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One tooth-One time (1T1T), immediate loading of posterior single implants with the final crown: Two-year results of a case series.

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Dear Editor,

We thank the reviewers for their review. The comments included in the PDF file were already addressed in the previous revision.

The point-by-point response to the reviewer is given below.

Looking forward to hearing from you,

Kind regards,

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The authors

Before the paper is accepted, please change the marginal bone loss to these 2 categories: Baseline to 1-year (physiological bone remodeling) and 1-year to 2-years (pathological bone remodeling). This will be more clear to the readers.
I am still having an issue of Table 2 which refers to this statement: "The mean crestal bone remodelling from baseline to one year was 0.87 (SD: 0.96) mm. After two years, no further bone loss was observed; a mean peri-implant bone gain was actually observed as the peri baseline to 2 year was actually : 0.55 (SD: 0.53) mm." This does not look normal at all and it is probably due to non-standardized x-ray.

We understand your comment. The Table 2 was modified accordingly and the related sentences in results and discussion were reworded and highlighted in blue. We hope this will fulfill your expectation.

One tooth-One time (1T1T), immediate loading of posterior single implants with the final crown: Two-year results of a case series.

ABSTRACT

AIMS: The aim of this study was to evaluate the two-year outcomes of the One Tooth-One Time (1T1T) completely digital workflow, allowing the immediate loading of a single implant in the posterior region with a final CAD-CAM crown made of a polymer-infiltrated ceramic network (PICN).

MATERIALS AND METHODS: A series of 10 implants were placed, and an intra-oral scan was taken after the surgery. A final screw-retained PICN crown was manufactured chair-side and placed the same day in full occlusion. Marginal peri-implant bone changes and soft-tissue health were evaluated, as well as restoration performance using World Dental Federation criteria and Pink and White Esthetic Scores. Patient-related outcome measures (PROMs) and time consumption data were collected.

RESULTS: After two years, the implant survival rate was 100%. The debonding of one crown from its Titanium Base led to a 90% prosthodontic survival rate and the remaining crowns were all considered successful. The mean marginal peri-implant bone changes yielded 0.87 (SD: 0.96) and 0.55 (SD: 0.53) mm after one and two years, respectively. Mild or no inflammation of peri-implant soft tissue was observed in most implants. The overall treatment time reached 175 min and PROMs displayed high patient satisfaction.

CONCLUSIONS: This study constitutes the first report considering immediate loading of a single implant in the posterior region with a final crown in occlusion. In this case-series, the two-year outcomes of the 1T1T protocol seem rather promising and fulfil patient expectations. However,

those preliminary results need to be confirmed by randomized control trials and patient selection is probably a key factor in this procedure success.

CONFLICT OF INTEREST: The implants materials were kindly provided by Straumann Belgium.

INTRODUCTION

In today's world, things are going increasingly fast, mainly due to the impact of digital technologies. The trend is similar in the dental field: digital workflows are increasingly used, especially for single-unit restorations, and a recent systematic review concluded that patients tend to prefer digital over conventional techniques [1]. In particular, advances in computer-aided design and manufacturing (CAD-CAM) materials and chair-side CAD-CAM systems offer a new landscape for implant dentistry and a complete virtual environment without any physical model situations [2]. These new developments can contribute to improvement in patients' expectations and satisfaction in offering straightforward and cost-efficient protocols, but those breakthroughs should not reduce treatment quality and prognosis.

The reliability of immediate loading on single implants in the posterior mandible, using provisional crowns, has been demonstrated in several reports; the evidence is weaker for the posterior maxilla [3-6]. In the reports describing immediate restoration in the posterior regions, non-occlusal immediate loading using resin-based provisional is often described, and the final crowns would be realized several weeks after implant placement once the osseointegration was achieved [7]. Although such protocols may improve patient satisfaction, several appointments and a significant contribution by the dentist and the lab technician are required, which affects the overall treatment cost [8].

