year recalls among all clinical parameters scores of the two Groups.

The little changes that were recorded (between baseline and 1- and 4-years recall) did not affect the clinical behavior of the restorations and were compatible with clinical success because c. In fact as shown by time-dependent Cox-regression analysis in Table 5, there isn't any significative difference between Alpha parameters in the two groups.

Accordingly with modified USPHS scores, the null hypothesis was accepted, since there were no statistically significant differences between the experimental groups in any of the assessed variables and at each recall. None of the nine parameters of modified USPHS scores showed statistically significant differences at recalls. The best scores were recorded for "caries presence", "post operative sensitivity", "tooth fracture" parameters, although all parameters showed good clinical values (Tables 4a-b). The limited observation time (4 years) might influence these scores and longer recalls will confirm or not the high clinical performances that were recorded till now. The good scores of 'Caries presence' can be related to the margins' position (equi- and/or supra-gingival) and with the professional recall and home oral hygiene regimes. Similarly, the high score of "Restoration wear" and "Antagonist tooth wear" could be related to the skill of lab technician on properly waxing-up, with both analog and digital workflows, in combination with proper occlusal thickness and functional check of each restoration ⁶ and in the absence of any parafunction in the selected patients. It can be

desirable that "Restoration wear" and "Antagonist tooth wear" parameters will be evaluated in patients with parafunction to report the behavior of lithium disilicate crowns under heavy occlusion. When considering the three periodontal parameters, all indicated good medium-term success and no differences were found between the two tested Groups.

When the cavity design of abutments is considered, it is evident that was not possible to standardize it, because it was related to specific clinical situations of each sample tooth. In this study, the sample teeth were collected when at least one cusp was to be replaced and when the cavity had one or two proximal boxes. The presence of proximal boxes permits to make proper contact areas, retain the temporary restoration and stabilize the partial crowns during cementation. (40, 41)

LD crowns need a proper fit and to be bonded and luted adhesively. (31-32) In this study all the restorations were cemented adhesively; cavity and the internal surface of LD restoration were etched and bonded or silanized. Luting steps were performed always under rubber dam isolation. The luting procedures is crucial to absorb occlusal forces and seal the enamel margins (40-41) and for both tested materials (pressed and CAD/CAM blocks) this procedure was very effective, after 4-years of clinical service.

The available number of RCT comparing pressed versus milled blocks of LD is limited. For that more similar RCTs and with a longer observation time are needed to confirm or not the results of this study. Based on the results of this trial, both workflows can achieve very good clinical performances. Also, another limitation of this trial is that the two LD formulations were tested only on posterior teeth but are also indicated to be used in anterior region. Recently, it was pointed out that an additional 0.5mm of incisal reduction is required when LD block formulation is used (to accommodate the over-milling in the thin incisal region) in anterior region. (42) Thus, a pressed method might be preferred to prevent unnecessary tooth preparation. Further clinical trials on anterior teeth are therefore very desirable and expected.

The main difference between the two experimental groups was the type of impression and the consequent workflow, traditional impression in Group 1 and digital impression by iOS in Group 2. The different workflow might determine or not different clinical results. Because no differences were found between Modified USPHS scores recorded on LD crowns made by the traditional and digital workflow at the 4-year recall it can be concluded that both can be clinically used. However, these clinical data are not in agreement with those reported by Schestatsky et al. (13) that recently evaluated, under lab conditions, the effect of two workflows (pressing-analog and digital-CAD/ CAM) to make LD crowns also on internal and marginal adaptation and reported that pressing technique leads to better marginal and internal fit than the complete CAD-CAM workflow. However, it must be considered that the investigation was performed in the lab and it can be also speculated that the iuxta

or supragingival margins' position of LD partial crowns can be properly kept clean although the marginal gap can be 100 microns or more.(13) More investigations are needed both in the lab and clinically to establish the acceptable marginal gap for a crown.

The clinical evaluation of restorations is a well discussed topic in dentistry. When partial crowns are under clinical periodical evaluation, different clinical parameters and scores are used.(35-37,42) The assessment usually starts immediately after luting as baseline and then at each recall to evaluate clinical behaviors and performances under clinical service. The USPHS and modified FDI criteria were elaborated in several categories with some sub-categories.(35-37,42) USPHS and modified FDI criteria want to evaluate direct and indirect restorations. In this study the Modified USPHS criteria were used.

The results of this study recorded with Modified USPHS scores showed that at 1- and 4-years recall showed that the crowns made with analog and/or digital workflow performed similarly. In summary, no mechanical and/or biological complications were observed at 1- and 4-years recalls thus 100% survival was reported. Only three chipping for Lisi blocks and 2 for Lisi pressed were recorded. Anyway, all the restorations were still in clinical service and did not need to be replaced.

These findings must be confirmed by a longer clinical observation time, possibly in a wider number of sample teeth, and with teeth of a less ideal nature, such as with sub-gingival margins or sub-optimal plaque control.

CONCLUSIONS

Within the limitations of the present RCT, the following conclusions can be drawn:

- The tested lithium disilicate materials presented comparable clinical outcomes and effectiveness at the baseline 1-year and 4-years recall.
- No differences were found between analog and digital workflow: the crowns of both Groups showed 100% survival and 90% success after 4-years of clinical service.
- Longer observation times are needed to confirm the findings of this RCT.

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4.2 A Randomized Controlled Clinical Trial on Lithium Disilicate Veneers Manufactured by the CAD–CAM Method: Digital Versus Hybrid Workflow

ABSTRACT

Pressed lithium disilicate is largely used for veneer manufacturing, but a new block formulation has recently been released on the market. This study evaluated the clinical performance of milled lithium disilicate veneers (LiSi Block, GC Co., Tokyo, Japan) realized with a fully digital or hybrid workflow using modified United States Public Health Service (USPHS) evaluation criteria and survival rates after 24 months of clinical service together with the patient's satisfaction using the Visual Analog Scale (VAS). A total of 105 veneers on natural anterior teeth were made on twentynine patients with LiSi Block (GC, Tokyo, Japan). Patients were randomly divided into three groups: Group 1, 35 veneers realized with a completely digital workflow using Trios 3 (3Shape A/S, Copenhagen, Denmark); Group 2, 35 veneers realized with a completely digital workflow using Experimental IOS (GC, Tokyo, Japan); and Group 3, 35 veneers realized with a hybrid workflow. The restorations were followed up for 24 months, and the modified USPHS evaluation was performed at baseline, 12 months, and 24 months together with periodontal evaluation. Repeated measures two-way ANOVA and the Tukey test were applied to compare the modified USPHS method values ($\alpha = 0.05$). STATISTICA 10.0 software and SIGMAPLOT 12.0 software were used to perform statistical analysis. There were no statistically significant differences between the three groups and with the interaction of group vs. time periods. The satisfaction scores of 7.35 ± 1.8 and 9.4 ± 0.37 were recorded before and after treatment, respectively. Milled lithium disilicate veneers showed a good clinical outcome after 2 years of clinical service. No difference was found between fully digital or hybrid workflow.

INTRODUCTION

Ceramic laminate veneers are considered a conservative solution for patients requiring an improvement in the shape, color, or position of their anterior teeth.(1,2) Due to growing patient demand for esthetic restorations, during recent decades, the use of veneers has become a widespread, reliable, and successful technique.(3) Traditionally, ceramic veneers are fabricated using a layering technique that incorporates refractory dies to support condensed layers of ceramic.(4) This technique gives the technician full control over the layers incorporated, resulting in a naturally looking restoration, but the process is technique-sensitive, and manual mixing and

layering of the porcelain may result in the incorporation of small voids. In recent years, however, lithium disilicate has become one of the most commonly used ceramics in dentistry,(5) and veneers are one of its more interesting applications as it gives clinicians the best compromise in terms of esthetics and strength for all-ceramic monolithic restorations.(6) Lithium disilicate was firstly introduced into the market as a core material in 1998 (Empress 2, Ivoclar Vivadent, Schaan, Lichtenstein) and was then replaced by IPS e.max Press (Ivoclar Vivadent, Schaan, Lichtenstein), which is suitable for monolithic restorations. To accommodate the material to the needs of the CAD/CAM production process, partially precrystallized blocks (IPS e.max CAD, Ivoclar Vivadent, Schaan, Lichtenstein) were introduced and are now largely used. Nowadays, many brands are releasing their block formulation into the market and one of the aims of this study was to test a new one (LiSi Block, GC Co., Tokyo, Japan) for veneers. The two types of lithium disilicate have different formulations and differ in their composition, giving them similar, but not identical, mechanical and optical properties. The main advantage of pressed porcelain is that the resulting veneers have a high level of accuracy as the manufacturing process may assure a better margin, resulting in a more precise adaptation of the veneers on preparations with a smaller gap in the marginal area.(7,8) In fact, the use of press lithium disilicate is already largely documented in literature. (9-11) Recently, CAD-CAM veneers from glass-ceramic blocks have become available, and their utilization is on the rise.(12) While such veneers are significantly stronger than feldspathic porcelain ones, the color of the blocks available is of a single shade. However, multi-layer blocks are in an experimental stage and may help to overcome this limitation. A great advantage of block lithium disilicate is that it allows a fully digital workflow. In fact, after veneer preparation, the impression can be performed with an intraoral scanner and sent to the lab. The technician will work directly on the digital model, realizing the digital project of the final restoration that will be directly sent to the milling machine. The lithium disilicate blocks will be directly shaped by a 5-axis milling machine into the final shape of the veneers based on the digital project and after being stained and polished will be ready for cementation. In recent studies, milled laminate veneers have shown a lower-quality marginal seal and adaptation and thicker cement layers than pressed veneers,(13–16) but this could also be due to the quality and update of the intraoral scanner, CAD software (DentalCAD version 2.2, exocad GmbH), and the milling machine used in the process. However, the marginal gap that has been recorded when lithium disilicate partial crowns were made through the CAD-CAM process was within clinical acceptability. (17) Survival rates of 94% (95% CI: 87-100%) for glass-ceramic and 87% (95% CI: 82-93%) for feldspathic porcelain veneers were estimated by Morimoto et al. (18) in a systematic review on the clinical outcome of veneers made by different types of ceramic. Their study also found that major complications of veneers include

debonding (2%), fracture (4%), secondary caries (1%), marginal discoloration (2%), and endodontic problems (2%). It should be taken into consideration that materials play an important role in the long-lasting results of a restoration but also other factors have to be considered such as: preparation technique,(19) thickness of the restoration, (20) quantity of residual enamel, and cementation technique.(21)

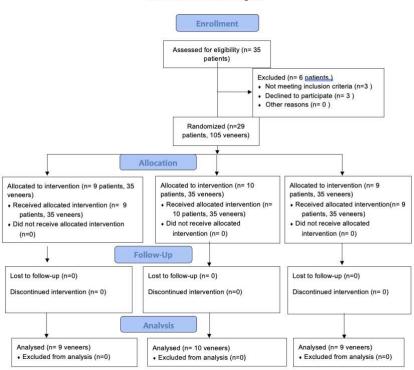
A factor playing a fundamental role in the realization of well-fitted, long-lasting veneers together with the accuracy of the laboratory phases is the quality of the final impression sent to the lab technician, whether traditional or digital. The accuracy of an intraoral impression depends on many factors, mainly related to the operator, (22) the patient, (23) and the quality of the intraoral scanners in terms of version and software update. (24,25)

Technologies are developing fast, and new intraoral scanners (IOSs) are being intro- duced on the market and their software is updated periodically. In this study, two IOSs were compared, one well known (Trios 3, 3 Shape, A/S, Copenhagen, Denmark) and the other an experimental system (Aadva 200, GC, Tokyo, Japan), versus a hybrid workflow: analogic impression, gypsum model, and then scanned with a laboratory scanner (Aadva Lab Scanner, GC, Tokyo, Japan). Randomized clinical trials on CAD/CAM veneers are scarce, as are reports about restorations made by early generations of chair-side CAD/CAM systems.(26) A 96.9% sur- vival rate at 5-years follow-up of CAD/CAM veneers was reported by Wiedhahn et al. (26) In a more recent study by Nejatidanesh et al., (27) the chair-side CEREC AC veneer survival rate was 99.0% after 5 years. In another study, milled and pressed lithium disilicate veneers had a similar clinical performance after the 1-year follow-up and both showed a great level of esthetic patient satisfaction.(7) However, only a few articles have evaluated the clinical performance of blocks lithium disilicate veneers obtained with a fully digital workflow with two different Intraoral scanners in terms of Modified United States Public Health Service (USPHS) method (28) periodontal values and patients' satisfaction (15) versus a hybrid workflow. The null hypotheses were: (1) the CAD/CAM ceramic veneers made using two different IOS have not statistically significant differences in clinical performance than those obtained with an analogic workflow, and (2) the laminates made digitally did not show a better and statistically significant degree of patient satisfaction before and after treatment than those analogically made.

Laminate veneers were realized on 29 patients for a total of 105 restorations equally distributed in the three groups between September 2021 and December 2021 and included in the present study. All patients were informed about the scope of the trial and provided their written consent. The study protocol was approved by Ethical Committee of University of Siena (clinicaltrial.gov

#CT01932049). Also, the clinical treatment was performed in accordance with the ethical standards of the Institutional and National Research Committee and with the Declaration of Helsinki of 1964 and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines. Patients enrolled in the present clinical trial were referred to the Prosthodontic department of the University of Siena asking for esthetic and functional rehabilitation of teeth in the esthetic area. Patients were recruited according to the following inclusion and exclusion criteria: Inclusion criteria: Periodontally healthy and without sign of parafunctions adults (18+ years), requiring between one to six laminate veneers for esthetic and functional rehabilitation of anterior teeth.

Exclusion criteria: Not adult age (< 18 years), pregnancy, disabilities, previous prosthodontic restorations of abutment teeth, endodontic treated teeth, severe and/or chronic periodontitis (plaque index higher than 20 or bleeding on probing higher than 10), sings of parafunction or history of bruxism, systemic disease or severe medical complications, allergic history concerning methacrylates, rampant caries, xerostomia, lack of compliance, language barriers. Selection of the participants was done according to the CONSORT 2010 Flow Diagram (Figure 1). FIGURE 1: CONSORT 2010 flow diagram



CONSORT 2010 Flow Diagram

The mean age was 44 years (range 18 to 65). There were 16 females and 13 males.

After being recruited, all patients underwent professional oral hygiene instruction and prophylaxis to achieve optimal plaque control and gingival health. Periodontal probing depth (PPD), bleeding on probing (BoP) (29), and full-mouth plaque index (PI) were recorded on each patient. Intraoral radiographs were taken, by customized radiographic trays made to each patient, to ensure that the teeth were vital and in endodontic health. All the patients didn't report any sign of parafunctions or bruxism.

Before starting the clinical procedures, the patients were randomly divided in 3 groups by a file generated by a software so that the 105 future restorations were realized by fully digital or hybrid workflow:

Group 1: 35 restorations scanned with Trios 3 (3Shape A/S, Copenhagen, Denmark) Group 2 : 35 restorations scanned with Experimental Aadva, (GC, Tokyo, Japan)

Group 3: 35 restorations made by hybrid workflow.

The mechanism used to implement the random allocation sequence (such as sequentially numbered containers) was electronically generated.

Group 1: 4 patients received 6 laminate veneers, 2 patients 2 laminate veneers, 2 other patients 3 laminate veneers and 1 patient only 1 laminate veneer.

Group 2: 4 patients received 6 laminate veneers, 2 patients 2 laminate veneers, 3 other patients 1 laminate veneer and 1 patient 4 laminate veneer.

Group 3: 4 patients received 6 laminates veneers, 4 patients 2 laminates veneers, 3 patients 1 laminate veneer.

Group 1 and 2: The initial situation of the patient was acquired using the selected IOS to realize an .stl file of the initial situation that was send to the same laboratory.

