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A novel coded healing abutment for a simplified digital workflow: A retrospective clinical study on 103 patients with a one year follow-up

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ABSTRACT

Objectives: To present the clinical results obtained using a novel coded healing abutment (CHA).
Methods: We evaluated 103 patients with fixed implant-supported zirconia restorations (90 single crowns, 26 partial dentures, and 6 full arches) manufactured via computer-aided-design/computer-assisted-manufacturing and starting from the point of intraoral scans of novel CHAs (i-Physio®, LYRA-ETK, Sallanches, France). Patients were followed for one year. We assessed the clinical precision of the final restorations at delivery (quality, fit, and occlusal and interproximal contacts), as well as hard and soft tissues stability and patient satisfaction at the one-year follow-up. All complications were recorded.
Results: The quality of the restorations was high, with satisfactory marginal fits (96.8% of the cases), occlusal contacts (95.1%), and interproximal contacts (94.3%). Excellent hard and soft tissues stability were found at the one-year follow-up assessment, with few complications (0.9% biological, 4.9% mechanical, and 1.6% technical) for an overall restoration success rate of 92.3% at the patient level and 91.9% at the restoration level. Patient satisfaction was high.
Conclusions: Within the limits of this study (retrospective design, short follow-up time) this novel CHA, with high prosthetic precision and esthetics, was clinically reliable and promoted hard and soft tissue stability. Further studies on a larger sample of patients and a longer follow-up period are needed to confirm these preliminary clinical outcomes.
Clinical relevance: High prosthetic precision can be achieved when scanning CHAs. CHAs simplify digital impressions, reduce the manipulation of soft tissues, and prepare them for scanning, thereby promoting tissue healing and stability over time. Additionally, CHAs can serve as temporary abutments for immediate, nonfunctional loading.

1. Introduction

Intraoral scanners (IOSs) have transformed the world of fixed prosthodontics and impression-taking procedures for the manufacture of temporary and permanent implant-supported restorations [1–4]. Compared to conventional or analog impressions that use classic trays and materials, the main advantages of optical impressions taken with an IOS include greater patient comfort, simplified clinical procedures (particularly in cases of complex impressions), workflow efficiency (it is unnecessary to pour plaster models, and it is possible to immediately send the scans to the laboratory, saving time and money), and better patient communication [5,6].

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The scientific literature has clarified that IOSs are sufficiently accurate to capture impressions of adequate quality for the design and manufacture of clinically precise, short-span, implant-supported restorations such as single crowns (SCs) [7–10] and fixed partial dentures (PDs) [11,12] via computer-aided-design/computer-assisted manufacturing (CAD/CAM) procedures. However, the use of IOSs for capturing implant impressions in the fully edentulous patient (particularly in the lower arch) for the design and manufacture of full-arches (FAs) remains under debate; some systematic reviews have argued that it is unfeasible [13–15], although several authors have clinically demonstrated its feasibility using appropriate knowledge, tools, and strategies [16–20].

The procedure for capturing the position of an implant (albeit with small differences between different IOSs) typically starts by capturing the opposing arch or hemiarch and, after the removal of the healing abutment (HA), the master model and bite register. The operator then screws the digital transfer, defined as scanbody (SB) inside the implant and captures its three-dimensional (3D) spatial position in the master model [2,3,5,7–12]. Once this position is captured, the SB is unscrewed, and the operator screws the HA back on. The impression is then sent to a dental technician who, using CAD software, models the prosthetic restoration (whether temporary or definitive) as a superstructure screwed onto the implants (cemented extra-orally on a titanium-bonding base) [16,21,22] or as a prosthesis cemented on an individual abutment [22,23]. The process is completed in the CAM phase (managed with milling and/or 3D printing) up to the point of restoration delivery.

Although these procedures are codified and successful, they have limitations. First, using a standard, non-individualized HA does not allow tissues to be prepared for impression capture and delivery of the prosthetic restoration [24]. Second, the procedure involves the need to unscrew the HA to capture the position of the implant via optical scanning of the SB. This device must first be screwed, then unscrewed, and subsequently, the practitioner must screw on the HA again. This procedure presents challenges as it requires exposure of the internal surface of the implant and forces the loss of the biological seal provided by the soft tissues surrounding the HA [25]. Furthermore, correctly screwing the SB requires time and concentrated attention.

There is, however, an alternative to this workflow, namely the use of coded healing abutments (CHAs) [26–29]. These components can simplify the capture of the optical impressions of implants [28,29]. Essentially, they are HAs that can be scanned with an IOS, as they represent an 'all-in-one' system that combines the functions of HAs and SBs into a single, digitally encoded component [27–29]. The concept of a CHA is not new. The first was the Zimmer Biomet Encode® system introduced in 2004, a three-in-one system that combined HA, impression coping, and the SB into a digitally coded, single component for implant impressions [30–33]. In the literature there are *in vitro* [32,34] and *in vivo* studies [31,35,36] that have assessed the clinical reliability of this system, which, given the limited use of IOSs at the time, was used primarily via analog impression taking, with the development of a plaster model digitized by a dental technician in the laboratory using a desktop scanner.

Recently, advances in digital technology have allowed working directly from intraoral scans (using model-free workflows) to produce temporary or definitive implant-supported restorations [37,38]. In this context, a novel CHA (i-Physio Profile Designer®, LYRA-ETK, Sallanches, France) has been introduced to the market, with the objective to simplify impression taking, and to allow the formation of an ideal emergence profile (EP) around the implant, through different morphologies and heights [39,40].

The i-Physio® CHA does not need to be removed during the impression phase. This reduces patient discomfort linked to the manipulation of soft tissues and the risk of apical migration of the junctional epithelium and consequent bone resorption [39]. The impression of the master model is acquired in a single session, with the CHA *in situ*, which is not unscrewed [39]. Moreover, i-Physio® is designed and available in different shapes and heights that are capable of replicating sections of natural teeth (incisors, canines, premolars, and molars) to satisfy specific esthetic and functional needs [39]. The possibility of choosing the most suitable geometric shape for clinical cases allows for the preparation of tissues for impression and, through CAD/CAM technology, to obtain prosthetic restorations (whether screwed or cemented) that are capable of replicating the EP determined by the CHA, ensuring patient comfort upon delivery of the restoration [39].

However, clinical documentation regarding the use of CHAs within fully digital workflows remains scarce. Moreover, doubts remain concerning the accuracy of using an IOS to scan these abutments, particularly when they are not emerging (as they are covered by soft tissues) or in instances of angled implants [40], and there is almost no literature on the clinical use of the new CHA i-Physio® [39].

Therefore, this retrospective clinical study aimed to report the results obtained with i-Physio® within a direct, fully digital workflow, and evaluate the clinical precision, reliability, and esthetics of fabricated, monolithic restorations starting from intraoral scans of new CHAs in various shapes and heights.

2. Materials and methods

2.1. Study design

This retrospective study was based on data collected from the individual records of patients treated under the same clinical protocol, by the same experienced operator (J.M.) in a private dental center between January 2022 and June 2023.

Inclusion criteria were patients who received fixed, monolithic, implant-supported restorations (SCs, PDs, and FAs) manufactured using a fully digital CAD/CAM workflow, starting from an intraoral scan of a novel, multifunctional CHA (i-Physio Profile Designer®, LYRA-ETK, Sallanches, France). Only patients treated with a single implant system (Naturactis®, LYRA-ETK, Sallanches, France) and restored with screw-retained monolithic restorations, and a minimum one-year follow-up after the delivery of the final prostheses were included in the study. In addition, patients had to be in good systemic and oral health and have complete records. All patients provided written, informed consent to undergo prosthetic implant treatment.

Exclusion criteria included patients treated with non-digital, analog protocols (through the capture of analog impressions with trays and materials) or patients treated with fully digital CAD/CAM protocols but with other implant systems and components. Additionally, patients who were not good candidates for implant therapy due to systemic and local issues (e.g., the presence of active periodontal infections and/or low levels of hygienic compliance), those who had no opposing dentition, and patients who failed to attend the one-year follow-up session were excluded from the study. The presence of parafunctions (bruxism and clenching) was not considered a reason for study exclusion.

This clinical retrospective research was conducted following the principles highlighted in the Declaration of Helsinki on Human Experimentation of 1975 (2012 Revision) and was approved by the local Ethics Committee.