On the other hand CAD-CAM composites, particularly of polymer-infiltrated ceramic network (PICN), also called hybrid ceramics (Vita Enamic, Vita Zahnfabrik, BadSackingen, Germany), now constitute an alternative to ceramics for definitive, single-unit restorations[9]. They exhibit some advantages over ceramics, such as their better machinability (faster and with lower-thickness milling, with less edge chipping) [10, 11], the absence of post-milling firing and the ease of in-mouth adjustments. Most of all, the material's stiffness (elastic modulus value between enamel and dentin,

whereas ceramics are stiffer than enamel) and damping effect ability may make them potential candidates for implant restorations [12, 13], particularly for immediate loading.

Intraoral scanning (IOS) of single-unit implants directly after surgery and the chair-side manufacture of a PICN crown enable the delivery of a final restoration within the same visit. Such a protocol was previously introduced, describing two pilot cases, as the One-tooth One-time (1T1T) approach [14]. However, clinical research remains to be developed to validate this approach.

The aim of the present study was to evaluate the clinical and radiographic outcomes prospectively after a two-year follow-up of 10 single implants placed according to the 1T1T protocol. In addition, the time necessary to perform the procedures and the patients' reported outcome measures (PROMs) were assessed.

MATERIALS AND METHODS

Regulatory approvals, screening and consent

The study was approved by the Ethical Committee of Liège University Hospital and was conducted in accordance with the Declaration of Helsinki Helsinki of 1975, as revised in 2000 and all applicable local regulations and standards (file: B707201629113, approved on 18/08/2016). Participants complying with the inclusion criteria were provided with written information about the study, advising them of the study requirements and possible risks. Enrolled patients signed the informed consent form according to local regulations.

Study Design

The present study was designed as a single-centre prospective case series of nine consecutive patients presenting one or several maxillary or mandibular single missing teeth in the posterior region. Patients were treated in the Dental Department of the University Hospital of Liège and recruited between June 2016 and September 2016. Both surgical and prosthodontic procedures were performed by a single periodontist and a single prosthodontist, respectively. The patients were followed for a period of two years. At each follow-up visit, the implant and prosthodontic data were collected **(Figure 1)**. In addition, possible patient dropouts and withdrawals, as well as adverse events, were carefully monitored during the entire investigation period.

Patient selection

Inclusion criteria

- Voluntarily signed the informed consent form before any study-related action
- Age: at least 18, with one or two missing teeth in the posterior area, seeking for implant therapy
- In good systemic health (ASA I/II)
- Healed alveolar crest (at least 12 weeks post-extraction)
- Bone volume allowing the placement of an implant of at least 10 mm in length and 4.1 mm in diameter in a straight position in the axes of the future restoration.

Exclusion criteria

- Medical conditions contraindicating implant placement
- Smokers
- Full-mouth plaque score (FMPI) lower than or equal to 25%

- Sites treated with socket preservation or bone reconstruction techniques
- Presence of intraoral infection (periodontitis, caries and so on)
- Absence of antagonistic fixed teeth
- Less than 4 mm of keratinised gingival tissue in the implant site (2 mm in buccal and 2 mm in lingual)

Clinical procedure (Figure 2)

The patients were treated according to the previously described 1T1T protocol [14]. They were subjected to a cone-beam computed tomography (CBCT) scan to evaluate the bone dimensions in the area of interest and to confirm that they comply with the inclusion criteria. All subjects received preoperative antibiotics (amoxicillin 2 g or, if allergic, clindamycin, 600 mg) one hour before the surgery. After local anaesthesia, minimally invasive incisions were made. The drilling sequence and implant insertion was carried out according to the protocol of the manufacturer for the placement of a tapered-effect (TE) implant, (Straumann Group, Switzerland) of at least 10 mm in length and 4.1 mm in diameter. Implants were included in the present study only if a primary stability of at least 35 Ncm was achieved. The implant, displaying a 1.8 mm transgingival smooth neck, was vertically positioned in order to place the limit between the rough and smooth surface adjacent to bone level. The implant stability was measured using the wrench key and recorded in N/cm. The loading procedure was considered only if the insertion torque was higher than or equal to 35 N/cm. The implants were covered with healing abutments before suturing with a resorbable suture (Vicryl, 5/0).