The files were imported to Exocad software (Exocad GmbH,Germany,2010) and for each patient a digital wax up was realized by the same technician to obtain a simulation of the future restorations. All the restorations were designed in centric occlusion of the patient without any change in vertical dimension. The final model was then printed with Asiga 3D printer (Asiga, NSW, Australia) and then a silicon guide was realized to make the mockup in the patients' mouth.

Group 3: The initial situation of each patient was acquired by alginates impressions. Then, in the lab a wax up was realized on the stone casts and a silicon guide was made to realize the mock-up in the mouth of the patient. At the second appointment, the same prosthodontist (M.F.) realized the mockup in each patient mouth with self-curing resin (Temp Print, GC, Tokyo, Japan) to obtain an esthetic simulation of the final rehabilitation. After the patient accepted the mock-up, the teeth were prepared. The preparation was guided by the mock-up (19) in order to minimize the tooth preparation and remain into the enamel as much as possible. The teeth reductions were checked with the silicone guide index. Laminate veneers were prepared with a buccal thickness ranging between 0.5–1.0 mm and 1.0 mm incisal.(30)

In order to standardize the clinical procedures, the same trained prosthodontist (M.F.) performed the clinical treatments, using a depth cutter bur (0.4 mm in thickness), and a round-end taper bur mounted on a handpiece and under irrigation with water spray. The first bur made parallel horizontal grooves that were marked with a pencil and then connected using the second bur. A thin 3.0 cord was gently placed as retraction cord into the sulcus and the specimens were prepared with a mini-chamfer cervical finish line of 0.3 mm and buccal depth of 0.6 m. The incisal margin was removed to a length of 2mm and a thin chamfer preparation was place palatal as stop. Then, the prepared surfaces were gently polished with rubber points. The quantity of exposed enamel was visually evaluated with 3.5X magnification loops by a trained prosthodontist (M.F.) for each group: 10% for Group 1, 7-8% for Group 2 and 9% for Group 3.(31) Then, the prepared teeth received an impression: Group 1 (Trios 3, 3 Shape Co.) and 2 (Experimental Aadva, GC Co.) were scanned with the selected IOS and in Group 3 an analogic impression was taken using Exa'lance (GC, Tokyo, Japan). The digital and analogic impressions of each patient were made strictly following manufactures' instructions. After the impression was made, temporary restorations were made directly at the chair, using the same silicon guide and the same bis-acrylic resin used for the mock-up.

The .stl files generated by the intraoral scanners used in Group 1 and 2 were delivered to the lab to be processed. Also, in the lab the traditional impressions of Group 3 patients were poured using type 4 stone (FujiRock, GC Co.) to realize a master model that were digitalized using Aadva lab scanner (GC, Tokyo, Japan) to obtain stl files as a reference.

All stl files were elaborated by the Exocad software (Exocad GmbH,Germany,2010) and the final project of the restorations was realized using the initial one approved by the patients as a reference. When the final projects of the veneers were ready, the generated .stl files were exported to the milling machine (n4 Plus, Vhf AG, Ammerbuch, Germany).

All the veneers were realized using Initial Lisi Blocks (GC, Tokyo, Japan).

Laminate veneers were delivered to the patient approximately after one week and then luted following manufacturers' instructions. The intaglio surface of each restoration was etched with 5%

hydrofluoric acid (IPS Ceramic, Ivoclar, Vivadent, Zurich, Switzerland) for 20 seconds, silanized with G-Multi Primer (GC, Tokyo, Japan) and then luted using G-Cem One (GC, Tokyo, Japan) in both groups. Rubber dam was placed in all cases to perform luting steps.

Finally, all patients were enrolled in an oral hygiene program in which recalls were planned every 6 months for professional cleaning and patients' motivation. Full periodontal charting was performent at baseline, 1 and 2 years recall. The outcomes were scored according to the modified USPHS method, (28) for marginal adaptation, color alteration, marginal discoloration, restoration fracture, tooth fracture, restoration wear, antagonist tooth wear, presence of caries, and postoperative sensitivity as reported in Table 1.

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		Alpha	No tooth fracture	

TABLE 1. Criteria of the Modified United States Public Health Service Methods

Tooth Fracture	Bravo	Small fracture fragments of tooth fracture (1/4)		
(TFRA)	Charlie	Severe tooth fracture $(1/2)$		
Restoration	Alpha	No wear		
wear (RESW)	Bravo	Wear		
Antagonist	Alpha	No wear		
Tooth Wear (ANTW)	Bravo	Wear		
Caries	Alpha	Absent		
Presence (CARP)	Charlie	Present		
Postoperative	Alpha	Absent		
Sensitivity (POSTS)	Charlie	Present		

The criteria were evaluated clinically using a mirror and an explorer with sharp tip was used to evaluate the marginal integrity, adaptation, discrepancies of the veneers. The clinical assessments were made by two calibrated and blinded examiners (G.V., E.F.C.) at the study periods: baseline, 12 and 24 months.

Regarding periodontal parameters, periodontal probing depth (PPD), bleeding on probing (BoP) and full-mouth plaque index (PI) were recorded.(29)

All the patients agreed to answer to a questionnaire and grade their satisfaction using a VAS before and after treatment.(7) The patients had to answer to 10 questions, scoring from 0 (very unsatisfied) to 10 (very satisfied). The questions were:

1. Are you happy with the appearance of your smile? 2. Are you happy of the color of your teeth? 3. Are you happy with the shape of your teeth? 4. Are you happy with the size of your teeth? 5. How are you feeling when chewing? 6. Regarding comfort, how are you feeling? 7. How are you feeling when speaking? 8. How are you feeling about your gums? 9. Are you satisfied with the shape of your lips? 10. What do you think about the alignment of your teeth?

Values were assigned to each clinical score as follows: Alpha=1, Bravo=2, Charlie =3 accordingly with modified USPHS scores. Repeated measures two-way ANOVA and Tukey test were used to

compare the modified USPHS method values (α =0.05). All statistical analyses were performed with STATISTICA 10.0 software and SIGMAPLOT 12.0 software.

RESULTS

Clinical assessment

At the 2-year recall, all patients come back to the recall and answered to 'patient's satisfaction questionnaire'; therefore, 100% of sample teeth were evaluated. All scores of clinical outcomes are reported in Tables 2 a-e.

TABLES 2 a-e: scores of clinical outcomes

Legends: MARA: Marginal adaptation, COA: Color Alteration, MARD: Marginal Discoloration, RESF: Restoration fracture; TFRA: Tooth fracture, RESW: Restoration wear, CARP: Antagonist tooth wear, POSTS: Postoperative sensitivity.

TABLE 2a. Group 1. Longitudinal findings for the different study parameters and significance of changes over time (non-parametric linear-by-linear test). Numbers between brackets indicate the number of cases with "Alpha"/"Bravo"/"Charlie" scores, respectively.

Parameter	Baseline	One-year recall	Two-years	Sig.
			recall	
MARA	34/1/0	34/1/0	33/2/0	.816
COA	35/0/0	35/0/0	35/0/0	n.a.
MARD	35/0/0	33/2/0	31/4/0	.131
RESF	35/0/0	35/0/0	35/0/0	n.a.
TFRA	35/0/0	35/0/0	35/0/0	n.a.
RESW	35/0/0	35/0/0	35/0/0	n.a.
ANTW	35/0/0	35/0/0	35/0/0	n.a.
CARP	35/0/0	35/0/0	35/0/0	n.a.
POSTS	35/0/0	35/0/0	35/0/0	n.a.

TABLE 2b. Group 2. Longitudinal findings for the different study parameters and significance of changes over time (non-parametric linear-by-linear test). Numbers between brackets indicate the number of cases with "Alpha"/"Bravo"/"Charlie" scores, respectively.

Baseline	One-year recall	Two-year recall	Sig.
35/0/0	33/2/0	32/3/0	.230
35/0/0	35/0/0	35/0/0	n.a.
35/0/0	33/2/0	31/4/0	.120
35/0/0	35/0/0	35/0/0	n.a.
35/0/0	35/0/0	35/0/0	n.a.
35/0/0	35/0/0	35/0/0	n.a.
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TABLE 2c. Group 3. Longitudinal findings for the different study parameters and significance of changes over time (non-parametric linear-by-linear test). Numbers between brackets indicate the number of cases with "Alpha"/"Bravo"/"Charlie" scores, respectively. *indicates sig. <0.05.

Parameter	Baseline	One-year recall	Two-year recall	Sig.
MARA	35/0/0	35/0/0	31/4/0	.016*
COA	35/0/0	35/0/0	35/0/0	n.a.
MARD	35/0/0	33/2/0	30/5/0	.055
RESF	35/0/0	34/1/0	34/0/1	.403
TFRA	35/0/0	35/0/0	35/0/0	n.a.
RESW	35/0/0	35/0/0	35/0/0	n.a.
ANTW	35/0/0	35/0/0	35/0/0	n.a.
CARP	33/2/0	35/0/0	35/0/0	.130
POSTS	35/0/0	35/0/0	35/0/0	n.a.

TABLE 2d. Comparison of findings at one-year recall for the parameters in which changes were observed and between-group significance of changes (time dependent Cox regression analysis). Numbers between brackets indicate the number of cases with "Alpha"/"Bravo"/"Charlie" scores, respectively. MARA: Marginal adaptation, MARD: Marginal Discoloration.

Parameter	Trios	Analogic Scans	Aadva	Sig.	
MARA	34/1/0	35/0/0	33/2/0	.372	
MARD	33/2/0	33/2/0	33/2/0	.983	

TABLE 2e. Comparison of findings at two-year recall for the parameters in which changes were observed and between-group significance of changes (time dependent Cox regression analysis). Numbers between brackets indicate the number of cases with "Alpha"/"Bravo"/"Charlie" scores, respectively. MARA: Marginal adaptation, MARD: Marginal Discoloration.

Parameter	Trios	Analogic Scans	Aadva	Sig.
MARA	33/2/0	31/4/0	32/3/0	.674
MARD	31/4/0	30/5/0	31/4/0	.905

At the baseline Alpha score was recorded for all laminate veneers for COA, RESF, TFRA, RESW, ANTW, CARP and POSTS.

At 1 year recall only two restorations of all Groups scored Bravo for MARA and MARD.

At 2 years recall there was an increase of Bravo scores in Group 1 and 2 and 3 and 1 Charlie for RESF in Group 3 (Table 2c). In this last case a delamination of the veneer was recorded, and the restoration replaced.

They were no statistically significant differences between the three Groups and with interaction of group vs time periods.

Regardless of color alteration, marginal discoloration, tooth fracture, restoration wear, tooth antagonist wear, and caries presence all restorations of both Groups scored always Alpha.

Assessment of the Patient's Level of Satisfaction

All participants (n=29) returned for the assessment and answered the questionnaire before and after treatment. The level of satisfaction before treatment was 7.35 ± 1.8 and 9.4 ± 0.37 after treatment as reported in Table 3a-b.

VAS	Baseline	1 year recall	2 years recall
Group 1	7.10 +- 1.5	9.2 +-1.9	9.5 +- 2.0
Group 2	7.55 +- 2.1	9.3 +- 1.5	9.6 +- 1.9
Group 3	7.22 +- 1.9	8.9 +- 2.3	9.1 +- 1.5

TABLE 3a: Mean and standard deviation of the patient's level of satisfaction for each Group. VAS: questionnaire from 0 to 10. MARA: Marginal adaptation, MARD: Marginal Discoloration.

TABLE 3b: Overall, VAS of patients' satisfaction of the three Groups at 2 years recall. VAS: questionnaire from 0 to 10.

	VAS
Before treatment	7.35 +- 1,8
After treatment	9.4 +- 0,35

Assessment of periodontal parameters

All patients showed no Periodontal probing depth (PPD) around the laminate veneers, no bleeding on probing (BoP) and a full-mouth plaque index (PI) lower than 20% as reported in Table 4a-c.

TABLES 4a-c. Periodontal parameters. No statistically significant differences were found at the baseline, 1- and 4-years recall between the two groups. Legend: PI: plaque index; PPD: Periodontal probing depth; BoP: Bleeding on probing. Same letter (a) indicates no statistically significative difference.

TABLE 4a: Baseline

	PI	PPD	BoP
Group 1	17.4±2.7 a	2.7±0.4 mm a	a 16.0±0.5 a
Group 2	17.3±1.4 a	2.8±0.5 mm a	16.2±1.2 a
Group 3	17.1±1.2 a	2.9±0.4 mm a	16.0±1.3 a

TABLE 4b: 1-year recall

	PI	PPD	BoP
Group 1	17.5±2.5a	2.9±0.5 mm	16.1±0.5 a
	17.J±2.Ja	а	10.1±0.5 a
Group 2	17.0±1 a	2.8±0.5 mm	16.8±1.2 a
	17.0±1 d	а	10.0±1.2 u
Group 3	17.1±1.2a	2.9±0.4 mm	16.0±1.3 a
	17.1±1.2a	а	10.0±1.5 a

TABLE 4c: 2-year recall

	PI	PPD	BoP
Group 1	18.5±2.5 a	3.1±1.2 mm	16.1±1.5 a
		а	
Group 2	18.0±1 a	2.5±1.1 mm	16.4±2.5 a
		a	
Group 3	18.1±1.2 a	2.8±0.5 mm	16.2±1.3 a
	10.1±1.2 a	а	10.2±1.5 a

DISCUSSION

The outcomes of the laminate veneers recorded in the three groups were shown to be equivalent. Also, the clinical outcomes recorded when the two intraoral scanners (Groups 1 and 2) were used showed no differences. The intraoral scanner used in Group 1 is already well known and is considered as the gold standard. The experimental IOS that was used in Group 2 is a new device with new software and was shown to be very promising. The hybrid procedure followed in Group 3 is a standard clinical procedure very commonly used by practitioners.

The second null hypothesis was also accepted. In fact, no statistically significant differences in patients' satisfaction were recorded among the three groups. The patients' satisfaction increased significantly from baseline to last recall.

All the periodontal values showed very positive outcomes. It must be noted that, after being recruited, all patients underwent professional oral hygiene instruction and prophylaxis to achieve optimal plaque control and gingival health and then they were inserted in a maintenance program with professional oral hygiene sessions every 6 months. Periodontal probing depth (PPD), bleeding

on probing (BoP), and full-mouth plaque index (PI) were recorded for each patient before treatment, at baseline, and every 12 months, so it is probable that patient collaboration and the easy position to be reached with the toothbrush and floss played a fundamental role in maintaining good periodontal parameters.

Another factor that played an important role in the maintenance of the periodontal parameters was probably the chamfer finish line placed juxta-gingivally that easily allowed the margin to be kept clean. The use of a knife-edge finishing line was avoided because more often this can cause a marginal fracture and discoloration. The limited infiltration at the margin can be due to the precision of the restoration on the chamfer finish line that was acquired using an intraoral scanner. In fact, it is largely documented in literature that intraoral scanners report good results in accuracy when used to scan supra- or juxta- gingival preparations.(24,25)

Another important factor that guaranteed the absence of infiltration was probably that the preparation design was maintained as much as possible into the enamel.

In fact, the bond between the tooth substrate, adhesive cement, and the restoration is fundamental for the success of veneers. Marginal gaps and subsequent staining of the interface between the tooth and the restoration can be due to bond failures.

Despite the advances in dentin bonding agents, bonding to enamel is more stable than dentin.(32,33) Adhesion to enamel consists of mechanical interlocking, while dentin is nonhomogenous, has moisture, and may have sclerotic areas.(32,33) Additionally, porcelain has a much higher modulus of elasticity than dentin, more comparable to that of enamel. Higher debonding and fractures of ceramic laminate veneers are reported when the restoration is bonded to dentin instead of enamel due to a difference in the flexibility of the two substrates. (31) Preparations confined to enamel should be preferred, when possible, to guarantee greater strength of the tooth and a high bond strength. Also, the absence of postoperative sensitivity is probably due to the preparation design that was maintained as much as possible into the enamel.(34)

Digital devices can be used in a complete digital workflow or in a hybrid workflow, where a traditional impression is firstly poured and then the stone model is scanned with a laboratory scanner. In this clinical study, Groups 1 and 2 laminate veneers were fabricated by a complete digital workflow, while those of Group 3 were fabricated with a hybrid workflow (analogic clinically and digital in the lab). Many studies have reported on the digital versus hybrid workflow.(35,36) The most recent studies have shown that the digital workflow can achieve positive outcomes similar to those obtained with traditional and hybrid workflows. (37,38) This clinical trial confirms these findings. Additionally, the IOSs demonstrated higher time efficiency, faster communication with the technician and the patients, and better patient acceptance compared

with those of conventional impression methods.(35–38). The high level of patients' satisfaction may be due to the previsualization of the final work through the intraoral mock-up and its exact reproduction in the final restoration thanks to digital technologies.