2.2. Surgical procedures

Among the patient cohort, all complex cases (with > 1-2 implants placed) were treated using static computer-assisted implant surgery (s-CAIS) to enhance the surgical precision and the predictability of the prosthetic rehabilitation. The guided implant system used in this study (TWIN-Guide®, 2Ingis, Brussels, Belgium) was based on open-frame and sleeveless templates, which guided the handpiece [41]. In all cases solved with s-CAIS procedure (Twinguide®, 2ingis, Brussels, Belgium), the digital imaging and communication in dentistry (DICOM) files from

cone beam computed tomography (CBCT) (CS 9600®, Carestream Dental, Atlanta, GA, USA) and intraoral scans (i-700®, Medit, Seoul, South Korea) of the patients were sent to the 2Ingis center for Twin-guide® planning. At the center, files were imported into planning software (SMOP®, Swissmeda, Baar, Zurich, Switzerland) and the intraoral scans were aligned with bone models generated from the CBCT scans. Alignment was achieved through a process involving both point- and surface-based superimposition techniques. Within the framework of the planning software, a virtual wax-up was either imported or constructed to serve as a prosthetic foundation. This step allowed us to visualize and plan the implants virtually and with precision concerning placement, depth, and angulation. To ensure optimal outcomes, the planning took into consideration the available bone volume and the desired prosthetic EP. An open-frame, sleeveless surgical guide was then designed (and then manufactured in resin or metal) in the same TWIN-Guide® specialized center using 2Ingis CAD software [41]. This specialized software facilitated the design of the open-frame, sleeveless surgical guide and was aligned with the established treatment plan, thus ensuring the precise execution of the dental implant surgery [41].

2.3. Prosthetic procedures

Implants were placed by the same experienced practitioner (J.M.) (with more than 25 years of experience). The fixtures (Naturactis®, LYRA-ETK, Sallanches, France) were placed across all sectors of the jaws. Then, the choice of i-Physio® shape and height was determined based on the specific clinical situation. The selection of the right shape and height of the i-Physio® (Figs. 1,2) was facilitated by reusable try-in abutments, which were exact replicas of the i-Physio Profile Designers®. These were kept in a sterilizable box and used to select the best CHA for each case.

In specific cases, such as those involving posterior teeth, the i-Physio® CHA was left in place, allowing for a gradual and natural healing process of the peri-implant soft tissues. This approach is well-suited for situations where esthetic considerations are less critical, and the focus is primarily on achieving stable and functional outcomes. In contrast, when there was a pronounced esthetic demand or the implant demonstrated sufficient primary stability (as with anterior tooth replacement) the restorative phase could be expedited and an immediate non-functional restoration could be provided. In such instances, the i-Physio® CHA served as the foundation for an immediate provisional restoration.

For all patients, the prosthetic procedures for the delivery of the final zirconia-fixed restorations began with an intraoral scan of the patient's dentition, including an antagonist model, a master model with the i-Physio Profile Designer® *in situ*, and the bite register. A single scan was used to capture all digital impressions (i-700®, Medit, Seoul, South Korea) to ensure the consistency of the results. Recently published studies have reported the i-700 IOS to be accurate and suitable for long-span restorations [42] used to allow the manufacture of CAD/CAM monolithic zirconia restorations. From these scans, a series of standard tesselletion language (STL) files were generated, which were the digital representations of the scanned surfaces.

The STL files were then sent to a dental laboratory to begin the CAD/CAM workflow. The STL files were imported into dental CAD software (Galway®, Exocad, Darmstadt, Germany), which contained a pre-

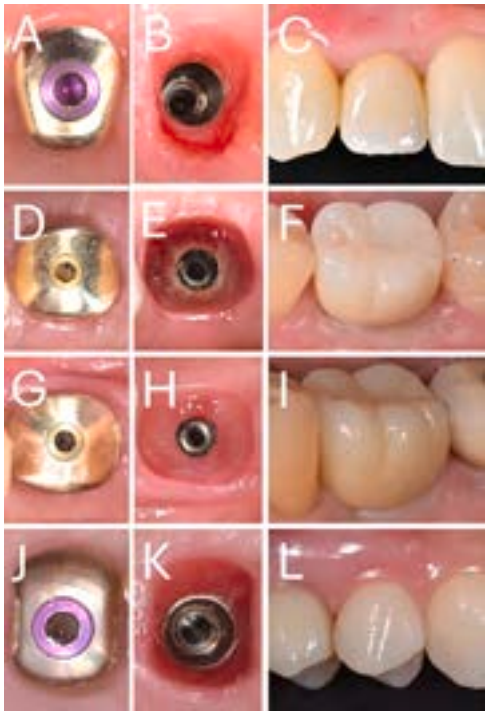

Fig. 2. Soft tissue conditioning and healing with the i-Physio® CHA.
(A,B,C) Shape A;
(D,E,F) shape B;
(G,H,I) shape C;
(J,K,L) shape D.

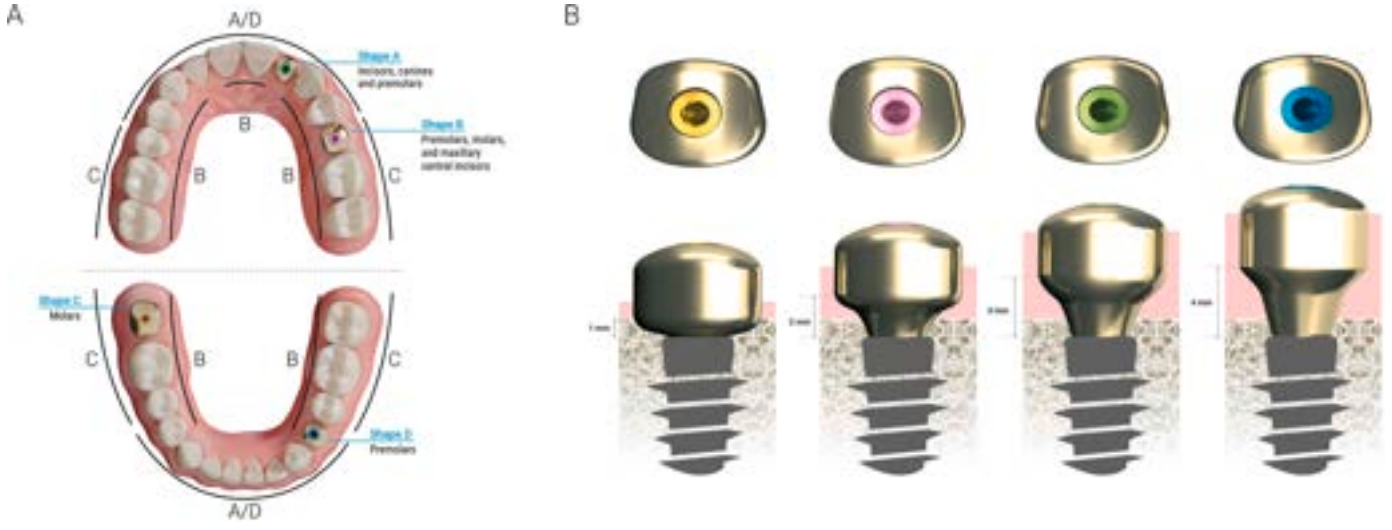

Fig. 1. The i-Physio® (Lyra ETK, Sallanches, France) coded healing abutment (CHA) range of anatomical shapes (A) and heights (B).

existing library of i-Physio® CHAs available for several implant brands, including LYRA-ETK, which was used in this study. Hence, this library contained the digital 'twins' corresponding to LYRA-ETK implants. The dental technician matched the correct components in the library with the specific CHA(s) scanned for each patient. The CAD iterative closest point (ICP) algorithm was then launched to perfect the match between the mesh of the i-Physio® CHA and the corresponding library file, i.e., the digital counterpart(s) available in the CAD software. Once the software identified the best match, it aligned the scanned CHA with its digital twin from the library. This alignment was crucial for accurately positioning the virtual implant in relation to the patient's scanned dental anatomy. Once the CHA was correctly matched and aligned, the digital workflow could proceed with a CAD modeling of the final screw-retained restorations, to be cemented extra-orally on a titanium-bonding base. Once the gingival margin was set at the correct level, the crown design could begin. The supragingival part was designed along with the screw hole, then the dental technician proceeded with the subgingival part by following the shape of the i-Physio® CHA.

Once the CAD phase was completed, the milling and finishing stages, which are critical to ensure restorations meet the highest standards of quality and esthetics, were initiated. Each zirconia restoration was milled using zirconia discs (DentalDirekt GmbH, Spenge, Germany) and a 5-axis milling machine (CORiTEC 350i PRO+®, Imes-Icore GmbH, Eiterfeld, Germany). The type of zirconia disc chosen depended on several factors related to each clinical case. The milled zirconia restorations then underwent inspections to identify any imperfections or defects that might have arisen during the milling process. The restoration was then cleaned to eliminate any residual dust or debris from the milling, before being placed in a sintering oven (Austromat 664®, Dekema, Freilassing, Germany) to prepare it for the cosmetic stage.