Directly after the surgery, titanium Variobase abutments (Straumann Group, Basel, Switzerland) and a CEREC plastic scan body were placed on the implant in order to take an IOS (Omnicam

camera, CEREC System, Sirona, Salzburg, Austria) of the upper and lower jaws as well as of bite registration, according to manufacturer recommendations. Healing abutments were placed during the chair-side crown manufacturing process. Screw-retained implant restorations were designed with CEREC 4 software and manufactured with the CEREC MCXL (CEREC System), using the dedicated PICN blocks, with a pre-shaped hole fitting the titanium base (Vita Enamic IS-16L, Vita Zahnfabrik, Bad Säckingen, Germany). The restorations were designed with a convex emergence profile in order to mimic the shape of a natural tooth and support the peri-implant soft tissues. The PICN crown intaglio was etched with hydrofluoric acid for 60 seconds, subsequently cleaned in a 90% ethanol ultrasonic bath for five minutes and recovered by a primer layer (Monobond Plus, Ivoclar Vivadent, Schaan, Lichtenstein), which was applied using a microbrush and left for 60 seconds and then air dried for 10 seconds. The Variobase abutment was screwed onto an implant replica to facilitate handling. After neck protection with a silicone impression material, the abutment was sandblasted (50-μm alumina particles, two bars), cleaned and recovered by a primer layer in the same way as the crown intaglio. After screw head protection with Teflon, the crown was cemented on the abutment with a resin composite cement (Multilink Hybrid Abutment, Ivoclar Vivadent), according to the manufacturer's recommendations.

Finally, if needed for aesthetic purposes, the restoration was stained with a light-cured nano-filled composite coating agent (GC Optiglaze colour, GC Corporation, Tokyo, Japan), according to the manufacturer's recommendation and after crown etching and silanisation, as performed for bonding. The final crown was subsequently polished with dedicated instruments (Vita Enamic Polishing set). Before placement, the crowns were cleaned for 2 min in three consecutive ultrasonic baths (cleaning agent, sterile water and then 90 °C ethanol). Once manufactured and cleaned, the PICN definitive crowns were directly placed on the freshly placed implants. In case of overcontact or in the absence of passive fit, the crowns were subjected to occlusal or proximal contact areas

146 adjustments and were screwed with a torque of 15 N/cm. The access channels were filled with
147 Teflon and temporary filling material (Cavit, 3M ESPE, St. Paul, MN, USA), and X-rays were taken
148 for baseline radiologic data. Chlorhexidine spray (0.12%) was prescribed twice daily on the surgical
149 sites for seven days; ibuprofen, 600 mg TID, was prescribed for 4–5 days according to the patient's
150 need. Patients were advised to avoid tooth brushing at the implant site for seven days and food
151 such as nuts or grain food was not recommended for a period of 2 months.
152

153 **Follow-up and data collection**

154 Patients were followed up at seven days, two months, six months, one year and two years. In case
155 of any complications, the patients were asked to contact one of the study dentists directly. After
156 two months, the osseointegration was verified with a radiograph and a clinical assessment. The
157 restorations were torqued at 35 N/cm and the access channel filled Teflon and then a light-cured
158 composite (Els Extra Low Shrinkage® Saremco, Rebstein, Switzerland).
159 At six months, one year and two years, the patients were recalled to evaluate both implant and
160 prosthodontic outcomes, and patient-reported outcome measures were collected.
161

162 ***Occlusal risk factors***

163 Occlusal relationships were classified based on the clinical examination of two independent
164 evaluators. Class I, class II.1, class II.2 or class III as well as malocclusion, anterior or posterior
165 crossbite, edge to edge or open bite were identified. The presence of bruxism was recorded if the
166 patient fulfilled at least two criteria: A) reporting of tooth grinding during the night or day; or B) the
167 presence of at least one clinical sign among the following: abnormal attrition wear facets on the
168 teeth; transitory pain or fatigue on waking felt in the jaw muscles; temporal headaches on waking;

and jaw locking on waking related to teeth grinding during sleep [15]. The use of an occlusal nightguard was noted.