The juxta-gingival location of the margin, easier to be scanned, and the good health of the periodontal tissues might played a fundamental role for the outcomes of this study. A limitation of the study is that the study protocol was performed to standardize the clinical procedures. All the restorations were realized from the same type of material (Initial LiSi Block, GC, Tokyo, Japan), using a standardized procedure for preparation and cementation. Recent studies have highlighted the differences of fracture resistance of CAD–CAM lithium disilicate crowns and found statistically significant differences depending on the type of lithium disilicate ceramic material used and the adhesive luting cement used. (39,40)

Also, other limitations of this study are the limited number of patients and of the restorations that were tested, and the limited time of clinical service. Longer clinical trials of a wider number of patients and restorations, and with a multicenter design, are desirable to confirm the outcomes of this study.

CONCLUSIONS

From the outcomes of this study the following conclusions can be drawn:

- Milled lithium disilicate veneers showed a good clinical outcome after 2 years of clinical service.
- The two intraoral scanners used in this study are reliable and equivalent to the hybrid workflow for the realization of milled lithium disilicate veneers.
- The satisfaction of the patients of all three groups at the 2-year recall (9.4 ± 0.37) is superior to the one recorded at the baseline (7.35 ± 1.8) .

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4.2 A randomized controlled clinical trial on press, block lithium disilicate and 3D printed partial crowns in posterior teeth: one-year recall.

ABSTRACT

This study compares the clinical performances of two lithium disilicate (Initial LiSi press vs. Initial LiSi Block, GC Corp.) and a 3D printed resin (Temp Print, GC Corp.) partial crown using modified United States Public Health Service (USPHS) evaluation criteria and survival rates after one year of clinical service. Eighty-nine partial adhesive restorations on posterior teeth were realized using different materials: Group 1 used Initial LiSi press, Group 2 used Initial LiSi Block, and Group 3 used Temp Print. An analog workflow was used to realize the restoration of Group 1, while a fully digital workflow was used for Groups 2 and 3. The modified USPHS parameters, together with periodontal parameters, were collected at baseline and at the one-year recall. Contingency tables to assess for significant differences of success over time in each group were used. All modified USPHS parameters showed Alpha or Bravo; no Charlie was recorded. No statistically significant difference emerged between the three groups in any of the assessed variables (p > 0.05). All modified USPHS scores were compatible with the outcome of clinical success, no restoration was replaced or repaired, and the survival rate was 100% at the one-year recall. No difference was found between the traditional and digital workflows used to fabricate the restorations.

INTRODUCTION

Partial coverage restorations are a viable option to restore teeth in case of a substantial loss of tooth substrate compared to the direct option since can assure a reduced polymerization shrinkage, prevention of tooth' fracture and better clinical performance over the years.(1)Partial coverage restorations can be realized using a wide range of materials such as ceramics, resin composites, and metal alloys. (2) Milled Cad-Cam resin composite blocks have been used for partial coverage restorations and showed great clinical performances since the indirect restoration shows a higher degree of conversion, filler content and chemical stability compared to the direct alternative. (3) Nowadays, 3D printing is rapidly spreading as a new technology that overcomes the limitations of subtractive manufacturing systems in dentistry thanks to the current developments of printable materials.(4-8) In prosthodontics, 3D printing is mainly used during the workflow to produce models, custom trays, silicone indices, surgical guides, tooth preparation guides and interim restorations, but up to now it's rarely used to realize the final restoration.(9)This can be

addressed to the lower mechanical properties of the 3D printable materials present on the market up to now. In fact, some in vitro studies, pointed out lower values for fracture resistance when compared to the milled options.(10-12)

Lately, new interesting materials have been lunched on the market with the possibility to remain intraorally for a longer period of time due to their characteristics of occlusal stress dispersion and high durability under occlusal loading. (13,14) In recent in vitro studies a new class 2 a highly silica filled 3D printable composite resin reported high values for flexural strength comparable to the ones of different PMMA milled resins (15) and good dimensional stability compared to others 3D printable materials (16) and for that its use to produce restorations in vivo should be investigated. In recent in vitro studies, addictive manufacturing onlay restorations showed high intaglio surface trueness and adaptation comparable to the subtractive manufactured ones.(17,18) Additionally, 3D printing allows less waste of materials, and minor costs of production when compared to subtractive manufacturing.(19,20)

Lithium disilicate (LD) is a well-accepted prosthodontic material by both dentists and dental technicians (21) and it is available on the market in two different formulations: press and blocks. Pressed LD has to be manufactured in the laboratory, pressing the material at a high temperature into the final shape and the clinical use of it to realize partial restorations has already largely been tested. (22,23) Blocks LD are an attractive alternative for realizing restorations as they have good mechanical properties, and it allows a reduction in time and costs being milled also chairside.(24,25) Recently a RCT study have demonstrated the good clinical performances also in vivo.(26)

The aim of this short-term randomized clinical study (RCT) was to evaluate the clinical outcomes of two LD materials, press and block, and one 3D printed composite after 1 year of clinical service for partial posterior restorations. The null hypothesis was that there is not statistically significative difference between the two LD formulations and the 3D printed composite at 1-year follow-up.

MATERIALS AND METHODS

Between October 2022 and January 2023, 99 restorations were placed in periodontally 49 healthy patients (18+ years). All patients were informed about the trail's scope and after they provided written consent were enrolled in the present study.

Patients were collected accordingly with the following Inclusion criteria:

Periodontally healthy or successfully treated adult patients (Bleeding on Probing (BOP) <10%) in need of an overlay or onlay partial crown (one restoration each and not more than two) on a posterior tooth. Some patients were excluded from the study based on the following exclusion criteria: age < 18 years, disabilities, severe medical disease, pregnancy, insufficient compliance, previous indirect restorations of the abutment teeth, active periodontitis, bruxism, endodontic treated abutment. The study protocol was approved by Ethical Committee (clinicaltrial.gov #CT01932049). Also, the clinical treatment was performed in accordance with the ethical standards of the Institutional and National Research Committee and with the Declaration of Helsinki of 1964 and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines.

All patients before starting the treatment underwent professional oral hygiene session and periodontal probing depth (PPD), bleeding on probing (BoP) and full-mouth plaque index (PI) were recorded. An individual X-ray tray was specifically fabricated for each abutment tooth, to standardize radiographic examinations and have the possibility to make the radiograph at baseline and in the same position at future recalls.

The same prosthodontics (M.F.), after anesthesia removed all carious lesions and previous direct restorations under rubber dam and prepared all the abutment. Preparation's design was made accordingly the presence of caries and pre-existing restorations with a chamfer finish line. Teeth with a Residual dentin thickness (RDT) lower than 0.5 mm between the bottom of the cavity and the pulp were excluded from the study. Margin thicknesses was between 0.5-1 mm and 1.0-1.5 mm of occlusal clearance. When possible, margins were kept equi- or supra-gingivally and into enamel (i.e. more than 50%); only interproximal boxes had cervical margins below the cementum-enamel junction. Universal bonding agent (G-Premio Bond; GC Corp.) and a thin layer of flowable composite (Genial Flow; GC Corp.) was placed as a dentine sealing on the prepared dentine. Rubber points were used to finish and polish the preparations before final impression. The eighty-nine teeth were randomly divided in three experimental groups according to the materials used for the restoration: Initial LiSi Press (GC Corp.); Initial LiSi Block (GC Corp.); Temp Print (GC Corp). Treatment assignment form was kept by the study. Opaque, sealed and sequentially numbered envelopes were used for allocation concealment. The allocation sequence was computer-generated, and the statistician assigned a sealed opaque envelope containing the type of restoration material to be used that was opened by the operator only before the impression taking. Elastomeric material (Exa'lence; GC Corp.) was used to take traditional final impression for Initial LiSi Press (GC Co, Tokyo, Japan) restorations and master model was realized using Type IV gypsum (FujiRock; GC Corp.). For the other two groups the final impressions were performed

using an intraoral scanner (Aadva 200 iOS; GC Corp.) realizing a .stl file that was send to the technician. The restorations were digitally waxed up and the final project was sent to a milling machine (n4 Plus; Vhf AG) or to a 3D printer (ASIGA MAX UV). In group 2 the restorations were milled using LiSi Blocks (GC Corp) while in Group 3 the partial crowns were made with Temp Print resin (GC Corp). A self-curing acrylic resin provisional was temporary cemented to protect the prepared teeth with no eugenol temporary cement (TempBond NE; Kerr Corp.). After one week all the restorations were delivered and tried in: some restorations needed minor adjustments and no piece was remade. For the lithium disilicate restorations the internal surface of the restoration was etched with 10% hydrofloridric acid for 20 seconds and silanized with G-Multi Primer (GC Corp.). For the 3D printed restoration, the internal surface of the restoration was cleaned after try in, sandblasted and a drop of G- Multi Primer (GC Corp.) was applied for at least 1 minute. The abutment teeth were etched with orthophosphoric acid, and a universal adhesive was placed (G-Premio Bond, GC Corp.). Adhesive cementation was performed under rubber dam using G-Cem One (GC Corp.) for all the restorations. The patients were recalled every 6 months for oral hygiene session. A clinical examination was performed immediately after the seating of the crown as baseline, as well as after 6, 12, months of clinical service. Modified USPHS scores were assessed and recorded (Table 1), at baseline and at the 1-year recall. A standardized intraoral radiograph was taken using a customized X-ray tray for each restoration.

Topics	Score	Criteria
X · 1	Alpha	Margin continuity(without prominence or crack)
Marginal adaptation	Bravo	Little discontinuity detectable by explorer, but it
(MARA)		does not require replacement
	Charlie	Prominence or crack; require replacement
	Alpha	No color alteration close to the tooth structure
Color Alteration (COA)	Bravo	Little color alteration, clinically acceptable
	Charlie	Esthetically unacceptable
Marginal	Alpha	No marginal discoloration
Discoloration	Bravo	Marginal discoloration
(MARD)	Charlie	Deep discoloration
Restoration Fracture (RESF)	Alpha	No fracture
	Bravo	Small fracture fragments (1/4 of the restoration)
	Charlie	Severe fracture (3/4 of the restoration)
	Alpha	No tooth fracture
Tooth Fracture (TFRA)	Bravo	Small fracture fragments of tooth fracture (1/4)
	Charlie	Severe tooth fracture (1/2)
Restoration wear	Alpha	No wear
(RESW)	Bravo	Wear
Antagonist Tooth	Alpha	No wear
Wear (ANTW)	Bravo	Wear
Caries Presence	Alpha	Absent
(CARP)	Charlie	Present
Postoperative	Alpha	Absent
Sensitivity (POSTS)	Charlie	Present

TABLE 1. Criteria of the Modified United States Public Health Service Method.

At the 1-year recall, two examiners (E.F.C. and M.F.) after being calibrated, blindly evaluated all the subjects and assessment was taken by consensus. Also, periodontal parameters as BOP and PI and stain and gap at margins were recorded as well at each recall. To clinically classify each single crown, "Success" was considered when it did not show any biological (such as pulpal or periodontal problems) or technical complication (such as debonding, chipping or fractures of the restorations) at the last recall, and "Survival" when it was still in place at the last recall but with a biological or technical complication that needed to be treated, but without the need to remake the crown; if the restoration was lost at last recall or, because of mechanical or biological complications, needed to be replaced, it was classified as "Failure".

Statistical analysis - Contingency tables to assess for significant differences of success over time in each group to test for differences among the three groups were used and the level of significance was set at P< 0.05. The Mann-Whitney 'U' test was used and the level of significance was set at P< 0.05 to analyze the periodontal parameters. The statistical analysis was calculated by dedicated software (PASW Statistics 18). Modified USPHS scores was assessed and recorded after cementation (baseline) and at 1-year of clinical service as reported in Table 2 together with periodontal parameters. At 1 year follow up appointment x-rays were taken for each restoration.

RESULTS

The patients' recall rate was 100%. At 1 year recall, survival and success rates were 100%, since no major technical or biological complications were observed. Clinical parameters related to the restorations results are shown in Table 2.

Topics	Material	Baseline	ine Time 1				
Topros	Material	Alpha	Bravo	Charlie	Alpha	Bravo	Charlie
	Lisi Press	30	/	/	29	1	/
Marginal adaptation	Lisi Blocks	30	/	/	29	1	/
(MARA)	Temp Print	29	/	/	27	2	/
Color Alteration	Lisi Press	30	/	/	30	/	/
(COA)	Lisi Blocks	30	/	/	30	/	/
(COA)	TempPrint	27	2	/	26	3	/
Maria IDia Institu	Lisi Press	30	/	/	29	1	/
Marginal Discoloration	Lisi Blocks	30	/	/	29	1	/
(MARD)	TempPrint	29	/	/	27	2	/
	Lisi Press	30	/	/	29	1	/
Restoration Fracture	Lisi Blocks	30	/	/	29	1	/
(RESF)	TempPrint	29	/	/	29	/	/
To the Encoderm	Lisi Press	30	/	/	30	/	/
Tooth Fracture	Lisi Blocks	30	/	/	30	/	/
(TFRA)	TempPrint	29	/	/	29	/	/
Detection	Lisi Press	30	/	/	30	/	/
Restoration wear	Lisi Blocks	30	/	/	29	1	/
(RESW)	TempPrint	29	/	/	29	/	/
	Lisi Press	30	/	/	30	/	/
Antagonist Tooth Wear	Lisi Blocks	30	/	/	29	1	/
(ANTW)	TempPrint	29	/	/	29	/	/
Caria Davan	Lisi Press	30	/	/	30	/	/
Caries Presence	Lisi Blocks	30	/	/	30	/	/
(CARP)	TempPrint	29	/	/	29	/	/
De ste menstione Compitient	Lisi Press	30	/	/	30	/	/
Postoperative Sensitivity	Lisi Blocks	30	/	/	30	/	/
(POSTS)	TempPrint	29	/	/	29	/	/

TABLE 2. Modified USPHS scores for Lisi Press, Lisi Blocks, and Temp Print at baseline and 1year.

No Charlie score was recorded at 1-year recall. At the 1-year recall, only several restorations of each Group showed Bravo score for MARA, COA, MARD, RESF, RESW and ANTW. Regarding COA score, 3 restorations of Group 3 (3D Printed onlays) showed Bravo while in Group 1 and 2 all restorations were scored Alpha. Regarding MARA and MARD, 2 restorations of Group 3 were scored Bravo, while in the two other Groups only 1 was scored Bravo. Periodontal parameters at

baseline and 1 year follow up are reported in Tables 3 and 4 and no statistically significative difference was found among the groups.

	PI	PPD	BoP
Group 1 (Initial LD Press)	17.5±2.5 ª	2.9±0.5 mm ^a	16.1±0.5 ^a
Group 2 (Initial LD Block)	17.0±1 ^a	2.8±0.5 mm ^a	16.0±1.2 ^a
Group 3 (Temp Print)	17.7±1,5 ª	2.9±0.5 mm ^a	16.0±1.7 ^a

TABLE 3: Periodontal parameters at baseline.

Table 4: Periodontal parameters at 1-year recall.

	PI	PPD	BoP
Group 1 (Initial LiSi Press)	17.5±2.5 ª	2.9±0.5 mm ^a	16.1±0.5 ^a
Group 2 (Initial LiSi Block)	17.0±1 ^a	2.8±0.5 mm ^a	16.8±1.2 ª
Group 3 (Temp Print)	17.5±1 ª	2.6±1 mm ^a	16.3±0.5 ª

No statistically significant differences were found among the experimental groups in any of the assessed variables (P > 0.05) and among baseline and 1-year recall.