Localized polishing on the EP of the restoration, i.e., the segment in direct contact with soft tissue was performed, for minimizing irritation and promoting soft-tissue health. The screw-retained restoration was then cemented on the selected titanium bonding base in the laboratory and under magnification. Excess cement was carefully removed, and the restoration underwent a final comprehensive polishing. This was done to enhance the EP—to achieve a superior smooth and glossy finish—which is important for replicating the natural esthetics of a tooth and ensuring patient satisfaction. Esthetic verification was achieved for shape, color, and translucency, ensuring that each restoration met the predefined criteria.

2.4. Outcome variables

The three main outcomes of this study were: 1) the clinical precision (quality, fit, and occlusal and interproximal contact points) of the final prosthetic restorations, assessed immediately upon delivery [23,38]; 2) the hard and soft-tissues stability, assessed at the one-year follow-up exam; and 3) patient satisfaction with the treatment, assessed at the one-year follow-up exam.

The first two outcomes were evaluated by two independent evaluators (a periodontist and a prosthodontist, both with 15 years of experience in the field of implant-supported restorations) who had not inserted the dental implants, and who had not captured the intraoral scans of the fixtures. These evaluators were asked to provide, for each of the abovementioned variables, a score from 1 to 5 (with 5 expressing full, satisfactory quality; 4 for satisfactory quality; 3 for acceptable quality; and 2 and 1 expressing unsatisfactory quality) based on the clinical precision of the restoration (at delivery). In instances of differing opinions regarding a restoration, the evaluators were asked to discuss it and reach an agreement to formulate the final score. The same evaluators were also asked to report any possible intra or postoperative complications, either biologic or prosthetic (mechanical or technical), encountered during the follow-up period. The evaluators annotated these additional variables in each patient's record.

Patient satisfaction was evaluated using a 5-item questionnaire, assigning a score from 1 to 5 to the restorations (with 5 as the highest value, expressing full, satisfactory quality; 4 for satisfactory quality; 3 for acceptable quality; and 2 and 1 expressing unsatisfactory quality).

The clinical precision of the restorations was evaluated using the following parameters: 1) the quality of the fit or marginal adaptation of the restorations; 2) the quality of the occlusal contacts; and 3) the quality of the interproximal contacts. These qualitative assessments were carried out using an identical protocol by the two independent evaluators [38] who were asked to assign a score from 1 to 5 and, in the absence of agreement, were asked to formulate a single opinion after discussion. The quality of the fit and marginal adaptation of the restorations was clinically verified via inspection with magnifying glasses (4.5x®, Zeiss, Oberkochen, Germany) and circumferential probing with a periodontal probe. The quality of the occlusal contacts was checked using occlusal registration papers (Bausch Articulating Paper®, Bausch Inc., Nashua, NH, USA), while the quality of the interproximal contact points, where they existed, was assessed by inspection and through the passage of dental floss, which needed to put up a certain resistance. At the end of each evaluation (and having reached an agreement), restorations that received a sufficient score ($\geq$3 for each of the three precision parameters) were delivered to the patient and screwed onto the implants. However, if there was a single insufficiency ($\leq$2) in one of the three parameters, the restoration was sent back to the laboratory with specific indications for remaking. By insufficiency, the evaluators meant restorations that did not close properly due to obvious positional errors generated by the impression or in the CAD modeling, restorations with excessive occlusal contacts that could not be eliminated through polishing or those with missing occlusal contacts (infra-occluded), and restorations with excessive contact points that could not be corrected through polishing or those with absent interproximal contacts. Under all these scenarios, the dental technician could directly intervene in remaking the restoration or ask the operator to capture a new scan to proceed with new CAD modeling.

Regarding the quality of the tissues around the implant-supported restorations, at the one-year follow-up exam, the stability of the hard and soft tissues was evaluated:

1. Stability of the hard tissues over time,i.e., marginal bone levels (MBLs): the level of the marginal bone around the implant was checked over time using endoral peri-apical radiographs.
2. Stability of the soft tissues over time: monitoring the stability of soft tissues involved regular follow-up appointments (every three months) to check for any changes in tissue contour, color, or texture. Clinical photographs and digital scans were useful tools for documenting any change at this level.

Regarding the questionnaire on patient satisfaction, the first three questions were:

1. Are you satisfied with the functioning of your restoration?
2. Are you satisfied with the esthetic integration of your restoration?
3. Are you satisfied with the workflow that led to the manufacture of the restoration?

For each of these questions, the patient was asked to assign a rating from 1 to 5 (with 5 as the highest value, expressing full, satisfactory quality; 4 for satisfactory quality; 3 for acceptable quality; and 2 and 1 as the lowest values) to the functional and aesthetic integration of the restoration, and to the quality, convenience, and efficiency of the workflow that led to the manufacturing of the restoration.

The last two questions were related to the opportunity to undergo the same treatment again, if necessary, or to suggest the treatment to friends or relatives:

4. If necessary, would you undergo the same treatment?
5. If a friend or relative of yours needed an implant-supported restoration, would you suggest they undergo this treatment?

For these questions, patients were asked to assign a rating from 1 to 5 (5 absolutely yes, without a doubt; 4 certainly yes; 3 very probably yes; 2 probably not; 1 absolutely not).

The independent evaluators recorded any complications (biological [43], prosthetic, mechanical, or technical [44,45]) that occurred during the follow-up period in each patient's record.

Biological complications included: minor and reversible issues such as swelling and/or pain after implant surgery, peri-implant mucositis with gingival swelling, discomfort, or bleeding with no radiographic evidence of bone resorption; and major and irreversible complications such as peri-implantitis with pain, suppuration, bleeding and radiographic evidence of marginal bone resorption, and/or implant failure [43].

The prosthetic complications were in agreement with Bragger & Salvi [44] and of a mechanical nature, i.e., affecting pre-formed components sold by the company manufacturing the implants (abutment screw loosening or decementation of the titanium base) or technical, i.e., affecting components made by the dental technician (fracture of the restoration or chipping).

Based on these considerations, a restoration was defined as successful when it did not incur any negative ($\leq$2) points at the one-year follow-up and did not present any major complications (biological or mechanical/technical) during the entire follow-up period. Following these rules, the existence of just one negative point ($\leq$2) from a patient at follow-up or one of the major biological and/or prosthetic complications, meant the restoration was defined as unsuccessful, even if it was still functional and in the presence of an osseo-integrated fixture.

2.5. Statistical analysis

All data were obtained from the individualized records of the enrolled patients. The collected variables included patient demographics (age, gender, smoking habit, and the presence of parafunctions, i.e., bruxism or clenching) and the characteristics of the restorations (location and position of the restorations, presence of immediate provisionalization, and type of restoration, i.e., SCs, PDs or FAs, and the type of CHA used). Mean ranges were calculated for quantitative variables. Absolute and relative (%) distributions were calculated for qualitative variables. Absolute and relative distributions were calculated for variables investigated at the delivery of the final restorations (marginal adaptation and closure and quality of the occlusal and interproximal contacts) and the one-year follow-up period (thickness, keratinization, stability of the soft tissues, and patient satisfaction), and the scores given by the independent observers (prosthodontist and periodontist). The incidence of failures and complications was also calculated. The success of the restorations was assessed at the patient and restoration levels.

3. Results

3.1. Patient Population and implant-supported restorations

One hundred and three patients (56 males and 47 females, aged between 20 and 80 years) met the inclusion criteria and were enrolled in the study. Among them, 39 were smokers, and 44 presented with parafunctions (bruxism or clenching). Patient-related data is summarized in Table 1. The patients represented a diverse range of cases, encompassing single tooth replacements to full mouth rehabilitations. All patients received the same dental implants (Naturactis®, Lyra ETK, Sallanches, France) with implant surgery, immediate provisionalization (when adopted), and the final digital impression was performed by the same experienced practitioner (J.M.). In total, 203 implants were placed and restored prosthetically with fixed monolithic zirconia restorations (90 SCs, 26 PDs, and 6 FAs). In total, 122 monolithic prosthetic restorations were delivered (90 SCs, 11 two-unit, 11 three-unit, and 4 four-unit PDs, 3 six-unit and 3 eight-unit FAs) (Figs. 3–14). Implants were positioned in healed sites and post-extraction sockets and, in cases where insufficient bone and/or soft tissue volume were present, augmentation procedures were performed to ensure optimal implant placement. All patients were followed for one year after the delivery of the final restorations. Implant- and restoration-related data are summarized in Table 2. A summary of the types (shape and height) of the i-Physio CHAs used is provided in Table 3.