Marginal peri-implant bone changes and soft-tissue health

Marginal peri-implant bone changes of the mesial and distal bone levels were assessed based on intra-oral X-rays, using the parallel technique performed immediately after surgery and 1 and 2 years after the procedures. The degree of physiological remodeling after implant placement was determined as the crestal bone level changes from baseline to one year. Any further bone loss beyond the crestal bone level changes resulting from initial bone remodeling was considered as pathologic.

Marginal bone changes were measured using the Image J64 (National Institutes of Health, Bethesda, MD, USA) image processing software. The peri-implant soft-tissue health was also assessed by scoring peri-implant bleeding on probing (BOP) using the Silness and Loe index on each implant [16]. Gingival index scores below or equal to one were considered healthy peri-implant soft tissues. Moreover, at each follow-up visit, a full-mouth plaque score was collected using the O'Leary plaque index [17].

Clinical evaluation of PICN screw-retained restorations

At each follow-up visit, clinical pictures of the restorations were taken, and two independent evaluators clinically evaluated the restorations, following the criteria of the World Dental Federation (FDI) [18, 19]. Three dimensions, which represented 18 items, were described: aesthetic, functional, and biological. Each item was assessed on a five-point Likert scale, 1 corresponding to an excellent restoration and 5 corresponding to a restoration that needs to be replaced. In cases of discrepancy,

an agreement was found between evaluators to determine the final score. Scores 4 and 5 were considered failure.

Aesthetic outcomes (PES-WES)

Although it was initially described to evaluate the esthetic outcomes in the anterior region, the pink aesthetic score/white aesthetic score (PES/WES) index was used in this case in the posterior region as previously described [20]. A score of 2, 1, or 0 was assigned to each PES/WES parameter. Hence, the highest possible score was 14 for the PES according to Furhauser et al. [21] and 10 for the WES according to Belser et al. [22], which represented, respectively, a close match of the peri-implant soft-tissue conditions and the clinical single-tooth crown compared to the respective features present at the contralateral natural tooth site.

Time

The time necessary for each step of the clinical procedures and chair-side manufacturing (respectively, implant placement, IOS, chair-side manufacturing and restoration placement) were recorded in minutes. Patient installation and patients cares before and after the technical procedures were not taken considered. In addition, the overall time necessary to perform the 1T1T procedure was calculated by summing up the time necessary for each of these steps.

Patient Reported Outcomes Measures

The patients received satisfaction questionnaires related to the procedure, the function and the aesthetics of their crown(s) following the intervention as well as at the one-week, one-year and two-year follow-ups. The questionnaire included items that score the level of patient satisfaction related to the global appearance of the crown (1), crown colour (2), crown structure (3) and crown position

(4). Each item was evaluated using a visual analogue scale (VAS-10-point Likert scale). Additionally, patients were asked whether they would recommend the procedure to a friend (5) and whether they would undergo the treatment again (6).

Statistical analyses

Results were expressed as means ± standard deviations (SDs) or medians for quantitative variables, whereas frequencies and proportions (%) were used for categorical variables. Statistics are only descriptive, because there was no failure. Calculations were always carried out with the maximum amount of data available.

Missing data was not replaced. Data analysis was carried out using GraphPad Prism (GraphPad Software, San Diego, CA).