DISCUSSION

To the authors' knowledge, this RCT is the first that report short-term clinical performances of 3D printed resin partial single units made with addictive manufacturing methods. The use of 3D printing is rapidly spreading in dentistry with numerous applications especially in prosthodontics,(5,7) but while the in vitro performances of these new printable materials have been investigated with promising results, scientific evidence for intraoral use concerning permanent restorations is still quantitatively limited.(8)

This study reported 100% success and survival rates of 3D printed partial crowns at 1-

year follow up with no statistically significative difference compared to milled lithium disilicate ones, so the null hypothesis was accepted. Accordingly with modified USPHS scores, the null hypothesis was accepted, since there were no statistically significant differences among groups in any of the assessed variables at 1 year recall.

Cakmak et al, (17) in an in vitro study, reported high intaglio surface trueness and adaptation together with marginal integrity of 3D printed onlays and their result are in accordance with the ones of Canto Naves et al(18) that reported significant better adaptation of the addictive manufactured onlays compared to the subtractive manufacturing ones. In the present study all the restoration reported good Marginal Adaptation (MARA) and only two 3D printed onlays scored "bravo" at 1 year follow up. The data is not statistically significant different from the result obtained from Group 1, where the restorations were realized in LD with a traditional workflow, or Group 2, where the restorations were realized in LD but with a fully digital workflow. The good results reported in all the Groups for Marginal discoloration (MARD) can be related to the optimal marginal adaptation of the restoration resulting in a thin layer of adhesive cement between the two interfaces and to the adhesive cementation protocol under rubber dam.(27,28) The latter together with immediate dentine sealing right after preparation probably influenced the good scores for the Postoperative sensitivity (POSTS). Scores for Caries presences (CARP) can be addressed to the strict oral hygiene program of the patients enrolled and to the limited observation time that also influenced the absence of the antagonist tooth wear (ANTW). Regarding Restoration Fracture (RESF) and Restoration wear (RESW) no statistically significative difference was found between the 3 Groups despite some of the in vitro study reported lower mechanical properties of the composite 3D printed restorations compared to the milled ones.(10-12) The in vivo results of this clinical study can be related by those of Rosentritt et al (29) that reported acceptable in vitro performance and fracture force for clinical mid-term application and also by those of Zimmermann et al¹³ that obtained greater results for 3D printed composite crowns compared to milled ceramic crowns after fatigue testing. It could be speculated that the 3 Bravo scores reported for Color Alteration (COA) can be addressed to the lower color stability of 3D printable resins compared to the subtractive manufacturing ones as reported in vitro by Cakmak et al.(30) and by Daghrery et al, (31) but at least at 1 year recall no statistically significative differences were found among the groups probably thanks to the post processing procedures applied to the printed restorations in the laboratory and to the short follow up time.(32) The limited observation time might influence the Modified USPHS score registered, and future recalling may confirm the high clinical performances that were recorded till now. Additionally it must be taken in to consideration that only one type of 3D printed material (Temp Print, GC Corp.) with high silica filling was tested in this study and the

good clinical performance could be reconducted to the high filler content of the tested material that may differ from other printable materials as reported by Bauer et all.(33) The 3D printed restorations can have a very limited lab cost when compared to lithium disilicate and consequently it can be expected that will become more and more popular in the future. Mechanical properties of 3D printed resins are much more similar to resin for direct restorations than lithium disilicate.(20,34,35) For that, randomized controlled trials also comparing 3d printed resins and resins for direct restorations are desirable. Longer randomized clinical trials are desirable to investigate the medium- and long-term results of 3D printed resin restorations for partial crowns.

CONCLUSIONS

Under the limitations of this clinical trial the following conclusions can be drawn:

- No significative difference was found between pressed, blocks lithium disilicate and 3d printed composite restorations at 1 year follow up.
- 3D printed onlays are a viable option for restoring posterior teeth.
- No difference was found between traditional and digital workflow.

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5. Chapter 5: Intraoral scanners and implants

5.1 Accuracy evaluation of two different intraoral scanners in implant prosthodontics.A comparative in vitro study

ABSTRACT

To test differences in term of accuracy among two Intraoral Scanners used in implant fixed prosthodontics. A reference stone model was prepared, representing a partially edentulous maxilla on area #23 and from #14 to #16, with three implant analogues and polyether-ether- ketone (PEEK) scanbody screwed on to represent the situation of a single crown on implant (SB) and a implantsupported partial prosthesis (2SB). The model was digitized with a laboratory scanner (Aadva lab scanner, GC, Tokyo, Japan) used as a reference, and with two intraoral scanners (Trios 3; 3Shape A/S; I700, Medit). Ten scans were performed using the two different intraoral scanner. Scanning and processing time as well as the number of images were reordered for each scanner. All datasets were loaded into reverse-engineering software (Geomagic Control X 2018), where digital impressions were superimposed on the reference model to evaluate trueness in the full arch, in the SB area (#23) and in the 2SB areas (#14 and #16). Therefore, all the scans of the same group were superimposed onto the cast that recorded the best result of trueness whose trueness corresponded to the actual reference value for precision. Mann-Whitney U-test test was performed to analyze differences between the groups (P<0,05) (SPSS software Version 26,IBM). Statistically significative differences where found between Medit i700 and TRIOS 3 regarding trueness and precision in the full arch, with Trios 3 showing better results than Medit I700. Trios 3 performed statistically better also in the 2SB area regarding precision. No statistically significative differences were found regarding trueness and precision in the other areas. Trios 3 performed statistically significative better than Medit I700 in acquiring scanbody position when the full arch model was analyzed. Both the tested Intraoral scanners reordered good values in line with the previous literature.

INTRODUCTION

Digital devices such as intraoral scanners (IOS) and processing software together with a new wide range of materials and powerful manufacturing devices are changing dentistry, in particular the prosthetic field.(1,2) Intraoral scanners are able to collect optical impressions of jaws thanks to a

beam or light grid that captures through a high-resolution camera the distortion that such a beam or grid undergoes when it hits structures like teeth.(3) Then, different softwares processes the collected pieces of information and reconstruct the 3D dimensional model. (4) Digital impression has been used for different applications in prosthodontics, such as study cast, for an impression of natural abutments, and for rehabilitation of single and multiple implants too.(5,6)

The digital workflow for implant-supported restorations begins with intraoral direct digitization of soft tissue and implants' position and proceeds with the laboratory steps of computer-assisted design (CAD) and computer-assisted manufacturing (CAM). The final prosthesis can be realized in a monolithic design from zirconia, lithium disilicate, or hybrid ceramic materials.(7) Passive fit between prosthetic structures and supporting implants is considered a key factor in preventing subsequential mechanical and biological complications. Screw loosening or fracture, prosthetic breakage, and even implant fracture can in fact be caused by tension and compression due to a poor passive fit.(8,9)

Fit of the restorations depends on the accuracy of implant impression taking, which may be realized using long-term established conventional techniques or more recently introduced digital techniques.(10) Traditionally the master model is realized in gypsum from a polyether (PE) or polyvinylsiloxane (PVS) impression that can be performed using the pickup or transfer technique. The final outcome is strongly affected by dimensional changes of both impression materials and gypsum, due to variations in temperature, time elapsed between impression making and pouring, surface wettability of the gypsum, and disinfection procedures. (11,12) In the digital workflow, one of the key factors is the accuracy of the intraoral scanner used to capture the position of implants. As reported in the glossary of digital terms, the accuracy of a digital scanner is the closeness of agreement between a measured result and a reference value.(13) It is described by precision and trueness. Trueness is the closeness between the test object and the reference object, whereas precision is the variability of repeated measurements of the object.(14,15) The accuracy of a digital scan can be affected by clinical circumstances such as ambient light, scanning protocol, limited spacing between abutments and adjacent teeth, and edentulous span length.(16-20) Currently, there is a wide range of intraoral scanners on the market and new software and hardware versions are constantly released by the manufacturers that claim improved scanning accuracy. The aim of these in vitro studies is to compare the accuracy of two different intraoral scanners in the impressionmaking of single and multiple implant restoration.

Null hypothesis: there is no statistically significant difference in the accuracy between Trios 3 Shape and Medit i700.

MATERIALS AND METHODS

A model representing a partially edentulous maxilla (PEM), with implant analogs in position #23 (to imitate the situation of an implant-supported single crown) and in positions #14 and #16 (to simulate the situation of an implant-supported partial prosthesis), was prepared. Three high-precision non-reflective polyether-ether-ketone (PEEK) scanbodies (SBs) were screwed on the implant analogs.

Two intraoral scanners (Trios 3, 3 Shape, Copenhagen, Denmark, and I700 Medit, Seul, South Korea) as well as a powerful reference scanner (Aadva Lab Scanner 2, GC) were used in the present study.

The scans proceeded in the following order. First, the model was scanned with the reference scanner three times. The three .stl files were imported into powerful reverse-engineering software (Geomagic, Morrisville, NC, USA) and superimposed on each other, in order to validate the manufacturer's data and one dataset was then selected as the reference model (RM). Secondly, an operator initiated the process of acquiring model scans using each of the two intraoral scanners involved in the study. For each IOS, the operator performed 10 scans of the entire arch focusing on the area with 2 scanbody #14 and #26 (2SBs) and on the area with a single scan body #23 (SB), resulting in a total of 20 scans. The operator began the scanning process from the right vestibular posterior sector, proceeding to the incisal vestibular area, and subsequently the left vestibular area. The operator then continued scanning the right occlusal area, followed by the left occlusal area, without placing the scanner's handle down. Finally, the palatal section was scanned. All scans were conducted under consistent environmental conditions, in a room with moderate sunlight and a temperature of 22 °C. The time taken by each scanner to register the impression, the number of images captured, and the scan processing time were recorded for each device. All the .stl files (RM as well as all .stl files obtained with the 2 different intraoral scanners) were imported into the reverse-engineering software (Geomagic, Morrisville, NC, USA). Here, small artifacts identified as independent polygons were automatically removed, and models were cut/trimmed to remove all unnecessary information, using the "cut with planes" function. A preformed template was adopted to cut files in the most uniform manner: with this, uniform files were obtained and saved in specific folders. Then, it was possible to proceed with the superimposition for the evaluation of the trueness. All the stl files obtained from each intraoral scanner were superimposed to the corresponding RM, using the "three-point registration" function as shown in Figure 1.

FIGURE 1 The .stl file obtained with the IOS in superimposed on the RM reference model.

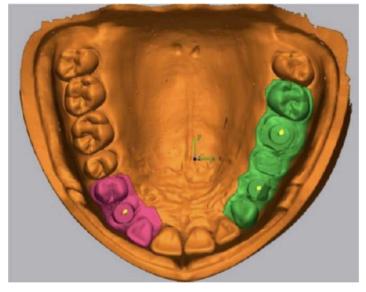


The three points were easily identified on the surface of the implant scan bodies. After this first rough alignment, the "best fit" alignment function was used for the final registration. Then, the root mean square (RMS) was calculated based on all cloud points of dRT by using the following formula:

FIGURE 2

$$RMS = \frac{1}{\sqrt{n}} \cdot \sqrt{\sum_{i=1}^{n} (X_{1,i} - X_{2,i})^2},$$

where X_{1,i} indicates a measurement point at it in RM and X_{2,i} indicates a measurement point at it in each stl of the intraoral scanner. "n" is the number of all points evaluated. Therefore, the RMS value is the absolute average distance of all cloud points and means the degree of agreement between RM and each stl IOS file. For each experimental group, the trueness was calculated considering the RMS value resulting from the superimposition of each stl file and the RM. The precision was evaluated by taking as a reference model the .stl file that recorded the best trueness value for each group. Therefore, all the scans of the same group were superimposed onto this selected cast, whose trueness corresponded to the actual reference value for precision. RMS values were recorded for the whole model surface as well as for the area of the single scan body (SB) and two scan bodies (2SB) as shown in Figure 3 with different colors. FIGURE 3 Different areas of the model where the RMS value was evaluated: the full model surface is highlighted in orange, the single Sb and the 2SB areas were highlighted respectively in pink and green.



Therefore, the distances between corresponding areas of RM and all superimposed models were color-coded on the superimposed models to analyze the result, using the "3D deviation" function. A color map was generated, where the distances between specific points of interest were quantified, overall and in all three planes of space. All deviations were therefore visualized and calculated. The color maps indicated inward (blue)or outward (red) displacement between overlaid structures. An absence of change was indicated by a green color. The collected data then underwent statistical analysis (SPSS software Version 26 IBM).

RESULTS

For trueness, Trios 3 performed statistically better than I700 in the full arch acquisition while no statistically significant differences were found in the 2 Scan abutments and 1 Scan abutment sections. Regarding precision Trios 3 performed statistically significative better than I700 in the full arch and in the 2 scan abutments area. No statistically significant difference was found in the section of 1 Scan abutment. The scanning performances of the two scanners are reported in Table 3. Statistically significative differences were found between Trios 3 and I700 regarding scanning time and processing time. Regarding the number of images, a statistical difference was found since I700 acquired more than double of images of Trios 3 in the same scanning time.

TABLE 1. Trueness values (µm)for the two tested IOSs.

Scanner	Full Arch	2SB	1SB
Trios3	29.8 ± 4.05	55.2±3.47	44.1±15.12
1700	40.9±7.18*	52.4±4.34	40.4±15.97

TABLE 2. Precisions values (µm) for the two tested IOSs.

Scanner	Full Arch	2SB	1SB
Trios3	35.5±7.19	28.2±12.26	17.7±5.39
1700	60.2±7.08*	50.9±19.85*	16.8±6.38

TABLE 3. Scanning performances for the two tested IOSs.

Scanner	Scanning time	Processing time	Number of images
Trios3	202.30±10.00	34.53±1.81	3798.50±252.20
I700	201.40±10.86	206.70±17.68*	8374.90±474.29

DISCUSSION

It is many years since the long-term success of implants was confirmed by Branemark et al.(21) Since then, new surgical and prosthetic techniques have added enhancements to improve the clinical outcomes of implant treatments. About that, one of the biggest improvements has been guaranteed by digital impressions. (22-25) In fact, with the advent of IOSs, it's possible to scan the patient's mouth and register the position of implants in a few minutes with no need for impression trays and materials. (26-29) Obviously, a high impression accuracy of the IOSs is needed to realize a digital cast for implant-supported prostheses even if no impression technique can achieve an absolute passive fit. (30,31) The aim of this in vitro study was to assess the trueness and precision of two different intraoral scanners (TRIOS 3 SHAPE and Medit i700) in capturing impressions of a single scan body or two scan bodies. Statistically significant differences between the two tested Intraoral scanners were reported thus the null hypothesis was rejected. When trueness was taken into consideration, Trios 3 performed statistically better than Medit I700 in the full arch scan, but when the area of 1 scan body and 2 scan body was taken into consideration the values for accuracy were comparable. These results are similar to the one obtained in a previous study by Imburgia et al. and Chew and al. where a discrepancy of trueness around 50-60 μ m was found in scanning two implants for a partial prosthesis.(32,33) In research by Mangano et al., the discrepancy reported was much lower and they put 30 μ m as a threshold for trueness.(34) Anyway, previous clinical studies have shown that the biological and technical complications increased when a misfit of 30 to 150 μ m was found between the prosthetic framework and the implant abutments.(35) Mangano reported better accuracy of IOSs in scanning the position of a single implant, but it must be noticed that the whole surface of the model was analyzed while in this study the discrepancy was calculated also in the restricted area of the single scan body.(33)

Regarding precision, Trios 3 performed statistically better in the full arch scan and in the 2 scanbodies area but in the single scan body area did not report any difference. When the precision was analyzed in the single scan body area lower values were reported for both scanners compering to the precision in the two scan body areas and full model.