Table 1
Patient demographics.

Patient characteristics	n° of patients	Proportion (%)
Gender		
Males	56	54.4%
Females	47	45.6%
Age at surgery		
20- 35 years	11	10.6%
36- 50 years	20	19.4%
51- 65 years	35	34.0%
66- 80 years	37	36.0%
Smoking habit		
No	64	62.1%
Yes	39	37.9%
Parafunctions		
No	59	57.3%
Yes	44	42.7%
Total	**103**	**100%**

3.2. Prosthetic precision

The quality of the fit and the marginal adaptation of the restorations were high, with restorations scoring 4–5 (the highest possible scores) in nearly all cases (89.4%). Only 7.4% of the cases required some minor adaptation to reach a sufficient quality fit and adaptation (score = 3). However, in 3.2% of the cases, the fit was insufficient and the restorations had to be returned to the dental technician; in nearly all of these cases, this was caused by poor visualization of one or more CHAs during scanning due to the selected i-Physio® being covered by the soft tissues and not sufficiently exposed to be captured by the intraoral scan. Therefore, in these cases, the dental technician asked the operator to re-scan the patient using longer CHAs, and the procedure led to clinical success with excellent marginal adaptation.

For occlusal contacts assessed using articulating paper, it was found that a perfect occlusal fit (score = 5) was achieved directly at placement in 32.8% of the cases. This highlights the nuanced challenges of achieving ideal occlusion in a direct digital workflow, despite its many advantages. However, most cases (62.3%) scored 3–4 because they required minor adjustments to attain optimal occlusal relationships. Only a small fraction of cases (4.9%) required more chairside adjustments, scoring 1 or 2.

Assessments of interproximal contact points, a critical factor in periodontal health and the functional integrity of a restoration, were conducted using dental floss. The results were excellent, with 71.3% of cases demonstrating ideal contact points (scores of 4–5), suggesting a high degree of accuracy in the digital design and fabrication process. However, challenges persisted in a minority of cases, with 23% exhibiting tight contact points that necessitated intra-appointment adjustments, including the reduction and repolishing of the zirconia restorations to ensure optimal fit and function (score = 3). Open contacts, occurring in 5.7% of the cases, represented a more significant clinical concern that required either the addition of ceramic to recover the contact point or milling a new restoration (scores = 1–2).

The quality of the fit, marginal adaptation, and the occlusal and interproximal contact points of the restorations are summarized in Table 4.

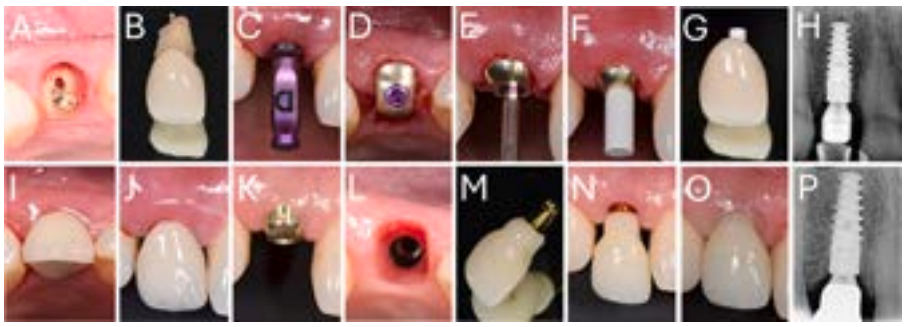

Fig. 3. Clinical case showing the use of the i-Physio® CHA in the anterior maxilla.
(A) An unrestorable broken lateral incisor (#12) needs to be extracted;
(B) extraction of the tooth;
(C) immediate implant placement of a Naturactis® (Lyra ETK, Sallanches, France) implant, and use of try-in abutment;
(D) the i-Physio® CHA is placed immediately after implant insertion;
(E) the colored screw of the i-Physio® is removed;
(F) the temporary abutment of the i-Physio® in position;
(G) the temporary restoration is adapted and relined onto the prepared temporary abutment;
(H) radiographic control;
(I) the temporary *in situ*, occlusal view;
(J) the temporary *in situ*, buccal view;
(K) after the healing period, the i-Physio® can be scanned in the final digital impression;
(L) the soft tissues after the removal of the i-Physio®, before the delivery of the final monolithic zirconia restoration;
(M) the final monolithic screw-retained restoration;
(N) delivery of the final restoration;
(O) clinical control;
(P) radiographic 1-year control.

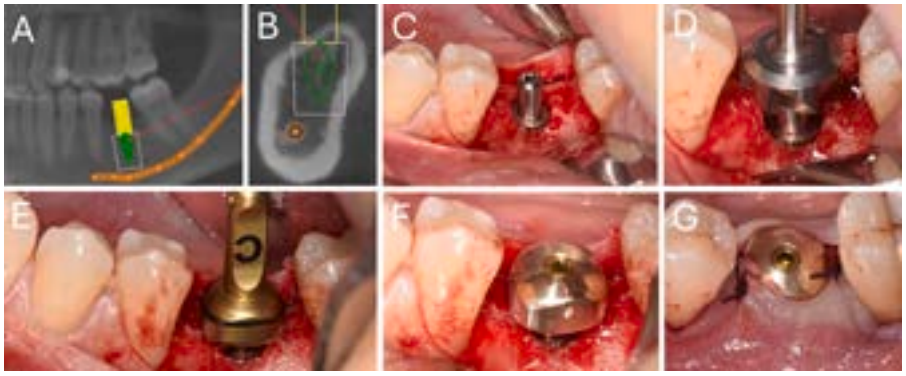

Fig. 4. Clinical case showing the use of the i-Physio® CHA in the posterior mandible.
(A,B) Implant planification;
(C,D) implant site preparation (#36);
(E) try-in abutment in place;
(F) placement of the i-Physio® CHA, shape C (molar), 1-mm transmucosal height (yellow screw);
(G) sutures.

3.3. Hard and soft-tissue stability

The stability of hard tissues was high, according to the MBL registered 1 year after implant placement (0.85 ± 0.75 mm). The soft tissues healthy was confirmed by the clinical pictures obtained 1 year after the delivery of the final restorations.

3.4. Patient satisfaction

All patients exhibited overall satisfaction with the prosthetic treatment they received. Patients assigned high scores (68% assigned a score of 5 and 32% a score of 4) to the monolithic zirconia restorations supported by implants. Furthermore, there were no patients who reported dissatisfaction with the function of the prosthetic restorations they received. Regarding the esthetics of the restorations, 98.1% indicated that they were very satisfied (scores of 4–5) or otherwise satisfied (score of 3) with the treatment, while 1.9% considered the esthetic integration of the monolithic zirconia restorations not entirely satisfactory. All patients (100%) were satisfied (scores of 4–5) with the workflow they underwent, which guaranteed them prosthetic restorations with fixed monolithic zirconia restorations supported by implants in a relatively short time, and without having to attend many appointments. For the patients, the use of optical scanning represented the main advantage of the procedure, which is in accordance with what has been reported in the scientific literature [46,47]. Patient satisfaction was further strengthened by the use of CHAs, which could be used as temporary abutments for immediate restorations in aesthetic cases and allowed the impression to be captured without having to unscrew and screw prosthetic components. In addition, all patients (100%) confirmed their willingness to undergo a similar treatment again, without prejudice to