RESULTS

Patients' and site characteristics

A total of 10 implants were placed in nine patients; four were female and five were male, with a mean age of 45.7 years (ranging from 30 to 62 years). No patients dropped out during the follow-up of the study. Patient-related parameters, including occlusal risk factors, are detailed in **Table I**. The presence of clinical signs of bruxism, and consequently high occlusal stress, was suspected in six patients out of nine, and only one patient wore a nightguard (on the treated jaw) for this reason. The mean bucco-lingual bone thickness of the future implant site at baseline was 8.1 (SD: 1.1).

Implant survival rates

All implants reached a primary stability of at least 35 N/cm and all were immediately loaded with the final crown. No implants failed over the two-year follow-up period, leading to an implant survival rate of 100%.

Marginal peri-implant bone changes and soft-tissue health

The mean crestal bone remodelling from baseline to one year (physiological bone remodelling) was 0.87 (SD: 0.96) mm. After two years, no further bone loss was observed as a mean peri-implant bone gain of 0.32 (SD: 0.53) mm was actually observed. Most of the implants (80%) showed no or mild inflammation on probing, whereas more severe BOP was found on two implants at both one and two years, respectively. Full-mouth plaque scores above 15% were observed in two and four patients, respectively, at the one- and two-year follow-ups. Details related to survival rates and clinical parameters are displayed in **Tables II and III**.

Clinical evaluation of PICN screw-retained restorations

All crowns could be successfully manufactured and placed. Only minor occlusal or interproximal adjustments were necessary. The most frequent complication was crown unscrewing, which occurred in half of the crowns within two months after the procedure. These restorations were then torqued at 35 Ncm and no further unscrewing occurred. In addition, at the two-year recall in a single case, the PICN crown appeared to be slightly moving. In fact, it was debonded from the titanium Variobase and the crown was immediately replaced with a new one within the same appointment, using the original file in the CEREC system, that is, without taking a new optical impression **(Figure 3)**. The replacement of this crown led to a prosthodontic survival rate of 90%. Aesthetic, functional and biological properties related to the remaining original restorations (nine out of 10) were

sufficient to excellent, according to the FDI rating. Details are presented in **Table IV**. No complications were detected on antagonistic teeth.

PES/WES

The mean global PES score yielded 11.6 out of 14 after two years. The lowest values were found for the 'alveolar process' and the 'presence of the distal papilla'. The mean global WES reached 9.2 out of 10 after two years, and the lower value was found for the surface texture. Details for the PES/WES scores appear in **Table V.**

Time

The mean overall net treatment time, including clinical and chair-side procedures, reached 175.7 ± 60.7 minutes. The mean necessary time, respectively, for the surgery, the prosthodontic steps and the manufacturing process were 15.7, 54.9 and 105.1 minutes. Details appear in **Table VI.**

PROMs

The general satisfaction related to the overall treatment and the aesthetic perception of the crown both reached a score of 9.5. The scores for comfort during the surgery and the prosthodontic procedures were, respectively, 9.3 and 9.5. All patients said that they would do the treatment again and that they would recommend it to a friend. PROMs-related data is available in **Table VII**.

DISCUSSION

According to the present preliminary study, the innovative 1T1T protocol displayed rather successful outcomes after a two-year follow-up. To our knowledge, this is the first report