It should be noted that the same intraoral scanner, Trios 3, performed in a different manner in different articles.(31,33) This can be correlated with different reference models used or scan bodies. Scanbody plays an important role in digital implant impressions as recently reported by Mizumoto and Yilmaz.(36) Regarding scanning time, no statistically significant difference was found, but the number of images acquired by I700 was more than double the ones acquired by Trios 3. It can be speculated that the higher number of images acquired by I700 caused the differences in processing time between the two IOSs with Trios 3 being much faster than I700. Anyway it should be noticed that I700 allows the operator to take new scans and proceed with a new case during the processing time of each scan so the longer processing time does not interfere with the workflow schedule or chair time.

This is an in vitro study and the findings may not fully reflect the trueness and precision of IOS in real-life clinical scenarios. Conditions detectable in vivo could be the presence of blood and saliva, as well as technical problems during intraoral scanning and patient movements, that can significantly affect the quality of scans.(37)

CONCLUSIONS

Within the limit of the present in vitro study, statistically different results were found in the full arch scan with Trios 3 showing better results than Medit I700. Concerning the scan abutment areas no statistically significant differences were found between the two tested Intraoral scanners except for precision in the 2 Scan abutment where Trios 3 performed statistically better than Medit I700. Both

the tested Integral scanners obtained accuracy results in line with the standard values reported in the literature.

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6. Chapter 6: Digital technologies in removable prosthodontics

6.1 Flexural Strength Analysis of Different Complete Denture Resin-Based Materials Obtained by Conventional and Digital Manufacturing

ABSTRACT

PMMA (Polymethylmethacrylate) is the material of choice to fabricate denture bases. Recently, with the introduction of CAD-CAM and 3D printers in dentistry, new materials have been proposed for complete denture manufacturing. Aim: This study compared the flexural strength of different resins fabricated using different technologies (conventional, CAD-CAM-milled, and 3D-printed) and polymerization techniques. Methods: A total of 11 different resins were tested: six PMMA conventional (Acrypol R, Acrypol LL, Acrypol HI, Acrypol Fast, Acryself and Acryslef P), two milled obtained from UDMA PMMA disks (Ivotion disk and Aadva disk, control groups), two 3Dprinted PMMA resins (NextDent Denture 3D+, and SprintRayEU Denture Base), and one 3Dprinted composite resin (GC Temp Print). Flexural strength was measured using a universal testing machine. One-way ANOVA and Bonferroni post hoc tests were performed; the p-value was set at 0.05 to consider statistically significant differences among the groups. Spearman test was used to evaluate the correlation between polymerization technique and the flexural strength of 3D-printed resins. Results: CAD-CAM-milled specimens showed the highest flexural strength (107.87 MPa for UDMA) followed by 3D-printed composite resins (102.96 MPa). Furthermore, 3D-printed resins polymerized for 40 min with the BB cure unit showed no statistically significant differences with conventional resin groups. Moreover, in all the 3D-printed specimens, a high correlation between polymerization technique and flexural strength was found. Conclusions: In terms of flexural strength, the polymerization technique is a determinant for both acrylic and composite resins. Temp Print can be a potential alternative to fabricating removable dentures and showed promising results when used in combination with pink color resin powder.

INTRODUCTION

Removable complete dentures represent, for edentulous patients, the least invasive and most costeffective prosthodontic rehabilitation. (1) Acrylic resins have been the material of choice for denture bases since they were introduced in dentistry by Dr. Walter Wright and the Vernon Brothers in Philadelphia in 1937. To this day, PMMA (polymethylmethacrylate) remains the most used acrylic resin for denture base fabrication.(2) The PMMA used in the dental field is conventionally obtained by mixing a liquid and a powder. The powder is composed of repolymerized polymethylmethacrylate particles as well as a peroxide initiator. The liquid component is made of a cross-linking agent, an inhibitor, and a monomer of methyl methacrylate (MMA). In the transparent powder, pigments and other substances, such as acrylic synthetic fibers and nylon, are added to imitate oral tissues.(3)

PMMA gained popularity due to its good physicochemical properties as well as its low cost and acceptable aesthetics.(4,5) Nevertheless, there have been increasing concerns about some characteristics of this material, such as the frequent fractures of dentures,(6)polymerization shrinkage, and cytotoxicity. (3,7) For instance, the addition of nanoparticles and nanotubes was tested to improve the material's mechanical properties.(8–11) To overcome polymerization shrinkage found in heat-cured and cold-cured resins, injection molding was introduced. (12,13) Chemical changes were tested to be stabilizers of PMMA, but newer innovative methods have yet to be investigated.(14)

The introduction of computer-aided design/computer-aided manufacturing technology (CAD-CAM) and 3D printers in the dental field added new possibilities to improve the materials and workflows used for denture fabrication. Some of the advantages of CAD-CAM fabrication are a decreased denture weight and lower resin volume, two qual- ities that can increase the patient's comfort. (15) Moreover, the issue of polymerization shrinkage was eliminated thanks to the use of pre-polymerized discs, leading to a better adaptation fit and higher mechanical performance. In fact, in the milling technique, an already polymerized block is milled to the final dimensions. (16,17) In terms of 3D-printing technologies, the most commonly used in dentistry are stere- olithography apparatus (SLA) and digital light processing (DLP), which are two different photopolymerization devices. Once the CAD model is converted into an STL file, it is sliced into different layers and then built one layer at a time. To complete a layer, the SLA technique cures it line by line using a laser beam, whereas DLP cures layer by layer using a projector. This makes the DLP technique faster and less prone to errors caused by repeated printing. Post-processing, defined by cleaning the object and post-curing, is different according to each technology and recommendation of the manufacturer.(18–21)

In the last few years, the mechanical properties of both acrylic and composite 3D- printed resins have been investigated in the dental field. Printed composite resins are mostly used for temporary crowns and bridges, and promising results in terms of flexural strength, fracture load, and hardness have been found.(22,23) Moreover, composite resins such as urethane dimethacrylate (UDMA) showed good dimensional stability and a lack of residual monomers, reducing the risk of contact

allergies.(24,25) For these reasons, UDMA could be considered a suitable alternative for denture base fabrication. Therefore, PMMA-milled resin-based materials were included in the present study as control groups for the evaluation of different resin-based materials' mechanical behavior. Concerning the mechanical properties, flexural strength is the most frequent test applied to dental materials, along with impact strength and hardness. Flexural strength is the combination of compressive, tensile, and shear stress and is defined as the maximum stress that a material experiences at its yielding point. This test is fundamental in the evaluation of denture base materials as it gives an indication of the material's resistance to fracture and a prediction of its behavior under static loads. High values of flexural strength will reduce the risk of denture base fractures. Conforming to the ISO-20795-1:2013 (26) recommendations, the three-point bending test is the most commonly used to assess the flexural strength of polymers. (27,28) Many studies have been conducted to compare the flexural strengths of denture base materials fabricated analogically and through CAD-CAM technologies using the three-point bending test. (22,29–35) The mechanical performance of resin composites is closely related to their formulation.(36,37) The molecular backbone characteristics of the co-monomers involved will determine the hydrophilicity, mobility, and kinetic parameters. When acrylic resin strengths are compared, those with a lower degree of conversion exhibit inferior mechanical properties.(38) The higher flexural strength values of CAD-CAM specimens may be attributed to a higher degree of conversion.(15) Nevertheless, despite the numerous investigations on the advantages of digital work- flow, few studies exist comparing conventional, CAD-CAM subtractive, and additive manufacturing methods at the same time.(34,35) In this study, the aim was to compare the flexural strengths of denture base resins fabricated conventionally, CAD-CAM-milled and 3D printed with different polymerization techniques. The null hypothesis was that there is no statistically significant difference in flexural strength between the different tested materials.

MATERIALS AND METHODS

In this study, 170 rectangular specimens of resin-based material having dimensions of $64 \times 10 \times 3.3$ mm were fabricated according to the ISO-20795-1:2013 standard.(26) Twelve different resins were used: Six analog acrylic resins, two PMMA-milled resins, two 3D-printed acrylic resins, and one composite 3D-printed resin, as described in Table 1. They were divided according to the type of fabrication (analog, CAD-CAM-milled, or 3D-printed) and their polymerization method, as reported in Figure 1. Each group was composed of 10 specimens.

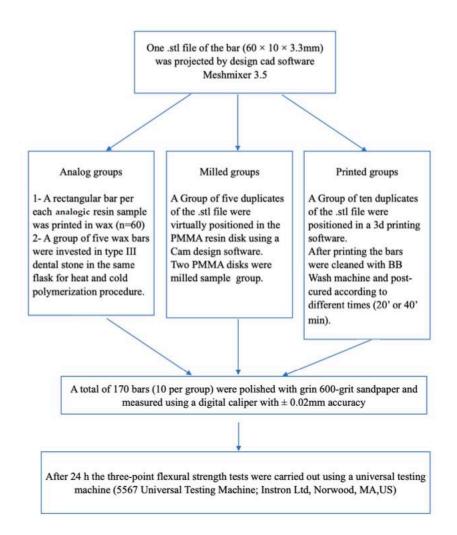
Name	Manufacturer	Material Content	Batch n°
ACRYPOL R	Ruthinium-Dental Manufacturing S.p.A., Italy	Heat curing, acrylic resin (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate.(EDMA) Powder: benzoyl peroxide, methyl methacrylate.	Powder: J1584 Liquid: J1571
ACRYSEL P	Ruthinium-Dental Manufacturing S.p.A., Italy	Polymerizable cold-curing resin (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate, N-N- dimethylparatoluidine. Powder: benzoyl peroxide, methyl methacrylate.	Powder: LOT J0086 Liquid: LOT I0727
ACRYSELF	Ruthinium-Dental Manufacturing S.p.A., Italy	Polymerizable cold-curing resin (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate, N-N- dimethylparatoluidine Powder: benzoyl peroxide, methyl methacrylate.	Powder: LOT J2163 Liquid: LOT I0727
ACRYPOL HI	Ruthinium-Dental Manufacturing S.p.A., Italy	Heat curing acrylic resin with a high molecular weight (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate. Powder: benzoyl peroxide, methyl methacrylate.	Powder: LOT H1172 Liquid: LOT J0890
ACRYPOL LL	Ruthinium-Dental Manufacturing S.p.A., Italy	Heat curing acrylic resin with a high molecular weight (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate. Powder: benzoyl peroxide, methyl methacrylate.	Powder: LOT J1352 Liquid: LOT I1608

TABLE 1. Materials tested in the study.	
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ACRYPOL FAST	Ruthinium-Dental Manufacturing S.p.A., Italy	Fast heat curing acrylic resin with high molecular weight (PMMA) Liquid : methyl methacrylate, ethylene dimethacrylate. Powder: benzoyl peroxide, methyl methacrylate.	Powder: LOT I1160 Liquid: LOT H0759
IVOTION (control group)	Ivoclar vivadent, Liechtenstein	PMMA Polymethyl methacrylate, pigments	IBPink- YB5WNZ- 117 IBPink- YB5WNZ- 118
AADVA DISC (control group)	GC Corporation, Tokyo, Japan	РММА	NA
NEXTDEN T DENTURE 3D+	NextDent B.V., Soesterberg, Netherlands	3D-print resin (PMMA) 2-hydroxyethyl methacrylate; diphenyl(2,4,6- trimethylbenzoyl) phosphine oxide; 2-hydroxyethyl methacrylate	WW465N0
GC TEMP GC Corporation, PRINT Tokyo, Japan		Urethane dimethacrylate (UDMA) dimethacrylate component** quartz (SiO2) photoinitiator synergist UV-light absorber	2212091

		Urethane dimethacrylate		
	GC Corporation, Tokyo, Japan	(UDMA)		
GC TEMP PRINT+ Pink		dimethacrylate component** quartz (SiO2) photoinitiator synergist UV-light absorber Urethane dimethacrylate Methacrylate Monomer(s) Photoinitiator(s)	NA	
SprintRayE U Denture Base	SprintRay Inc., Los Angeles, USA	3D-print resin Ethoxylated bisphenol A dimethacrylate (BisEMA) 7,7,9 (or 7,9,9)-trimethyl-4,13- dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate, 2-hydroxyethyl methacrylate, Silicon dioxide, diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide, Titanium dioxide.	50920226	

FIGURE 1. Schematic diagrams on sample fabrication method and procedures reported for the different sample groups.



Analog Process

The analog group was composed of different resins: four resins were heat-cured (Acrypol R, Acrypol LL, Acrypol HI, and Acrypol Fast) and two were cold-cured (Acryself P and Acryself), as described in Table 2. All resins were produced by the same manufacturer, Ruthinium-Dental Manufacturing S.p.A., Rovigo, Italy.

They were fabricated according to the manufacturer's instructions with a 3:1 powder- to-liquid ratio, except Acryself P, which had a 2:1 powder-to-liquid ratio. To fabricate these resins, a wax die was 3D printed with rectangular shapes of accurate dimensions. Once mixed, the resin was then poured inside the die, which was itself placed in a flask. It should be noted that two different flasks were used for the fabrication of Acrypol LL.

Four resins were heat-cured (Acrypol R, Acrypol LL, Acrypol HI, and Acrypol Fast), and two were cold-cured (Acryself P and Acryself), as described in Table 2.

The heat-cured resins were prepared by applying 3 tons/6000 lbs pressure to the flask. While fore the cold curing resins, the polymerization was carried out in a pot at a pressure of 2 ATM (standard atmosphere) for 10 min at a temperature of 45 °C.

TABLE 2. Analog resins with corresponding polymerization technique used.

Name	Polymerization
ACRYPOL R ACRYPOL LL	Place the flask in water at room temperature until completely immersed. Heat the water in about 40/45 minutes at 70 ° C, keep this temperature for 30 minutes, then bring the water to a boil and keep it for 30 minutes, then let it cool slowly in the water for another 30 minutes. Then, removing it from the water, allow the muffle to cool to room temperature.
ACRYPOL HI	Place the flask in water at room temperature until completely immersed. Slowly bring the water to the boil in at least 45 minutes. Simmer for 30 minutes, then leave to cool slowly in the water for another 30 minutes. Then, removing it from the water, cool the muffle at room temperature.
ACRYPOL FAST	Heat cured in boiling water for 20 minutes, remove the flask from water and leave it to cool at room temperature. Then, restart the device and bring the water to the boil and keep the temperature constant for 20 minutes. Remove from the water and cool to room temperature.
ACRYSELF ACRYSELF P	Polymerization at a temperature of 22°/23°C starts approximately 12-15 minutes after mixing. It is recommended to carry out polymerization in a pot at a pressure of 2 ATM (Standard Atmosphere) for 10 minutes at a temperature of 45°C.

CAD-CAM and Milling Process

For the milled group, rectangular specimens of accurate dimensions were designed using the CAD software MESHMIXER 3.5. It was then saved as a Standard Tessellation Language (STL) and sent to the milling machine. Pre-polymerized PMMA discs were fixed on a sectioning machine and milled using a diamond saw.

3D Printing and Curing Process

Three types of 3D-printed resins were used: NextDent Denture 3D+ (NextDent B.V., Soesterberg, The Netherlands), GC Temp Print (GC Corporation, Tokyo, Japan), and SprintRayEU Denture Base (SprintRay Inc., Los Angeles, CA, USA).

The same STL file as the milled groups was used for the 3D-printed group. It was sent to the DLP printer Asiga MAX UV (wavelength = 385, pixel resolution = 62) and printed at a 0° build orientation, as suggested by the findings of Dai et al., 2023 [39]. After the printing process, the specimens were cleaned with Liquidtech BT for 20 min using the BB Wash machine (Meccatronicore S.R.L., Pergine Valsugana, TN, Italy). The resins then received different types of post-curing procedures (as described in Table 3).

Polymerization	
Polymerization with "LaboLight DUO" curing unit for 20 minutes.	
Polymerization with BB cure unit for 40 minutes.	
Polymerization with "LaboLight DUO" curing unit for 20 minutes.	
Polymerization with BB cure unit for 40 minutes.	
Polymerization with "LaboLight DUO" curing unit for 20 minutes.	
Polymerization with BB cure unit for 20 minutes.	
Polymerization with BB cure unit for 40 minutes.	
Polymerization with BB cure unit for 20 minutes.	
Polymerization with BB cure unit for 40 minutes.	