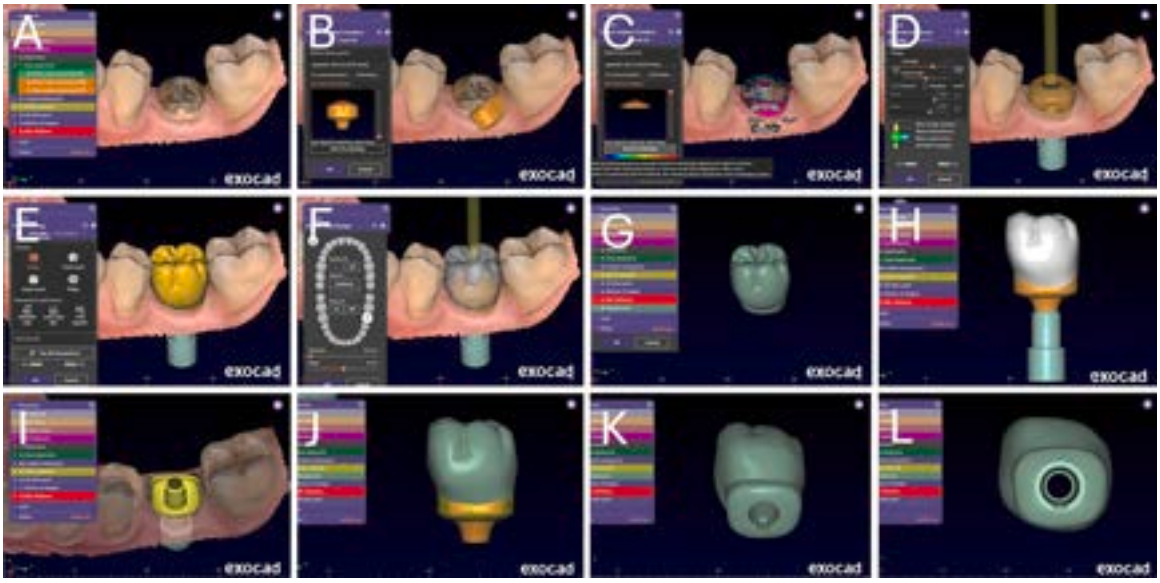

Fig. 5. The workflow in the computer-assisted-design (CAD) software (Galway®, Exocad, Darmstadt, Germany).
(A) The intraoral scan of the CHA i-Physio® is imported in the CAD software;
(B) replacement of the mesh of the CHA with the corresponding library file;
(C) colorimetric map for checking the quality of the superimposition;
(D) the library is superimposed and imported;
(E) 3D modelling of the crown;
(F) the screw channel is generated;
(G) the screw retained crown is ready;
(H) the crown and the emergence profile;
(I) the emergence profile given by the i-Physio®;
(J) incorporation of the design of the transmucosal design of the i-Physio® in the final crown;
(K) the final CAD model of the crown, bottom view;
(L) the design is transferred from the CHA to the final crown.

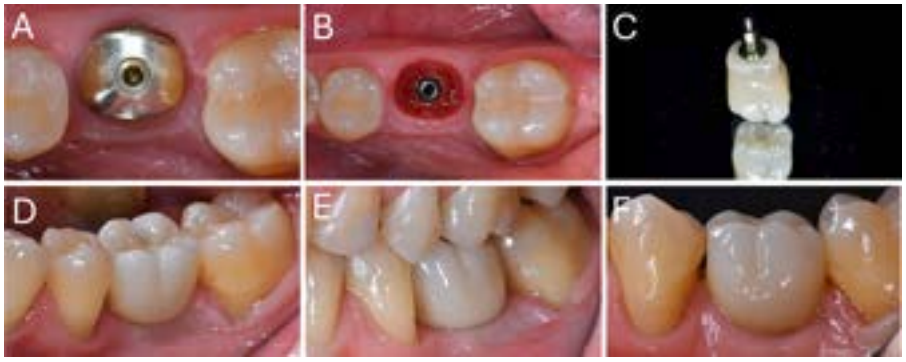

Fig. 6. Placement of the final monolithic zirconia crown.
(A) The i-Physio® CHA just before the removal and the delivery of the final monolithic zirconia crown;
(B) removal of the i-Physio® CHA;
(C) the final screw-retained monolithic zirconia crown;
(D) delivery of the final zirconia crown;
(E) picture of the crown;
(F) 1-year follow-up control.

the financial investment, and confirmed that they would suggest the procedure to friends and family. Data from the patient satisfaction questionnaire are shown in Table 5.

3.5. Complications

Among the biological complications, swelling and/or pain immediately after implant surgery was found in six patients (5.8%). These were classified as minor as they were successfully treated with analgesics and antibiotics. Peri-implant mucositis occurred in four patients (3.8%) one year after implant placement but was easily treated with a professional oral hygiene protocol, and thus classified as a minor complication. In total, only two implants (both in a heavy smoker) (0.9%) led to peri-implantitis with pain, suppuration, bleeding, and radiographic evidence of marginal bone resorption six months after the delivery of the final restoration (a two-unit PD). This peri-implant pathology was treated successfully through a series of professional oral hygiene sessions but was classified as a major complication. At the end of the study,

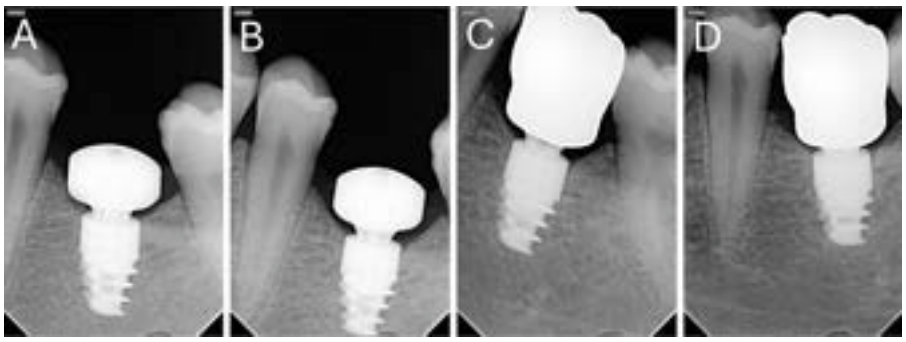

Fig. 7. Radiographic history of the case.
A. Implant placement (Naturactis®) with the i-Physio® CHA in position;
B. 1 month follow-up;
C.Delivery of the final screw-retained monolithic zirconia crown;
D. the final screw-retained monolithic zirconia crown 1 year after insertion.

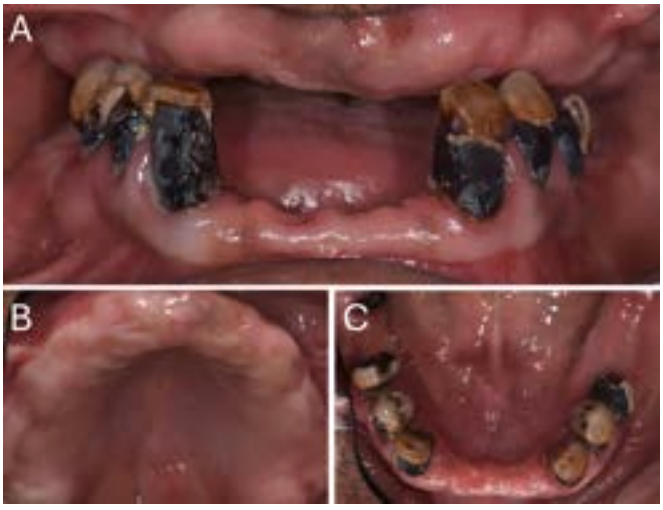

Fig. 8. A full arch case treated wih i-Physio® CHAs. Intake.
A. Frontal view;
B. Edentulous upper jaw;
C. Lower jaw with severely compromised teeth.

the biological complications amounted to 10.6% at the patient level, but only one patient (0.9%) suffered from a major biologic complication (peri-implantitis).

The prosthetic complications were less frequent, with abutment screw loosening documented in four SCs (four patients), and decementation of the titanium bases in two cases (one SC and one two-unit PD). The incidence of mechanical complications was 4.9% at the restoration level. Finally, regarding technical complications, two restorations (a three-unit PD and an FA) underwent fracture—an incidence of 1.6% at the restoration level.

Overall, given the two negative (<3) marks assigned by patients to two SCs for the esthetic integration at the one-year follow-up, the case with peri-implantitis, and the eight prosthetic complications (mechanical and/or technical) registered during the one-year follow-up, the success of the restorations was 92.3% at the patient level and 91.9% at the restoration level.

4. Discussion

This study certified the reliability and clinical precision of short-span (SCs and PDs) and long-span (FAs), milled, monolithic zirconia restorations obtained by direct digital workflows and based on optical impressions of CHAs and CAD modeling.

Of the 122 restorations (90 SCs, 26 PDs, and 8 FAs) delivered to 103

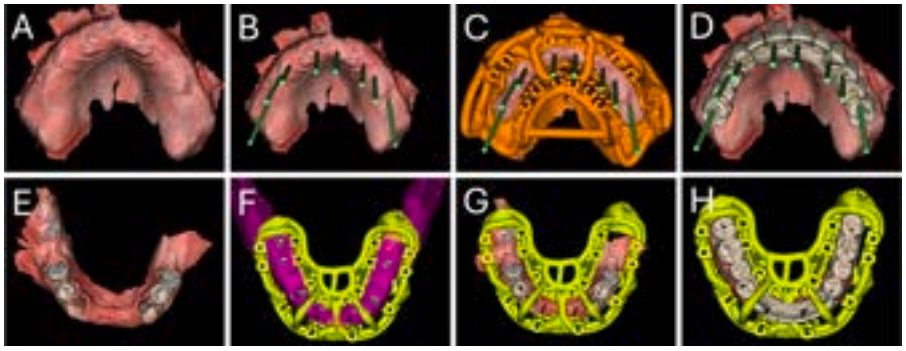

Fig. 9. Implant surgery planning.
A. Intraoral scan of the upper jaw;
B. Implant planning;
C. Implant planning and design of the open frame sleeveless surgical guide;
D. Implant planning and design of the immediate provisional restoration;
E. Intraoral scan of the lower jaw;
F. Implant planning with visualization of the bone and design of the surgical guide;
G. Implant planning with visualization of the scan and design of the surgical guide;
H. Implant planning and design of the immediate provisional restoration.