288 considering data of an immediately loaded single implant in the posterior region with a final crown
289 in occlusion, using a fully digital workflow without the use of physical models.
290 The present implant survival rates are encouraging; however, it is important to emphasise that
291 several key diagnostic factors, as described by Bahat et al., were taken into account and may have
292 positively influenced the results [23]. First, the patients were carefully selected regarding bone volume
293 and quality; all sites were healed, and the bone availability allowed placement of regular-diameter
294 implants of 10 and 12 mm. Moreover, smoking patients were excluded from the study. Although
295 tobacco use was not considered a risk for early implant failure in immediately loaded implants, it
296 seems to influence long-term peri-implant bone changes and therefore implant success [24, 25]. Yet,
297 it must be noted that patients exhibiting clinical signs of bruxism were not excluded. Consequently,
298 the majority of implants (70%) were probably submitted to high occlusal load, which could have
299 negatively influenced the treatment prognosis.
300 The choice of implant may have also influenced the present results. Tissue-level, tapered implants
301 with a highly hydrophilic surface were used to implement, respectively, the primary and secondary
302 implant stability and to respect soft-tissue integration. Indeed, as demonstrated by some authors,
303 it is preferable to insert single implants with a medium (>35 N/cm) to high (80 N/cm) insertion to
304 minimise early implant failures when loading them immediately [26]. In vitro and clinical studies have
305 emphasised the relevance of tapered implant design as employed in the present study to ensure
306 primary stability [27-29]. Highly hydrophilic implant surfaces have been shown to benefit
307 osseointegration [30-32]. Reaching faster secondary implant stability is, in principle, an argument for
308 an immediate loading protocol because the total stability of the implant would not drop in the first
309 weeks after implantation; therefore, such a hydrophilic implant surface was chosen for the 1T1T
310 protocol.

311 The choice of a PICN CAD/CAM restorative material characterised by a lower elasticity modulus
312 than ceramics [33] and, most of all, an ability to absorb occlusal stress by reversible deformation [34]
313 was also considered by the authors to be a key aspect of the procedure to have a restoration with
314 a damping effect. Because of their specific microstructure, PICN materials resulting from the
315 infiltration of a partially sintered glass–ceramic block secondarily infiltrated by monomers may
316 positively influence the biomechanics of immediately loaded implants and therefore the
317 osseointegration process. Although it was not demonstrated yet, the mechanical properties of this
318 material may also play a role on peri-implant bone stability and would therefore be an advantage
319 in the long-term outcomes of implants.
320 After two years of loading, a 100% implant survival rate was yielded and the marginal peri-implant
321 bone changes were comparable to what is described in the literature when using tissue-level
322 implants in a classic loading procedure [35] and can therefore be consider as physiological
323 remodeling, especially with tissues level implant in which the smooth surface may have been
324 potentially placed slightly sub-gingival in order to optimize the transgingival profile [36]. It is worth to
325 mentioned that the x-rays to measure bone level changes were not standardized and this may
326 explain the bone gain observed from 1 to 2 years. Although, the parallel technique was used in
327 order to minimize distortions, it remains a limitation of the present study.
328 As suggested by recent European Federation of Periodontology (EFP) consensus statements, peri-
329 implant soft-tissue health is an important criterion for implant success [37], and bleeding on probing
330 may be the first indicator of peri-implant disease such as mucositis or peri-implantitis [32, 38-40]. In the
331 present study, after two years of loading, 80% of the implants displayed no or mild peri-implant
332 soft-tissue inflammation, whereas some implants exhibited signs of mucositis with moderate
333 bleeding on probing (20%) [41]. Recently, experimental PICNs have been shown to exhibit
334 biocompatibility properties comparable to lithium disilicate and no monomer release, due to the