TABLE 3. 3D-printed resins with corresponding polymerization technique used.

SprintRayEU Denture Base Group (SprintRay Inc.) was further divided into two subgroups of n = 10 according to the polymerization technique used. One was polymerized for 20 min using the LED curing unit "LaboLight DUO" (GC Corporation, Tokyo, Japan), and the other was polymerized for 40 min using a BB cure machine (Model MTC-BB-CURE-COMPACT, Meccatronicore S.R.L., Pergine Valsugana, TN, Italy). The same procedure was carried out with the NextDent Denture 3D+ resin (NextDent B.V.).

The GC Temp Print specimens were divided into 3 subgroups depending on the polymerization procedure used: one group was polymerized for 20 min with the LaboLight DUO curing unit, the second group was polymerized for 20 min with the BB cure unit, and the third group was polymerized for 40 min with the BB cure unit.

Since GC Temp Print resin is white, another experimental group was made, mixing 3 mL of Formlabs color pigment (color MAGENTA) and 300 mg of GC Temp Print resin to reach acceptable esthetics. This resin was also divided into 2 subgroups of n = 10, with one group being polymerized for 20 min with the BB cure unit and one for 40 min with the BB cure unit.

Fabrication Accuracy

Once the curing procedure was completed, a slow-speed rotary instrument was used to remove excesses and the specimen's support structures. All specimens were polished with a 600-grit sandpaper and measured using a digital caliper with ± 0.02 mm accuracy. Before performing the test, they were stored in distilled water for 24 h.

Flexural Strength Analysis

The three-point flexural strength tests were carried out using a universal testing machine (5567 Universal Testing Machine; Instron Ltd., Nordwood, MA, USA), placing each specimen on circular support beams with a 50 mm span as reported in Figure 2. The loading force was applied to the center of each specimen at a crosshead speed of 5 mm/min. The fracture load was recorded, and the flexural strength was then calculated in megapascals (MPa) using the following formula: FS = $(3 P L) / (2 b d^2)$

{FS: flexural strength, P: maximum load, L: span length (50mm), b: width and d: thickness.} All measurements and tests were done by the same operator. FIGURE 2. Universal machine for three-point bending test.



Statistical analysis

Statistical analysis was carried out by using Statistical Package for the Social Sciences (SPSS) software, version 26 (IBM SPSS statistics, v.26, Inc., Chicago, IL, USA). Means and standard deviations were calculated for each group. The normality was tested using a Kolmogorov-Smirnov which confirmed a normal distribution of data. One-way ANOVA and Bonferroni post-hoc tests were then performed. All p-values<0.05 were considered statistically different. Spearman correlation test was also used to measure the correlation between polymerization technique and flexural strength of 3D-printed resins.

RESULTS

Table 4 shows the mean flexural strengths and standard deviations (SD) for each group of resin as well as ANOVA and P value. Inn Figure 3 all the flexural strength means are reported. Of all the tested groups the AADVA disc had the highest mean flexural strength (107.87 MPa) and Sprintray Denture Base 3D-printed specimens polymerized for 20 minutes with the Labolight curing unit had the lowest (54.07 MPa).

For the analog group, the heat-cured Acrypol Fast had the highest mean (98.86 MPa) whereas the lowest was found for the Acryself group (74.83 MPa).

The 3D-printed group with highest flexural strength was PINK Temp Print polymerized for 40 minutes with the BB-cure unit (102.96 MPa).

Resin type	Mean (MPa)	SD	Sign.
ACRYPOL R	89.15	14.31	adghij
ACRYSELF P	86.07	7.09	adghi
ACRYSELF	74.83	7.84	di
ACRYPOL HI	85.58	8.60	adghie
ACRYPOL LL	92.39	17.18	ghj
ACRYPOL FAST	98.86	10.66	hcj
IVOTION	91.88	4.43	egcj
AADVA DISC	107.87	7.56	cj
NEXTDENT LABO LIGHT 20"	60.11	5.72	b
SPRINTRAY LABO LIGHT 20"	54.07	3.55	b
TEMP PRINT LABO LIGHT 20"	75.58	9.36	i
TEMP PRINT PINK BB 20"	95.39	9.49	cghj
TEMP PRINT PINK BB 40"	102.96	9.37	j
TEMP PRINT BB 20"	90.87	7.44	aghj
NEXTDENT BB 40"	83.32	8.38	adgi
TEMP PRINT BB 40"	96.87	6.27	aghcj
SPRINTRAY BB 40"	85.44	5.30	adghij
ANOVA value	F=24.421		
Р	0.000		

TABLE 4. Mean flexural strengths(Mean), standard deviations (SD) and Significative differences (Sign.).

Same letters per Table denote no statistically significant differences (p>0.05)

120.00 ₫ ቅ • 100,00 ₫ ₫ ₫ ₫ ₽ ₫ 80.00 ቅ ₫ ₫ 60.00 Ð 40,00 20,00 0,00 NEXTDENT LABO LIGHT SPRINTRAY BB 40' Temp Print Mod Pink BB 40' ACRYPOL R PACRYSELF P ACRYSELF ACRYPOL FAST IVOTION SPRINTRAY LABO LIGHT ADVA DISK **NEXTDENT BB 40 TEMP PRINT BB 40** ACRYPOL HI ACRYPOL LL TEMP PRINT 20' BE TEMP PRINT LABO LIGHT TEMP PRINT MOD PINK BE

FIGURE 3. flexural strength means (MPa) for each resin type

Analog group

Acrypol R (89.15 MPa) showed no statistically significant differences with the other groups except with the Nextdent and Spintray resins polymerized for 20 minutes with the Labolight unit (p<0.001). Nextdent and Sprintray resins polymerized for 20 minutes with the Labolight unit showed no statistically significant difference between them (p=1.000) but had a significantly lower mean than all the other groups (p<0.05). Acryself (74.83 MPa) had the lowest flexural strength mean within the analog group; it was significantly lower than Temp Print resin polymerized for 20 minutes with the BB cure unit (p<0.013), Temp Print resin polymerized for 40 minutes with the BB cure unit (p<0.001) and the PINK Temp Print resin polymerized for 20 minutes with the BB cure unit (p<0.001). Acryself P (86.07 MPa) and Acrypol HI (85.58 MPa) were significantly lower than PINK Temp Print polymerized for 40 minutes with BB-cure (p=0.006, p=0.004, respectively). Acrypol LL (92.39 MPa) was significantly higher than Temp print polymerized for 20 minutes with

the Labolight unit (p=0.006).

Acrypol fast had the highest mean (98.86 MPa) within the analog group. It was significantly higher than the Temp Print resin polymerized for 20 minutes with the Labolight unit (p<0.001) and the Nextdent resin polymerized for 40 minutes with the BB cure unit (p=0,020).

There were no statistically significant differences between the analog groups themselves except Acrypol fast and Acrypol LL which were significantly higher than Acryself (p<0.001 and p=0.003 respectively).

Milled group

The AADVA disc's flexural strength was significantly higher than all the other groups (p<0.02) except the Temp Print group polymerized for 40 minutes with the BB cure unit (p=0.839), the PINK Temp Print polymerized for 20 minutes with the BB cure unit (p=0,275) and the PINK Temp Print polymerized for 40 minutes with the BB cure unit (p=1,000). It also showed no statistically significant differences with Acrypol fast (p=1,000). Nevertheless, it was significantly higher than the Ivotion disc (p=0.013).

The Ivotion discs presented a significantly higher flexural strength than Nextdent and Sprintray groups polymerized for 20 minutes using the Labolight unit (p=0.000) as well as the Temp print group polymerized for 20 minutes using the Labolight unit (p=0.010). Compared to the analog group, it showed statistically significant differences only with Acryself (p=0.005).

3D-printed group comparison

In the 3D-printed group, the lowest flexural strengths found were for Sprintray (54.07 MPa) and Nextdent (60.11 MPa) resins polymerized for 20 minutes with the Labolight unit. They showed no statistically significant difference between them (p=1.000), nevertheless, they did show statistically significant differences with all the other 3D-printed resins (p<0.04).

Nextdent and Sprintray groups which were polymerized for 40 minutes with the BB-cure unit were significantly lower than the PINK Temp Print polymerized for 40 minutes with the BB cure unit (p<0.003).

Within the Temp Print resins, the one polymerized for 20 minutes with the Labolight unit had the lowest mean (75.58 MPa). It was significantly lower than the Temp Print resin polymerized for 20 minutes with the BB cure unit (p=0.025). It was also significantly lower than the Temp Print polymerized for 40 minutes with the BB cure unit (p<0.001) and the PINK Temp Print groups polymerized with the BB cure unit for 20 minutes (p<0.001) and 40 minutes (p<0.001). Finally, the PINK Temp Print group polymerized for 40 minutes with the BB cure unit the 3D-printed group. It was significantly higher than the Nextdent (p<0.001) and SprintRay (p=0.003) groups which were polymerized for 40 minutes with the BB cure

Spearman tests showed high association between flexural strength and polymerization technique. The correlation coefficient was 0.811 for PINK Temp Print, 0.867 for Temp Print, 0.867 for Sprintray and 0.867 for Nextdent.

DISCUSSION

This study was conducted to compare the flexural strengths of acrylic and composite resins for denture base fabrication according to their fabrication technique (conventional, CAD-CAM-milled, and 3D-printed) and polymerization process. The results of this research revealed statistically significant differences among the resins tested. Therefore, the null hypothesis was rejected. Concerning the results obtained in the present study, it can be speculated that the content and the degree of chain conversion during the polymerization may influence the flexural strength of the different resin-based materials evaluated.

As previously reported for PMMA resins, the polymerization process can be initiated by benzoyl peroxide, which can be activated by thermal energy (heat curing resins) or by the use of tertiary amines (cold curing resins).(40,41)

In the present study, it was confirmed that the mechanical properties of self-curing resins were lower (Acryself P and Acryself) than those made with heat-activated resins (Acrypol R, Acrypol LL, Acrypol HI, and Acrypol Fast) because of excess residual monomer.

Regarding the high flexural strength of GC TempPrint, the enhanced strength can be at- tributed to the fact that the UDMA material has a lower molar volume and molecular weight than alternative resins. This could enhance the preliminary methacrylate functionality of the un-polymerized material. It is highly likely that this increased functionality increases the crosslink density within the matrix of the polymer. When this occurs, polymeric resins exhibit enhanced mechanical properties, one of which is flexural strength.(42)

The influence of BisEMA monomers with low viscosity and high MW on the me- chanical behavior of resin composites has not been extensively investigated. However, the total replacement of BisGMA by BisEMA in composites with TEGDMA resulted in higher conversion, but no improvement was observed in flexural and diametral tensile strengths.(43)

According to ISO-20795-1:2013, (26) the minimal flexural strength required for denture bases is 65 MPa. Of all the resins tested, only the Sprintray (54.07 MPa) and Nextdent (60.11 MPa) groups polymerized for 20 min with the Labolight unit did not meet such standards. Another study also found values under 65 MPa for the Nextdent resins using a different printer and printing orientation.(30)

The highest values for flexural strength were found for the CAD-CAM-milled groups, which supports previous findings.(33,35)

Flexural strength is affected by the degree of polymerization achieved. When acrylic resin strengths are compared, those with a lower degree of conversion exhibit inferior mechanical properties. The

higher flexural strength values of CAD-CAM specimens may be attributed to a higher degree of conversion.(44)

Thus, CAD-CAM-milled dentures can be considered a valid substitute for convention- ally fabricated dentures.

Three-dimensionally printed resins polymerized with the BB cure unit, either for 20 or 40 min, always showed higher flexural strength compared to the resins polymerized with the Labolight unit; moreover, the Spearman test showed a high correlation between flexural strength and the polymerization technique used. This confirms that polymerization does play a role in mechanical properties.(30)

Flexural strengths for Nextdent and Sprintray polymerized for 40 min with the BB cure unit showed no statistically significant differences with the analog groups except Acryself. Such a finding implies that 3D-printed fabrication can lead to similar results as those found for analog procedures while using a material with lower cost and less dependence on manual expertise. Three-dimensionally printed resins also implicate shorter chair time and working time, as a denture could be printed directly after scanning the edentulous arches or the analog impression. Additionally, the lower cost would also allow broader access to dental cures and reduce the economic issue of denture fractures, as it would be easier and cheaper to print a new denture compared with starting a full conventional process again.

Such an outcome is in accordance with al-Qarni et al. (2022) results, who conducted a similar experiment and found a mean flexural strength of $(93.4 \pm 10.8 \text{ MPa})$ for heat-cured analog resins and $(56.4 \pm 4.7 \text{ MPa})$ for NextDent specimens, which were printed with DLP technology and cured for 10 min at 60 degrees with an LC-D print box machine.(31)

This study also confirmed the data previously obtained by Di Fiore et al. (2021) in a study conducted with a similar protocol. A flexural strength of 80.79 (\pm 7.64 MPa) for heat-cured analog resins was found and of 110.23 (\pm 5.03 MPa) for the CAD-CAM-milled PMMA block (Ruthinium Disc; Dental Manufacturing Spa). The 3D-printed Nextdent specimens showed a very similar flexural strength (87.34 \pm 6.39 MPa) even though they were printed using an SLA printer and polymerized for 20 min with a light box (Moonlight; VertySystem).(34)

Temp Print resins showed higher flexural strengths than the other 3D-printed resins, which can be explained by the fact that it is a different material. It also showed statistically significant differences with the analog group. The use of a 3D-printed composite for a denture base could be a possible alternative, given that it also presents good dimensional stability. Temp Print showed good results of dimensional stability over time when used for full arch restorations,(45) but more studies should be carried out when used for complete denture fabrication. It was shown that the addition of a pigment

in order to have an acceptable aesthetic for the fabrication of dentures did not interfere with mechanical properties but improved the flexural strength. Since the material GC Temprint PINK is an experimental material never tested before the present study, it is mandatory to test in vitro and in vivo conditions in order to obtain a comprehensive evaluation before clinical use.

A limitation of its use for denture bases can be the lack of evidence on the bonding abilities of 3Dprinted composite resins to liners, which could mean a new denture should be printed with the added modifications each time relining is needed. Nevertheless, studies were conducted to find the best surface treatments for both PMMA and UDMA to increase their bond to soft liners.(46) More studies should be carried out on the use of pink pigment on 3D-printed composites for dentures since the good flexural strength values found in this study.

In order to validate the materials for clinical use, further tests should be carried out, such as impact strength tests, surface hardness tests, and color stability evaluations, but mostly dimensional stability tests. Long-term studies or the use of thermocycling to imitate resins' aging are needed to better understand the changes in mechanical properties over time.

Of course, in order to standardize the in vitro procedure, the specimens were prepared according to ISO-20795-1:2013, but further studies are indicated in order to evaluate the mechanical properties in the oral environment.

CONCLUSIONS

Within the limits of the present study, it can be concluded that:

- Temp Print specimens reported no statistically significant differences with both control groups, Ivotion and AADVA discs, proving that it can be a potential alternative to fabricating removable dentures.
- The experimental 3D-printed Temp Print composite showed promising results with the highest flexural strength within the combination of pink color resin.
- It was confirmed that flexural strength and polymerization methods are correlated.

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6.2 Outcomes evaluation of a patient treated with roots immediate digital denture: patient evaluation after full digital dentures

ABSTRACT

The immediate dentures fabrication in the analogic manner may be an hight time-consuming and unreliable procedure. The purposes of this article were both to describe a simplified protocol based on a digital workflow used to fabricate a set of immediate dentures and to report patient functional and quality of life data. The digital intraoral scans were recorded and used for dentures design, the teeth arrangement proposed by the software was superimposed to patient frontal photo in order to simulate the aesthetic proposal. The resulted Standard Tessellation Language files were exported to a milling machine for denture fabrication. After immediate denture delivery the remaining lower canine roots were used to retain the prosthesis. In order to evaluate the different effects of the treatment on masticatory efficiency, bite force and health–related quality of life (OHRQoL) data were measured before and after treatment. The patient reported a good adaptation form the delivery, an improvement for all the aspects evaluated after prostheses roots anchorage.