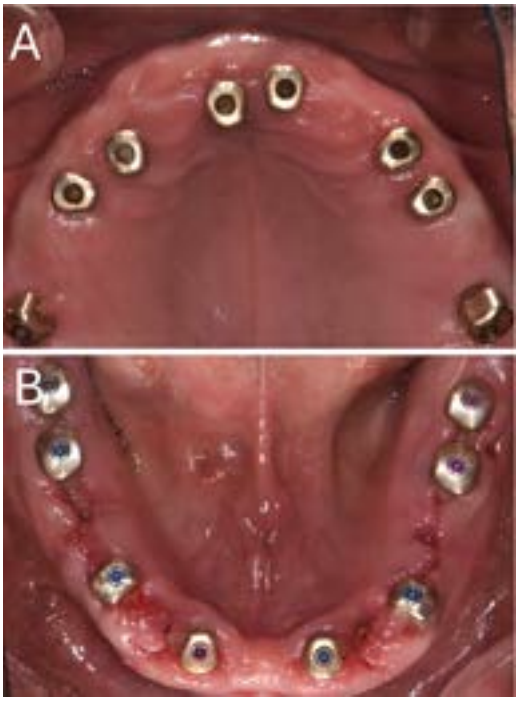

Fig. 10. Soft tissue healing after the surgeries.
A. Upper jaw with the i-Physio® CHAs in position;
B. Lower jaw with the i-Physio® CHAs in position.

patients, only four had insufficient scores (<3) for fit and quality of marginal closure. Two of these restorations were FAs, and the error was attributed to a stitching mistake caused by capturing the impression in a completely edentulous patient with an IOS [4,6,11,13,14,42]. However, two bad marks (one PD and one SC) were due to an inappropriate choice of the CHA from the point of view of height/depth. The intraoral scan showed only a small portion of the CHA in these cases, as the soft tissues covered the coded abutment. In these instances, the CAD ICP superposition algorithm likely had difficulty, and the position error was also reflected at the occlusal and interproximal contact levels [26,27,29,30,32,33]. Occlusal problems were registered in two additional cases (two SCs), and in three cases—two SCs and one PD—the expert evaluators recorded the absence of interproximal contact points, despite an excellent fit and marginal closure. These errors were attributed to mistakes in capturing the maxillo-mandibular relations [3,4] and in the CAD modeling. In all these cases, the restorations had to be redone, and the patients were recalled for further scanning.

The practitioner paid careful attention to scanning and choosing CHAs of appropriate height to evaluate their visibility [26,27,29,30,32,33]. Furthermore, at the one-year follow-up, the rate of major biological (0.9%) and prosthetic complications (mechanical 4.9% and technical 1.6%) recorded for implant-supported, monolithic zirconia restorations was low [43–45], contributing to the high degree of patient satisfaction. Overall, the restorations that did not present any problems, i.e., those demonstrating good clinical precision with no negative ratings (<3) by the expert evaluators at delivery, no biological or prosthetic complications over the entire follow-up period, and no negative evaluations by patients after one year, corresponded to 91.9% at the restoration level.

These clinical results are in accordance with the literature on *in vivo* CHA studies [31,35,36] and the highlights from a recent systematic review of the literature [40]. In 2017, Abduo et al. [31] compared the Encode® impression protocol from Biomet 3i with the conventional impression protocol for treatment duration, clinical accuracy, and clinical outcome. Forty-five implants were randomly allocated to the Encode® group (23 implants) or the conventional group (22 implants) [31]. At the time of surgery, all implants received two-piece Encode® HAs, and the implants were restored three months after placement [31]. In the conventional protocol, open-tray, implant-level impressions were taken, and the implants were restored with prefabricated abutments and metal-ceramic crowns [31]. For the implants in the Encode® group, conventional, closed-tray impressions of the CHAs were taken [31]. The generated casts were sent to a Biomet 3i scanning/milling center for custom abutment manufacturing on which the metal-ceramic crowns were fabricated. Treatment duration (laboratory and clinical), clinical accuracy of occlusal and proximal contacts, and outcomes (esthetics, patient satisfaction, and crown contour) were evaluated using a series of questionnaires [31]. At the end of the study, the CHA protocol required significantly less laboratory time (18 min) than the conventional protocol for adjusting the abutments [31]. The impression pour time, time for the laboratory to return the crown, time for crown insertion at the final appointment, and total clinical time for crown insertion did not significantly differ between the two protocols [31]. Clinical accuracy, esthetics, and patient satisfaction were similar for the two protocols. Thus, the CHA protocol was able to reduce the laboratory time before crown fabrication [31].

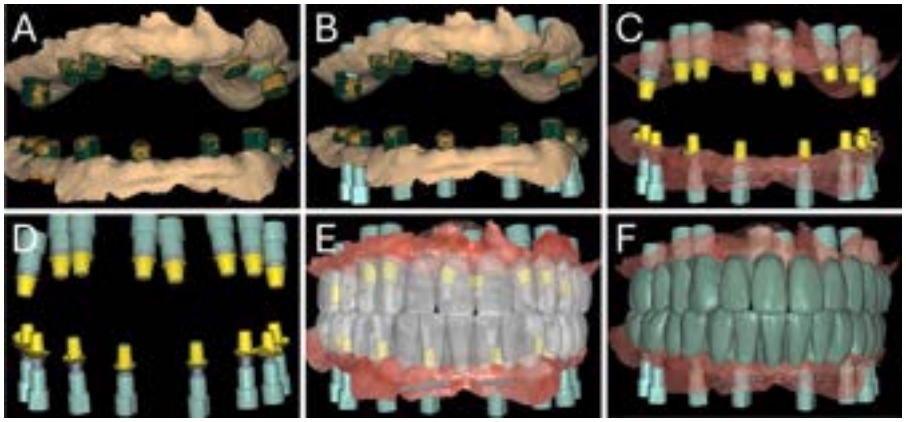

Fig. 11. Final scan of the i-Physio® CHAs and design of the final monolithic zirconia restorations.
A. Scans of the upper and lower jaw imported in the CAD software (Galway®, Exocad, Darmstadt, Germany).
A. Position of the implant analogs;
B. Position of the titanium bases;
C. The prosthetic components and their relationship in the space;
D. CAD modelling;
E. The final CAD files of the prosthetic structures.

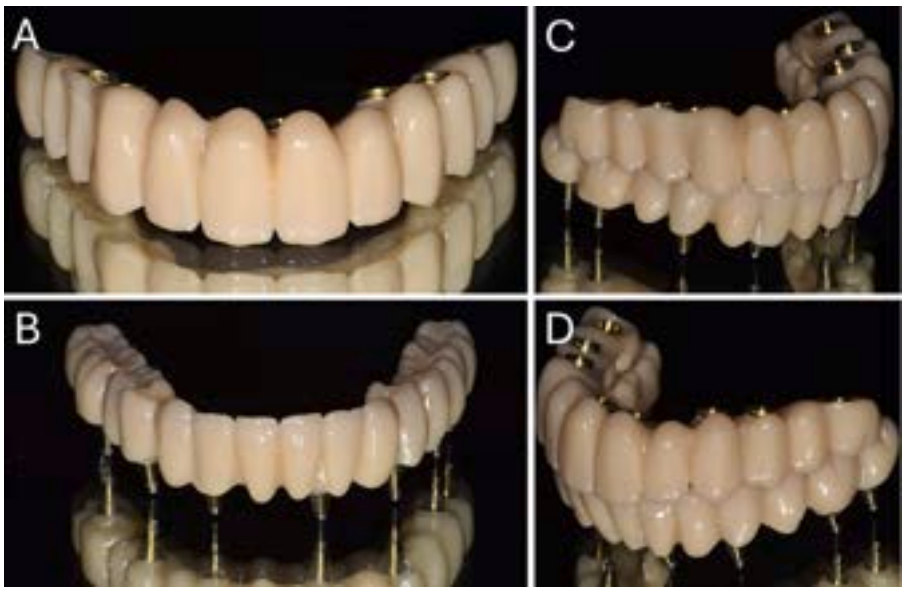

Fig. 12. The final monolithic zirconia restorations ready to be delivered to the patient.
A. Maxillary FA, frontal view;
B. Mandibular FA, frontal view;
C. The restorations in occlusion, prospective view (right side);
D. The restorations in occlusion, prospective view (left side).