335 original polymerisation process involving high temperature and high pressure [42, 43]. Even if those
336 properties are not as good as zirconia or titanium, which constitute the gold standard [42, 43], they can
337 contribute to the acceptable peri-implant soft-tissue health found in the present study.
338
339 The aesthetic results of implant restorations are also a critical parameter for treatment success,
340 especially because patient expectations tend to increase even in the posterior region in the maxilla
341 when they show up to the first molar. Although the PES/WES scores were described for the anterior
342 region, it is the only index proven to be very reliable and reproducible for implant-supported single
343 crowns [44] and it was therefore used in the present study. The PES was rather good, and the variable
344 with the lowest score was generally the 'alveolar process resorption', which is related to buccal
345 bone resorption after extraction [45]. Indeed, the study criteria excluded previous ridge preservation
346 techniques or extraction and immediate implants that may have limited this buccal bone remodeling
347 [46-48]. Also, the score related to the papilla depends on the anatomy of the adjacent tooth bone level
348 and anatomy [49, 50]. These parameters are not only related to the materials or protocol used in the
349 present study; therefore, this data should be interpreted cautiously. The PES scores may have also
350 been influenced by the immediate placement of the final crown with the ideal emergence profile
351 allowing prosthesis-driven soft-tissue healing. This aspect is a potential additional benefit of the
352 1T1T protocol **(Figure 4)**.
353 Regarding aesthetic properties of the PICN restorations, both WES and FDI evaluation at two years
354 displayed very good results; excellent or good scores were found for all crowns regarding luster,
355 staining and anatomical form; for color match and translucency, only one crown was scored as
356 sufficient, whereas the others were good or excellent (**Table IV)**. Moreover, the FDI results did not
357 change after two years, which is promising regarding material ageing. The FDI evaluation and
358 PROMs also highlighted high patient satisfaction from the aesthetic point of view. Patients were

shown to be totally satisfied with the result in this posterior area. Luster was noted as good and not excellent when the material was just polished and not glazed, but future perspectives include the development of more aesthetic PICN materials, which should show higher luster after polishing [34].

Over the two-year follow-up, crown unscrewing occurred only within the two months after the procedures in 50% of the crowns. The restorations were initially screwed with a torque of 15 Ncm, which does not seem enough considering that the single crowns were in full occlusion. Because primary implant stability of 35 Ncm was required to apply the 1T1T protocol, we recommend torqueing the restoration at 35 Ncm from the first day. Indeed, in cases of unscrewing, the crowns were tight to 35 Ncm and no further complication of that type occurred.

It must be noted that no material fracture was observed, despite the presence of high occlusal stress in the majority of patients, which was previously shown to promote chipping of zirconia-based restorations [51]. This can be attributed to the monolithic restoration design and the material's ability to absorb occlusal stress by reversible deformation. No antagonistic tooth complication was detected. The PICN material was easy to manufacture and to adjust on occlusal and interproximal contact areas. Those occlusal contact areas were shown to be able to evolve from one evaluation time to the other (**Figure 2**), which indicates that the material can adapt to occlusal relationships by a slight wear process, which could reduce the risk of occlusal contact area interference compared to harder materials. Indeed, PICN are composite materials: they are less wear-resistant than ceramics but their wear resistance was shown to be satisfactory and superior to other CAD-CAM composites with dispersed filler, while they are more antagonist-friendly than ceramics [52-55]. The only observed failure was related to a PICN crown debonding from the titanium Variobase at two years while proper surface pre-treatments were performed. The failure was located at the interface between the resin cement and the titanium base, and the resin cement was still present

on the PICN surface. Indeed, the PICNs were shown to exhibit very good bonding properties, significantly higher than other CAD-CAM composites and similar to lithium disilicate glass–ceramics, which are considered the gold-standard [34]. Consequently, it seems that the typical design of the used titanium base, which is round and short, could be improved to promote a better crown retention.

Finally, the 1T1T protocol is performed in a single day, compared to the conventional approach that would require three or more appointments. Overall, the procedure took about three net hours. However, the times to welcome the patients, install and uninstall them in the operation room as well as the breaks in between were not taken into account. It is fair to say that it takes half a day and that the learning curve may improve the results found in this case series. All in all, it may take the same time as a conventional approach, with the main difference that the patient has only one treatment visit, which in certain cases is seen as a strong benefit from the patient's side, and the technical needs are reduced. At this stage, time efficiency and cost-effectiveness are difficult to extrapolate from the present study design, and further controlled randomised trials are necessary. Patient-reported outcome measures are becoming important aspects in assessing the outcomes of implant therapies [56, 57]. Although excellent results related to the overall treatment satisfaction as well as comfort and aesthetic perception of patients were found, the data should be interpreted cautiously because, as already suggested by some authors, the perception of new technologies may have influenced the figures [58]. Moreover, in the absence of validated tools to assess PROMs for single-tooth replacement, the satisfaction questionnaires used in the present study might be discussable. However, according to the collected information, the 1T1T procedures seemed highly appreciated by the patients, particularly the single-visit characteristic, which is easier to manage