INTRODUCTION

When the complete arches extraction is required, the patient, becoming edentulous, may experience social, psychological and aesthetic consequences. To avoid these impairment conditions the fabrication of immediate dentures (ID) before the extractions can be provided(1). Anyway, the transition from the remaining teeth to a removable solution can be a challenge for the patient due to the lack of retention and stability. For this reason, when it is possible, leaving supporting roots can improve the patient's performance with immediate denture and facilitate adaption. Different procedures have been described to provide an ID, (2,3,4) but in all the conventional methods a lot of appointments and laboratory time are required. (5) Recently, computer-aided design and computer-aided manufacturing (CAM-CAM) technology has been used to fabricate complete dentures. (6,7) It was reported that Digital Dentures (DD) can provide improved denture retention and fit,(8,9) a time reduction of both clinical and laboratory procedures,(10) higher patient satisfaction,(11)and reduced costs compared to analogic protocols.(12) Most clinicians still use conventional procedures for impressions and occlusal recording that are then digitized in the laboratory,(13,14) however, it can determine a reduced precision of prostheses due to the several steps required. Recently it was reported that the intraoral scanners (IOS) may be accurate for complete denture fabrication.(15-

19)The use of this technology has allowed to minimize the inconveniences associated with the use of traditional impression materials.(20) The mobility of the remaining teeth would not allow easy removal of the impression tray without exposing the patient to the risk of avulsions. Additionally, the digital software design allows to simulation of the aesthetic proposal thanks to the possibility of superimposing additional IOS (temporaries or old dentures) face scans or patient face photos. The predictability of these digital options is still updated and is not fully documented in the scientific literature, for this reason, it was chosen to report this clinical case to evaluate the correspondence of the aesthetic results obtained from digital design software to patient mouth through immediate denture treatment.

To date, few studies reported a strong influence of dental loss over the masticatory efficiency and maximal bite force,(21) but the improvement it with different prosthetic treatment options has been confirmed.(22) In these studies the masticatory efficiency was evaluated using the two- coloured gums test proposed by Schimmel(23) and the bite force was recorded using a novel device called Innobyte (Kube Innovation, Montreal, Canada). Both aspects were registered at different phases of the treatment: at the beginning with the patient's terminal dentition, 3 weeks after immediate digital denture delivery and finally 3 months after the placement of attachment systems on the lower canines roots.

CLINICAL REPORT

A 58-year-old man presented in the Prosthodontics Department of the University of Siena with terminal dentition (Fig. 1). The patient was classified as ASA II due to treated hypertension. FIGURE 1A-C:Extraoral photos: A and C: lateral view B: frontal view

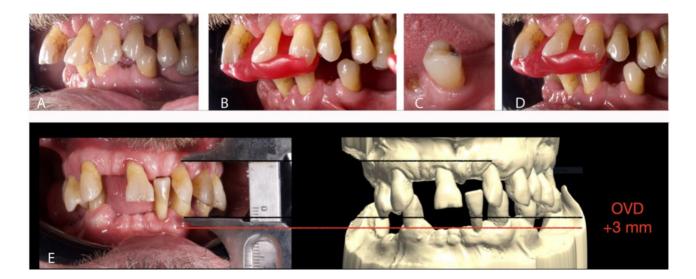


Clinical examination and radiographic assessment revealed an unrestored mouth due to severe periodontitis and several non-restorable teeth to support a prosthetic rehabilitation (Fig. 2). FIGURE 2 A-C: Intraoral photos D: panoramic radiograph.



He has been diagnosed with an IV-level generalized periodontitis with more than 70% periodontal attachment loss. Facial, dento-labial and phonetic analyses were performed. The parallelism between the commissural line was evaluated on the facial plane, as well as the relationship between the e-line and lips on the sagittal plane. The patient showed an altered pattern of incisal plane and midline. The remaining upper teeth were extruded and proclined resulting in a compromised phonetics. The initial occlusal evaluation revealed a loss of occlusal vertical dimension (OVD) with overreaction of 14 and 26.

FIGURE 3 A-D: Centric position recording steps D: OVD increase .



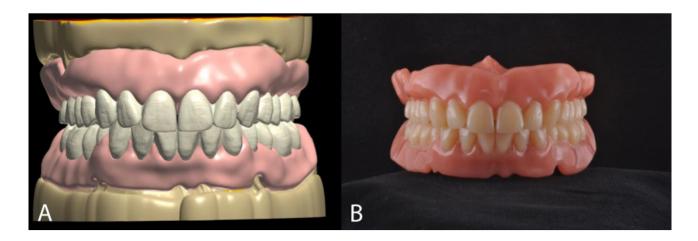
Absent conditions affecting the temporal-mandibular joints. Patient needs and Quality of life were recorded at the first visit. An oral health-related quality of life (OHRQoL) test, OHIP-14 in the Italian version was administered before treatment. Initial data on the patient's maximum bite force and masticatory function were also recorded. The bite force was analyzed using Innobyte (Kube Innovation, Montreal, Canada) using three 3-second measurements asking the patient to bite on the support. The final reported value of 167N was calculated as the average of the 3 measurements. The masticatory function was assessed through the Masticatory Performance Test (MP) in which individuals chew a standardized portion of test gum for 20 cycles. The uncertain periodontal prognosis and the patient's limited financial resources led to a treatment plan that included extraction of the maxillary and mandibular teeth and delivery of digital immediate removable complete dentures. Only lower canines were not extracted, in fact, canines were endodontically treated and maintained as supporting roots. Upper and lower arches were restored with ID obtained thanks to a digital approach. After 3 weeks after extraction and delivery of the dentures, the canine roots were prepared for a direct attachments system. The patient after healing had been reevaluated and a definitive treatment plan had been defined from 1 fixed Implant supported rehabilitations, 2 removable implant-supported rehabilitations, and 3 definitive complete dentures with root attachments. The IOS (TRIOS 3Shape A/S, Copenhagen K, Denmark) was acquired using edentulous dedicated retractors (Lo Russo retractors, ELDO S.r.l., Italy). Since the OVD collapsed, it was decided to raise it around 3 mm according to the patient's facial third support, phonetic and aesthetic parameters. The resulting centric position was recorded after selective grinding on the occlusal surface of the 34. The resulting occlusal position was recorded by IOS. A frontal picture of the patient in the "E" sound position was attached to the scanning data and sent to the laboratory. The obtained data were imported into denture design software (Dental System 2021 3Shape A/S, Copenhagen, Denmark) for ID design. The next step involved the virtual avulsion of dental elements residues resulting in two models of edentulous arches properly oriented in space. The software automatically generated a suggestion for setting up the selected teeth that were selected according to the patient teeth dimension and shape. This setup was customized according to the information obtained by the superimposition of the patient picture in order to evaluate better the esthetic parameters (Fig.4).

FIGURE 4A-C: A, Digital models preparation B, teeth arrangement C, superimposition with previous teeth and patient smile.



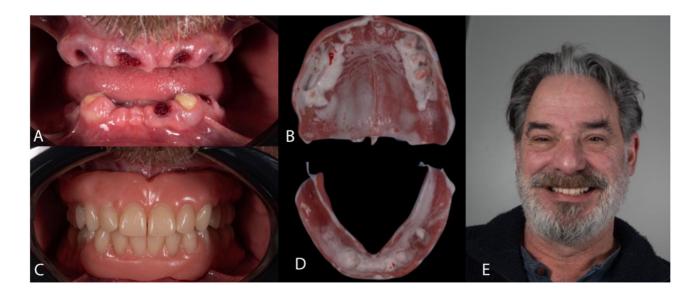
After the designs had been completed for an oversized milling process (Vivadent AG, Ivoclar Vivadent, Schaan, Liechtenstein) PMMA disks for bases and teeth (Ivotion base and Dent multi A3 (Ivoclar Vivadent AG Schaan, Liechtenstein) were selected and positioned inside a five- axis milling unit (PrograMill 7; Ivoclar Vivadent AG, Schaan, Liechtenstein). After the complete milling, the immediate dentures were sent to the office for delivery(Fig.5).

FIGURE 5: ID project and finalized prostheses.



The remaining teeth were extracted according to the treatment plan and the two lower canines previously endodontic treated, were cut. The set of dentures was immediately inserted after the extractions (Fig.6).

FIGURE 6: A intraoral view after teeth extraction, B and D prostheses adaptation evaluation, C and E intraoral and extra oral view of the prostheses delivered.



Very good adaptation was found so that no chair-side adjustments were needed. After 7 days the patient reported no pain and we proceeded with soft tissue conditioning (Gc Tissue conditioner, GC, Tokyo Japan). The IDs were anchored after 3 weeks, the patient achieved improved stability and satisfaction. After the healing time of 6 months, thanks to aesthetic and functional results, the patient decided to refuse implants and to maintain the ID relined as a definitive solution(Fig 7).

FIGURE 7: A Roots attachment systems and B final aesthetics



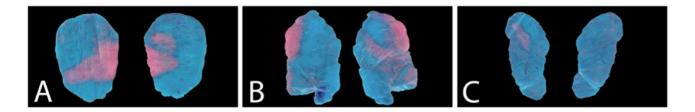
The data collected for OHRQoL, bite force and masticatory performances were reported at pretreatment time, 3 weeks after ID delivery and 3 months after root anchorage in the following table(Tab. 1). The two coloured gums images were reported at pretreatment, after delivery and 3 months after roots anchorage(Fig. 8).

TABLE 1

	Pre-treatment	3 weeks after delivery	3 months after anchorage
Ohip-14	39	25	9
Bite force	167	219	395
Masticatory performances	0.089	0.086	0.05

FIGURE 8: Gums obtained after 20 masticatory cycles at pretreatment A, after delivery B and 3 months

after roots anchorage C.



DISCUSSION

The purpose of this article was firstly to describe a digital workflow for fabricating immediate dentures before extractions and secondary to report the patient outcomes in terms of OHRQoL, bite force and masticatory performances. All the information was acquired by IOS, the IDs were obtained using DD design software and CAD- CAM technologies. As far as the authors are aware, this is the first published report describing such a technique in a patient with no pre-existing dentures and using a different OVD in the final treatment. The IDs are usually used in situations where the remaining teeth are heavily compromised and loose and the risk of being extracted during conventional impression is high.(24)

IOS can be useful to get around this problem and additionally, the images of the teeth are easily cut from the virtual 3D image of the arch without any risk of damaging the cast(25). With conventional ID protocols, registering the inter-maxillary position when the dental support is reduced, as in the presented case, may require a separate appointment from the impression. However, thanks to the bite scan registration predictability, once the new OVD was established in regard to the aesthetic and facial appearance of the patient with wax, it could be registered and exactly reported in the final restoration without any distortion. Additionally, the digital workflow allows to sending of patients' facial images to the laboratory and the technician can individualize the teeth arrangement according to lip lines and extra-oral parameters. In this case report the functional activities were also evaluated. An improvement in maximal bite force was reported in the first weeks after insertion, and a peak after attachments' insertion. Several studies (26-28) demonstrated that the masticatory performance of implant overdenture users increases, likely because the implants improve retention and stability of the mandibular prostheses, but the masticatory performance of overdentures on natural teeth, as reported in the present case should be better investigated. Additionally in this study, we found an improvement in OHRQoL score for the treated patient starting from terminal dentition, moving to ID and finally with lower overdentures retained by canine roots. The concept of OHQoL

is based on the perspective that oral health conditions and diseases can undermine someone's selfesteem and self-image, can cause other health problems, can discourage social interaction, and can lead to pain, stress, or depression.(29) One of the goals in dental care is to improve OHQoL of patients and in the reported clinical case this point was reached shortening the operating time and number of appointments thanks to IOS and digital workflow. More clinical studies could be performed in order to validate the clinical results obtained.

CONCLUSION

This article describes a digital workflow that facilitates the fabrication of IDs. The procedure described with roots supported over-denture improved functional and aesthetic parameters improving patient quality of life thanks to a reduced cost protocol. Digital workflow in ID is an innovative promising and predictable procedure that requires more clinical validation.

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6.2 Digital workflow from immediate to definitive CAD/CAM dentures: a case report

ABSTRACT

The present article describes a simplified protocol based on a digital workflow used for a patient rehabilitation from immediate pre-extraction (ID) to definitive complete dentures (DD). A 67 year old patient previously rehabilitated with removable partial dentures (RPD) referred to Siena University Prosthodontic Department complaining functional and aesthetic discomforts. The anamnestic data and photos were collected at the fist visit. The clinical observation and x-ray evidenced an hopeless dentition in both arches due to stage IV periodontal disease. Digital intraoral and bite scans were recorded with and without the existing Removable partial denture (RPD) for case study. The treatment plan included the extraction of all residual teeth and the delivery of ID maintaining the previous inter-maxillar relationship and all the aesthetics parameters. The ID were obtained by a single step milling procedure (Ivotion, Ivoclar Vivadent AG, Liechtestein) and after healing at 9 months it was decided to scan the relined ID in order to reproduce the cameo surface and tooth arrangement required for a new DD fabrication. The patient was collaborative during all treatment, reported a positive adaption from the ID delivery, a good aesthetic integration and optimal functional comfort even with DD. The digital workflow for complete dentures fabrication requires limited time and effort compared to conventional protocols. Thanks to the digital workflow the patient obtained a good adaptation to the prostheses and an enhanced aesthetics and functional results.

INTRODUCTION

Complete dentures (CD) still remains one of the most common and predictable treatment, in particular for edentulous patients who have systemic, anatomic, and/or financial limitations.(1-3) In case of terminal dentition, when the patient be- comes edentulous, he may experience detrimental effects on functional activities,(4) aesthetics, (5) and the self-esteem,(6) thus a decreasing their quality of life is usually expected (7,8). The construction of immediate dentures (ID) before the extractions can reduce this impairment condition (4) providing an efficient temporary prosthetic solution. Different procedures have been described to obtain an ID.(5,6,7) The conventional methods can be re- liable but require multiple clinical appointments, lengthy and complex laboratory schedules.(8) These aspects can lead to processing errors, inaccuracies, and increased time and cost. In order to obtain CD in a conventional workflow, five visits are usually required in

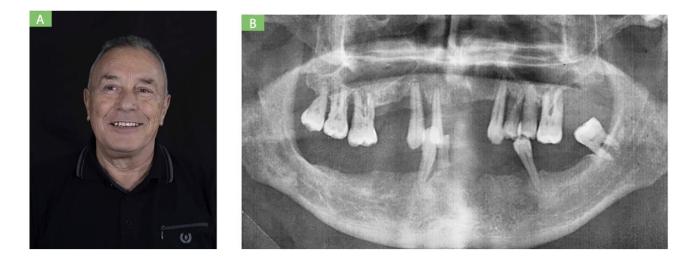
the dental practice, including preliminary impressions, final impressions, inter-maxillary registration (determining the centric relationship and the vertical dimension), teeth arrangement tryin (in order to verify aesthetic, phonetic and occlusal function) and delivery.(9) To date the most of the clinicians still to use conventional procedures for impressions and occlusal recoding that can be digitized in laboratory,(10,11) however it can determine a reduced precision of prostheses due to the several steps required. Recently, computer aided design and computer aid- ed manufacturing (CAM-CAM) technology has been used to fully fabricate ID (12-14) and digital complete dentures (DD).(15) It was been reported that DD can provide improved denture retention and fit,(16,17) a time reduction of both clinical and laboratory procedures (18), higher patients' satisfaction (19) and reduced costs (20) comparing to the analogic protocols. Recently it was reported that the IOS (Intraoral scanner) may be accurate for complete denture, (21-24) and the proof of concept for realizing a functional maxillary complete denture on intraoral scans have been reported.(25-28) The use of this technology allows to minimize the inconveniences associated with the use of traditional impression materials.(29) Especially in case of ID the mobility of the remaining teeth would not allow easy removal of the im- pression tray without exposing the patient to the risk of avulsions. Furthermore the deign software allow to simulate the aesthetic proposal thanks to the possibility to superimpose additional IOSs (temporaries or old dentures) to patient face scans or photos.(30,31) The predictability of this digital options are still updating and are not fully documented in the scientific literature, for this reason it was chosen to report this clinical case in order to evaluate the correspondence of the esthetic results obtained from digital design software to patient mouth thought immediate denture treatment. After the extraction, when sites have healed, the transition from the ID to DD can be done by rebasing the ID with a laboratory technique or fabricating new dentures.(32) Although the first option is economical, it deprives patients of their prostheses and does not permit repositioning of individual teeth.(33) The second option can be performed by using a digital workflow, that offers more a rapid and straightforward procedure, compared to the conventional workflow, for obtaining definitive CDs.(34-36) In fact a direct digital scanning of ID using an IOS can facilitate the transition toward definitive CDs (37) thanks to the possibility to because it can be obtained from the data from the ID tested by the patient during the healing time.