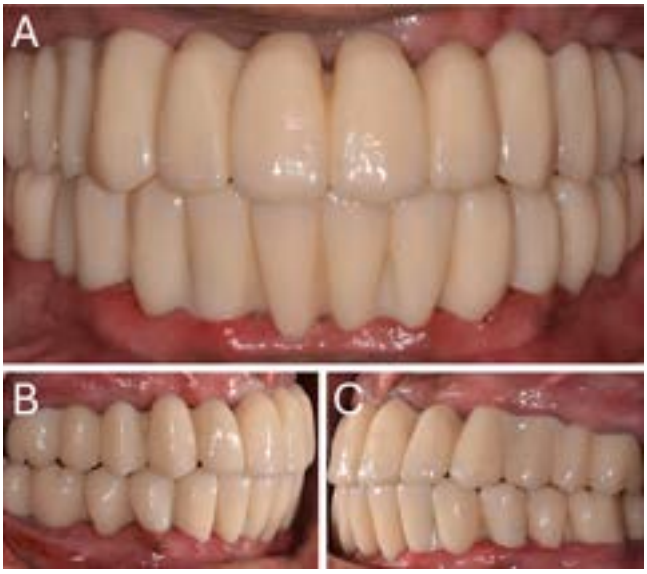

Fig. 13. Delivery of the final FA monolithic zirconia restorations.
A. Frontal view;
B. Lateral view (right side);
C. Lateral view (left side).

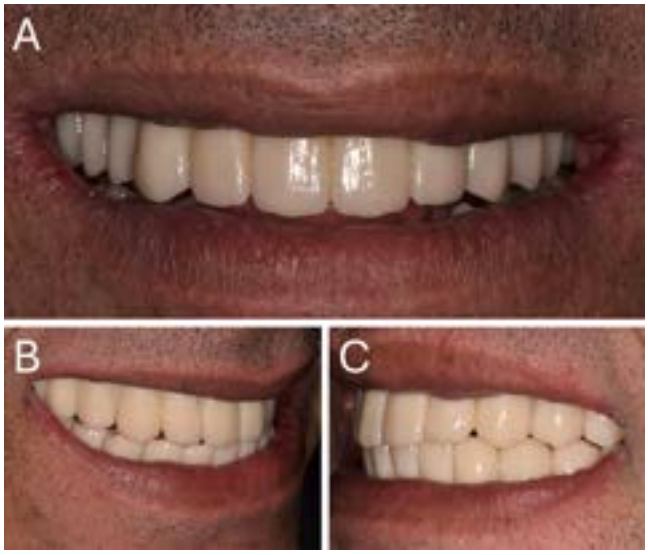

Fig. 14. 1-year follow-up control.
A. Frontal view;
B. Lateral view (right side);
C. Lateral view (left side).

In 2020, Pol et al. [35] tested the applicability of CHAs, IOSs, and monolithic zirconia for the fabrication of three-unit fixed PDs on two dental implants. Patients with three missing teeth in the posterior region of either the maxilla or mandible received two dental implants [35]. After healing, CHAs were placed. Full-arch intraoral scans were made to produce individual titanium abutments and three-unit fixed PDs. Peri-implant tissues were assessed two weeks after placement of the PD and again after one year [35]. Patient-reported outcome measures were registered before treatment and after one year. The quality of the PDs was assessed after one year [35]. Overall, 54 patients were treated with 60 restorations, and 51 patients with 56 restorations were available at the one-year follow-up. Implant survival was 99.1%, and prosthesis survival was 100%. The peri-implant tissues remained healthy, and patient satisfaction was high [35]. The authors concluded that CHAs and IOSs producing full-zirconia, three-unit PDs on two dental implants were feasible, with promising objective and subjective results [35]. However, technical challenges affected the treatment results, which resulted in a number of restorations having clinical or radiographic marginal gaps [35].

In a randomized controlled trial published in 2021, Abduo et al. [35] compared a two-year clinical performance of the Encode® and conventional protocols for restoring single implants. Forty-seven implants were randomly allocated for restoration by the Encode® (24 fixtures)

Table 2
Implant and restorations.

Implant features	n° of implants	Proportion (%)
Implant location		
Maxilla	109	53.7%
Mandible	94	46.3%
Implant position		
Incisors	28	13.8%
Cuspids	7	3.4%
Premolars	70	34.5%
Molars	98	48.3%
Type of surgery		
Immediate implant placement in post-extraction sockets	64	31.5%
Delayed implant placement in healed ridges	139	68.5%
Bone contouring		
Yes	47	23.2%
No	156	76.8%
Immediate non-functional provisionalization		
Yes	105	51.7%
No	98	48.3%
Type of restorations		
SCs	90	44.3%
PPs	71	35.0%
FAs	42	20.7%
Total	**203**	**100%**

Table 3
Types of CHA used in this study.

i-Physio Profile Designer®	n° of CHAs	Proportion (%)
Shape A	**54**	**26.6%**
Depth		
A1= 1 mm	24	11.8%
A2= 2 mm	27	13.3%
A3= 3 mm	0	0%
A4= 4 mm	3	1.5%
Shape B	**52**	**25.6%**
Depth		
B1= 1 mm	25	12.3%
B2= 2 mm	20	9.9%
B3= 3 mm	0	0%
B4= 4 mm	7	3.4%
Shape C	**53**	**26.1%**
Depth		
C1= 1 mm	23	11.3%
C2= 2 mm	27	13.3%
C3= 3mm	0	0%
C4= 4mm	3	1.5%
Shape D	**44**	**21.7%**
Depth		
D1= 1 mm	15	7.4%
D2= 2 mm	25	12.3%
D3= 3 mm	0	0%
D4= 4 mm	4	2.0%
Total	**203**	**100%**

Table 4
Quality of the marginal fit, occlusal and interproximal contact points, assessed at delivery by two experienced operators (n= number of restorations).

Score	Marginal fit	Occlusal contacts	Interproximal contacts
5	54 (44.3%)	40 (32.8%)	62 (50.8%)
4	55 (45.1%)	34 (27.9%)	25 (20.5%)
3	9 (7.4%)	42 (34.4%)	28 (23.0%)
2	2 (1.6%)	4 (3.3%)	4 (3.3%)
1	2 (1.6%)	2 (1.6%)	3 (2.4%)
Total	122 (100%)	122 (100%)	122 (100%)

and conventional (23 fixtures) protocols. The implants were reviewed after two years to evaluate patient satisfaction, esthetics, prosthesis cleanability, mucosal health, bleeding on probing, metallic discoloration, probing pocket depth, MBL, and the quality of the proximal and occlusal contacts [35]. At the end of the study, the two protocols were comparable for all variables [35]. Two Encode® (10.0%) and four conventional (21.1%) crowns had screw loosening, leading to the failure of two conventional crowns. Three Encode® (15.0%) and two conventional (11.8%) crowns displayed ceramic chipping [35]. The Encode® and conventional crowns had survival rates of 100.0% and 89.5%, respectively [35]. From the biologic, prosthetic, and esthetic perspectives, the Encode® and conventional protocols provided comparable clinical outcomes over a two-year duration [35].

Table 5
Patient satisfaction with the prosthetic treatment (n= number of patients, %= percentage).

1. Are you satisfied with the function of your restoration(s)?					
Scores	**5**	**4**	**3**	**2**	**1**
	70 (68.0%)	33 (32.0%)	0 (0%)	0 (0%)	0 (0%)
Total	103 (100%)				
2. Are you satisfied with the aesthetic integration of your restoration(s)?					
Scores	**5**	**4**	**3**	**2**	**1**
	70 (68.0%)	27 (26.2%)	4 (3.9%)	2 (1.9%)	0 (0%)
Total	103 (100%)				
3. Are you satisfied with the workflow that led to the manufacture of the restoration (s)?					
Scores	**5**	**4**	**3**	**2**	**1**
	95 (92.2%)	8 (7.8%)	0 (0%)	0 (0%)	0 (0%)
Total	103 (100%)				
4. If necessary, would you undergo the same treatment?					
Scores	**5**	**4**	**3**	**2**	**1**
	90 (87.3%)	13 (12.7%)	0 (0%)	0 (0%)	0 (0%)
Total	103 (100%)				
5. If a friend/relative of yours needed an implant-supported restoration, would you suggest he/she undergo this treatment?					
Scores	**5**	**4**	**3**	**2**	**1**
	90 (87.3%)	13 (12.7%)	0 (0%)	0 (0%)	0 (0%)
Total	103 (100%)				

The use of CHAs has meant reducing protocol steps and simplifying impression-taking [26–29,31–33,40]. This is especially true in the digital age as the practitioner does not have to remove the HA to screw the SB, capture the position of the implant, and then unscrew the SB to screw the HA back on [39,40]. This reduces practitioner work and the need for soft-tissue manipulation [26–29,31–33,40]. Research suggests that fabricating a prosthesis is susceptible to errors—whether from human interaction or material inconsistencies—that affect the prosthesis' final fit [3,4,6]. The simplification provided by CHAs enhances procedural efficiency and precision and reduces the complexity of the treatment workflow. This benefits the practitioner, contributing to improvements in daily dental practice [26–29,31–33,39,40]. Moreover, this strategy is friendlier to the soft tissues (and the underlying bone) as it favors undisturbed soft-tissue healing, avoiding any disruption of the soft-tissue interfaces, similar to the concept of 'one abutment, one time' [24,31,35,36,39,40]. Repeated detachment and reattachment of a HA may interfere with the mucosal seal adjacent to the abutment, potentially leading to apical displacement of the surrounding soft tissue [24,39,40,46,47]. Hence, CHAs not only ensure the preservation of mucosal attachment and critical biological width but may also reduce the risks associated with bacterial penetration and peri-implantitis [24,31,35,36,39,40,46,47]. Using CHAs ensures a clean implant-site environment throughout the treatment process, contributing to optimal healing and long-term success [24,31,35,36,39,40]. In addition, by minimizing soft tissue manipulation, the CHA also promotes patient comfort, as evidenced by the high satisfaction rate expressed by the patients towards the prosthetic workflow. Like its predecessors, the i-Physio® CHA used in this study exhibits all these advantages [39], which are further amplified by the new, fully digital protocols in implant prosthetics.

In digital impression workflows, the i-Physio® minimizes the number of required components [39]. The need for SBs, impression copings, and analogs is eliminated, reducing cost and simplifying the treatment process [39]. Hence, i-Physio® operates on a simplified protocol,

optimizing procedural and clinical efficiency [39]. i-Physio® also represents an evolution of the CHA concept, as it comes in various shapes and heights that are capable of being read by an IOS and are associated with a corresponding library in the CAD [39]. Furthermore, it adequately supports the tissues and guides the formation of the papillae. This guidance plays a pivotal role in achieving a natural and esthetic EP around dental implants [39]. One of the key elements for achieving aesthetics in an implant-supported restoration is represented by the EP, which must be natural [48–50]. The EP depends on several surgical and prosthetic factors that influence peri-implant tissue health and the stability and integration of prosthetic outcomes [48–50]. However, this depends on the position of the implant in 3D, and for this, guided surgery can help. An accurate study of each case, with appropriate diagnostic waxing capable of representing the best possible compromise between residual bone volume and an ideal prosthetic emergency can guarantee better results, as can a careful evaluation of the insertion depth and inclination of the implant [41]. However, the soft tissues must also be supported and stabilized appropriately, which requires suitable prosthetic designs. Therefore, the materials and restorative approaches play a fundamental role in the esthetic integration of an implant-prosthetic restoration [48–52]. With non-submerged implants—from the moment of insertion of the HA—the submucosal material that is in contact with peri-implant soft tissues is essential to their seal and adherence, whereas the supra-mucosal material determines the esthetic anatomical reconstruction [48–52].

Usually, ideal EP design can be obtained using various techniques [48,49] such as step-by-step conditioning with a provisional crown and constructing the supra-implant soft tissue, where multiple sessions are required for the successive modifications of the provisional implant [53]. However, such a time-consuming workflow results in numerous clinical appointments for the patient and dentist and the risk of biological trauma of the delicate soft tissue due to repeated changes of the provisional implant. The i-Physio® offers notable advantages in this sense. First, the i-Physio® Profile Designer reduces chairside time, making dental implant procedures more time efficient [39]. Regarding biological factors, it is a zirconia-coated titanium component. Titanium and zirconia are currently the only two materials that exhibit these characteristics, and should be used in the submucosal area, be highly polished, and free of any glaze, ceramic, or stains [54–56]. To promote adherent cell integration, it is essential to use materials with maximum biocompatibility in the subcritical region of the EP, when the prosthetic components interface with connective tissue and the hemidesmosomes of the apical third of the junctional epithelium [54–56]. The chemical composition and surface condition of the HAs play an essential role in the appearance of recession or bone loss [47–56]. The wettability of the surface must be decreased for cells to adhere and develop. The continuity of the EP between the implant and the coronal surface of the concave or convex type allows for the preservation of the gingiva [48–52,54,55]. Hence, the i-Physio® design supports the development of harmonious soft tissue contours, enhancing overall treatment outcomes.

Finally, a noteworthy aspect of the i-Physio® is its multifunctionality. It serves as a single component for enhanced soft tissue healing, high-precision impression-taking, and temporary restoration placement, thus offering protocol rationalization [39]. In fact, it offers special temporization solutions to accommodate a range of clinical scenarios, from single to multiple implants, ensuring flexibility and adaptability in treatment planning [39]. In anterior sectors, the i-Physio® facilitates the placement of esthetic restorations. This capability enables clinicians to achieve superior esthetic outcomes while maintaining patient comfort and satisfaction. In the present study, from the esthetic point of view, the digital workflow exhibited remarkable success, with 98.1% of cases deemed to have acceptable final esthetics. This high satisfaction rate with the esthetic outcomes reported by patients at the one-year follow-up confirmed the ability to produce restorations that were not only functionally precise but visually harmonious with the natural dentition and gingival architecture.

The present study does, however, have several limitations. The retrospective design is not optimal for gathering highly reliable clinical data, and the follow-up of this study is limited, with only 103 patients treated with 122 restorations completed in a single clinical center. Hence, further multicenter prospective clinical studies and randomized controlled trials on larger patient sample sizes and with longer follow-up periods are recommended to confirm the positive outcomes found in the present study, and to clinically validate this novel CHA. In particular, more clinical evidence is needed for better understanding the tissue response to this CHA, and the soft tissue stability around the monolithic prosthetic restorations designed and fabricated following this concept and these principles. Additionally, the ideal conditioning of the tissues and the preparation of the EP with i-Physio® depends on the 3D position of the implant, as the position of the CHA is linked to the hexagonal index of the fixture; therefore, for an ideal use of the system, the placement of the implants via a static guided surgery procedure is recommended. Finally, the support from a dental technician with experience with CAD design is also recommended.

5. Conclusions

Within the limits of this study, the novel i-Physio Profile Designer® CHA appears promising and clinically reliable. This CHA provided high prosthetic precision of final, monolithic, screw-retained, implant-supported restorations, through a direct, fully digital CAD/CAM workflow. In addition, it promoted hard and soft-tissue healing, stability, and health over time by simplifying the digital impressions, reducing the number of interventions on soft tissues and, therefore, the risk of contamination of the implant site caused by repeated screwing and unscrewing of prosthetic components. Furthermore, in esthetically sensitive cases that need immediate restorations, this CHA acted as an abutment for immediate nonfunctional loading. Overall, the CHA-based workflow provided high patient satisfaction with a minimal incidence of biological and prosthetic complications. Further studies on a larger sample of patients and with a longer follow-up period are needed to confirm these positive, preliminary, clinical outcomes.

Abbreviations

Coded healing abutment (CHA); intraoral scanner (IOS); computer-aided-design/ computer-assisted manufacturing (CAD/CAM); single crown (SC); partial denture (PD); full-arches (FA); healing abutment (HA); scanbody, (SB); three-dimensional (3D); static computer assisted guided surgery (s-CAIS); digital imaging and communication in dentistry (DICOM); cone beam computed tomography (CBCT); standard tesselletion language (STL); iterative closest point (ICP); pink esthetic score (PES); marginal bone level (MBL); emergence profile (EP).

CRediT authorship contribution statement

Jaafar Mouhyi: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Conceptualization. **Maurice Salama:** Visualization, Software, Resources, Methodology, Investigation, Formal analysis. **Adam Mouhyi:** Writing – review & editing, Validation, Supervision. **Henriette Lerner:** Supervision, Funding acquisition. **Bidzina Margiani:** Writing – review & editing, Project administration, Funding acquisition. **Carlo Mangano:** Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors report no conflict of interest for the preparation of this study.

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