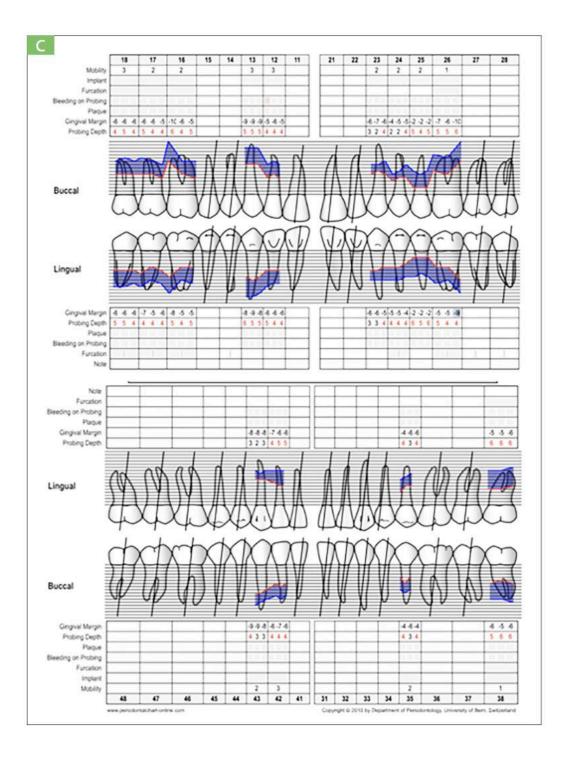
This technique article presents a digital workflow to rehabilitate a patient with an ID and a DD.

CASE REPORT

In 2020, a 67-year old man referred to Siena University Prosthodontic Department complaining about chewing efficiency, due to mobility of residual teeth and poor fit of the existing RPD, and aesthetics. The patient requested a simple prosthetic rehabilitation for both maintenance and costs, and to obtain a good comfort with a removable solution. At first visit all the evaluations (clinical, periodontal status and ortopanoramic XR) confirmed a diagnosis of stage 4 and grade c periodontitis (Fig. 1).

FIGURE 1 Preoperative condition. A: Full-face view B: Ortopantomography C: Periodontal Charting



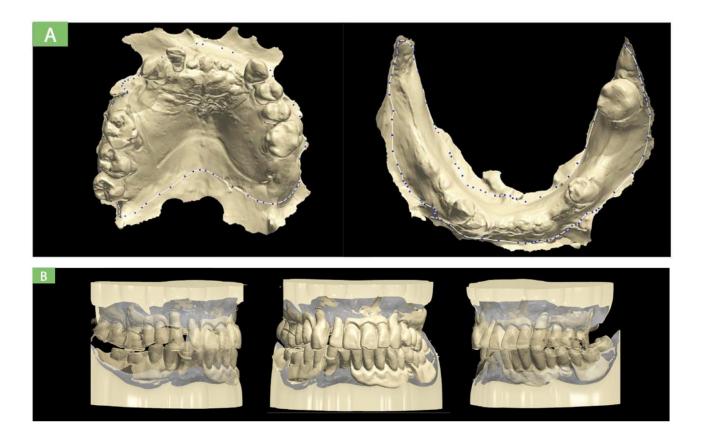


Digital intraoral photographs were taken from a retracted frontal view and lateral view and extra oral photos (Fig 2).

FIGURE 2. Intraoral photos

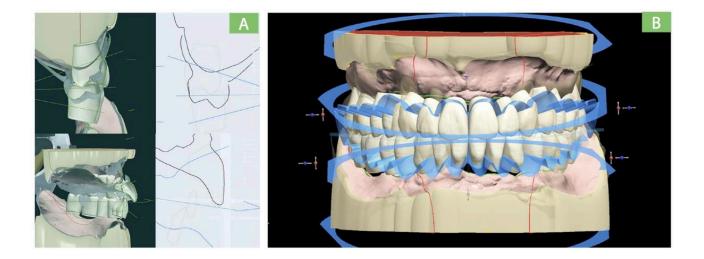


The uncertain periodontal prognosis and his limited finances led to a treatment plan that included extraction of the remaining maxillary and mandibular teeth and delivery of digital ID followed by digital CD after the extraction sites had healed. The IOS of both arches were recorded with intraoral scanner (3Shape, Trios, Denmark), the first one registered the residual teeth and the supporting area, the second was recorded with RPD in situ . The inter-maxillar position was registered thanks to the first one; whereas the other impressions were used for the aesthetic of the frontal teeth. (Fig 3) FIGURE 3 A: Intraoral impressions B: Digital master models superimposition with study models.



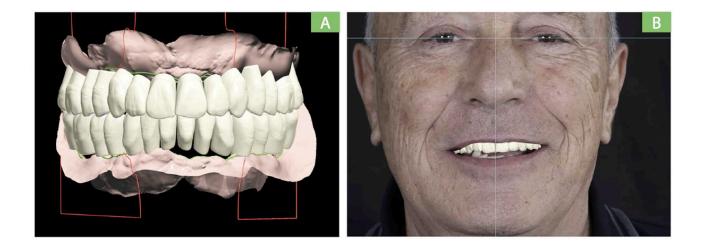
From the outcome of the smile design and alignment of the intraoral scans, the digital immediate complete dentures were designed (Dental System 2020; 3Shape A/S, Denmark) after the virtual extraction of the residual dentition from the master models. At this point the denture teeth were chosen from the software library of denture teeth, and the design program advised a virtual tooth setup. The tooth setup could be modified according to the demands of the clinician and patient or finalized by adding the gingival portion of the dentures if no changes are requested. It was possible to evaluate in cross section views the position of the new CD teeth compared to the preparative condition.(Fig. 4)

FIGURE 4 A: cross section of the text arrangement and the previous prostheses scans, B: Definitive computer-aided design and shell geometry (blue rings) positioned for definitive production.



In addition, to analyze the aesthetic parameters the teeth setup was customized according to the informations obtained by the superimposition of the IOS obtained with RPD to the patient face photo. (Fig 5)

FIGURE 5 A: teeth arrangement, B: superimposition to patient face for Smile design simulation.



Finally, the prostheses were designed, the output CAM file was processed for a single step milling procedure using disks with shell geometry technology (Ivotion Ivoclar Vivadent AG). Base shade preference and tooth shade A3 were selected and positioned inside a milling unit (PrograMill 7; Ivoclar Vivadent AG, Liechtenstein). Finally the digital immediate complete dentures were textured and polished.

The remaining maxillary and mandibular teeth were extract- ed, and the digital immediate complete dentures were de- livered. (Fig 6)

FIGURE 6 A: intraoral photos arches after extraction sockets B: Prostheses at delivery frontal view.



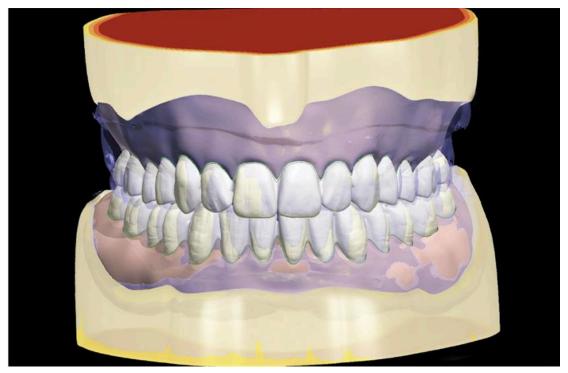
The patient was then followed through the healing phase. The prosthesis was maintained with soft material until the complete healing, during which the dentures were relined every 15 days during the first 2 months and then monthly to adapt to new tissue conformation. After the extraction sites healing, thanks to good patient adaption, the transition from the ID to DD was planned.

After 9 months from the extraction tissues were considered stable, the DD definitive complete dentures were produced with the reference denture technique 34 using scans of the digital immediate complete dentures as the references for the design. (Fig 7) FIGURE 7 Patient frontal view after 9 months, ID relined for definitive data acquisition, STL file obtained from IOS.



The ID bases were relined with a high-precision material in a closed-mouth technique, then the extraoral scan of the cameo and intaglio surfaces of the maxillary and mandibular prosthesis using an IOS (TRIOS3; 3Shape A/S, Denmark) according to the manufacturer's indications. The scanning workflow started from the most distal molar, progressively all occlusal surfaces were recorded since the contralateral molar. The digital scan continued with palatal and buccal surfaces of the teeth and then with the the intaglio surface to gather borders. Finally the scan was completed by capturing the missing surfaces and controlling all the impression, in particular in areas such as the denture posterior seal, lingual flange and retromolar area. The digital definitive complete dentures were designed from an alignment of the copy denture scans and smile design for the appropriate tooth positioning. Some modifications respect the ID in accordance to clinical evaluation were perfomed (Fig.8).

FIGURE 8 Digital design for DD alined with ID scan



After the DD designs had been finalized, the prostheses were milled (PrograMill7; Ivoclar Vivadent AG, Liechtenstein), textured, polished, and delivered.

The definitive dentures were controlled at delivery for base adaption (Fig. 9).

FIGURE 9 DD at delivery. A/C: adaptation test, B: DD polished



The final esthetic transition of the patient from ID to DD was gradual according to patient needs where the position of the 21 was corrected form pretreatment to DD (Fig. 10).

FIGURE 10 Patient frontal view. A: pre treatment, B: after ID, C: after DD



DISCUSSION

The purpose of this article was to describe a fully digital workflow from ID to the DD transferring all data using an IOS device.

The use of digital workflow for ID rehabilitations has a whole ranges of advantages, such as: no risk of extraction during impression of mobile teeth, time saving procedure (no need for cast pouring, articulator mounting, and removing the teeth from the cast) and virtual occlusal registration is stored and can be reused for future replacement dentures

As reported by Silva et al. there are some disadvantages of the workflow when include positioning the shell geometry during the CAD process.(43) The architecture of the gingival papilla cannot be modified; therefore, the height of the papilla peaks is not adjustable. Moreover, as the shell geometry has static papilla architecture, the positioning of the disk for the tooth and base design can lead to an undesirably thin milled base, with tooth color being visible through the base, particularly at the tuberosity and retromolar pad regions. However in the case presented the shell geometry allowed to obtain a good esthetic result for the ID thanks to the high amount of space in between the arches. For patients for whom the monolithic disk could not be used based on these limitations, the alternative approach is to mill a pink base (Ivotion Base; Ivoclar Vivadent AG, Liechtenstein) and the teeth (Ivotion Dent; Ivoclar Vivadent AG, Liechtenstein) separately to then bond them together. After healing there is also the possibility to use the immediate denture as a prototype for the border molding and the definitive impression, and to transfer all aesthetic ad occlusal parameters to the laboratory. The fabrication of new DD in this manner can be simplified, as shown in the recent papers,(40-43) only two appointments are required to complete the treatment, as long as major corrections are needed. The potential disadvantages due to the lack of border moldering of the IOS performed for the ID can be overcome thanks to the chairside adjustments and a soft relining procedures that are always necessary to compesate the healing tissues modifications. Concerning the definitive DD, even in this case of major modifications are required all the data

obtained from ID can be used to prepare a denture prototype. It can be recom- mended it to test them with the patient before fabricating the definitive dentures.

In the case described in the present paper major corrections from ID to DD weren't required thus it was possible to to take the final impression and to digitize it together with the occlusal and functional parameters and to finish the DD without any intermediate step.

Anyway DD workflow is a flexible options, and it can im- prove communication between the dentist and the dental laboratory technician.

Although patient selection is important, fabricating milled complete dentures from prepolymerized

PMMA disks result in a digital removable complete denture that is highly dense, stable, and precise. The monolithic disk is homogenous with minimal porosity, which may improve resistance to bacteri- al and fungal infiltration into the resin. Patient satisfaction should be high, as the process requires fewer appointments and provides more accurately fitting prostheses. In this way it will be very easy to give to the patient a definite treatment in short time and with high

In this way it will be very easy to give to the patient a definite treatment in short time and with high quality.

CONCLUSIONS

This article describes a fully digital workflow that facilitates the fabrication of IDs and allows the delivery of the DD with just 2 appointments. The procedure here described improves the stability and retention of the prosthesis and allows dentists to acquire data easily for fabricating dentures. Digital workflow in CD is an innovative and predictable procedure.

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SUMMARY

The goal of this Ph D thesis was to evaluate the impact of new digital technologies in the field of prosthodontics and to assess the advantages and disadvantages of them through in vivo and in vitro studies to implement their use in everyday practice.

Firstly, in vitro studies for fixed and removable prosthodontics were conducted to test the devices and materials in laboratory without variables and potential confounding factors present in whole organisms and to evaluate parameters before testing them in vivo.

Different intraoral scanners have been tested to assess the accuracy in terms of trueness and precision in different possible clinical scenarios: vertical or horizontal finish line designs, supra or subgingival margins, implant scanbodies.

Additionally in vitro studies assessed also the outcomes of a completely digital workflow: from digital intraoral impression of abutments with two different intraoral scanners to the final milled lithium disilicate complete crowns that have been evaluated in terms of accuracy of marginal and internal fit.

From these studies emerged a high accuracy of intraoral scanners when used for detecting vertical iuxta or supragingival margins and good fit of the milled restorations.

Since the positive outcomes of in vitro studies, in this thesis in vivo protocols have been performed thorough three different Randomized Controlled clinical trials. Clinical research lays the groundwork for progress in medicine and is an indispensable prerequisite for evidence-based medicine. Randomized controlled clinical trials (RCTs) are the gold standard for ascertaining the efficacy and safety of a treatment or device. As reported in the present thesis , it emerged that there aren't any statistically significative differences between traditional, hybrid or digital workflows for the realization of partial restorations or veneers. Additionally traditional pressed lithium disilicate partial restoration have been compared with UHPHS evaluation criteria to milled ones and to 3D printed PMMA restorations and no statistically significative difference was found.

This RCT studies have reported encouraging results regarding the new materials tested and digital workflow but longer periods of follow up and larger sample are needed to confirm the present data. Regarding removable prosthodontics, interesting flexural strength values of printable resins emerged when compared to milled and traditional ones. Additionally, two different case reports have been conducted to report the clinical performances of cad-cam milled complete dentures realized with a completely digital workflow that highlighted once again the advantages of using intraoral scanners and new prosthodontics material in a completely digital workflow.

CONCLUSIONS AND FUTURE DIRECTIONS

These new 3D materials and technologies have the potential to replace traditional fabrication methods both in fixed and removable prosthodontics, even if there is still a great variability of mechanical properties depending on the fabrication method and settings, type of intraoral device and clinical situation in which are applied.

The digital revolution in prosthodontics is already stared and new devices and materials are realized on the market faster than ever before. In this particular time, research remain fundamental and more important than ever to assess all the variables and dictate the clinical behavior that clinicians should embrace to ensure the maximal performances of these new technologies. Further studies are still needed but for sure the future of prosthodontics is digital.