406 with their own professional activity and can decrease global stress related to the procedure of tooth
407 replacement.
408
409 **CONCLUSION**
410
411 Despite the limitation of the present study, this is the first report considering single implant
412 immediate loading in the posterior region with a final crown in occlusion. These 2-year outcomes
413 of the 1T1T protocol, using a fully digital workflow, seem rather promising. The straightforward
414 technique provides immediate results, allows prosthesis-driven soft-tissue healing, is free of
415 substantial complications and highly appreciated by the patients. However, patient selection is
416 probably a key factor for the success of this procedure. Further clinical research is needed,
417 including randomised controlled trials (RCTs) comparing this new protocol to conventional
418 procedures.
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TABLES

Table I Patients and implant-related data

Patients (n tot= 9)	% (n)
Tobacco use	
Yes	0 (0)
No	100 (9)
Occlusal relationships	
Class I, II1	55,6 (5)
Class II2	11,1 (1)
Class III	0 (0)
Crossbite	11,1 (1)
Edge to edge	22,2 (2)
Guidance	
Group	55,6 (5)
Canine	44,4 (4)
Occlusal stress	
Yes	66,7 (6)
No	33,3 (3)
Nightguard	
Yes	11,1 (1)
No	88,9 (8)
Implants (n tot = 10)	**% (n)**
Location	
Maxillary premolar	20 (2)
Maxillary molar	20 (2)
Mandibular premolar	0 (0)
Mandibular molar	60 (6)
Implant lengths	
10mm	60 (6)
12mm	40 (4)

Table II Survival rates and peri-implant bone changes

	Baseline -1Year	Baseline - 2 Years
Implant survival rate (n tot = 10)	100%	100%
Peri-implant bone loss (mean±SD)	0.87 ± 0.96mm	0.55 ± 0.53mm
Prosthodontic survival rate (n tot = 10)	100%	90%

	Baseline -1Year	1Year - 2 Years
Implant survival rate (n tot = 10)	100%	100%
Peri-implant bone changes (mean±SD)	-0.87 ± 0.96mm	+0.32 ± 0.53mm
Prosthodontic survival rate (n tot = 10)	100%	90%

Table III Plaque and gingival indexes

Full-mouth plaque score	**1 week**		**2 months**		**6 months**		**1 year**		**2 years**	
	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)
Patients (n tot = 9)	8	1	2	7	5	4	7	2	5	4
Gingival index	**1 week**		**2 months**		**6 months**		**1 year**		**2 years**	
	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)
Implants (n tot = 10)	9	1	9	1	9	1	8	2	8	2

Table IV FDI criteria

1 year (n tot = 10) **2 years (n tot = 9)**	**Clinically excellent**		**Clinically good**		**Clinically sufficient**		**Clinically unsatisfactory**		**Clinically poor**		**Acceptable**		**Unacceptable**	
	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)
A. Esthetic properties														
Surface luster	30	30	70	70							100	100		
Staining														
a. surface	70	70	30	30							100	100		
b. margin	80	80	20	20							100	100		
Color match and translucency	40	40	50	50	10	10					100	100		
Anatomical form	80	80	20	20							100	100		
B. Functional properties														
Fracture of material and retention	100	90								10	100	90		10
Approximal anatomical form														
a. contact area	90	80			10	20					100	100		
b. contour	100	100									100	100		
Radiographic examination	100	100									100	100		
Patient’s view	90	90	10	10							100	100		
C. Biological properties														
Periodontal response	100	100									100	100		
Adjacent mucosa	100	100									100	100		
Oral and general health	100	100									100	100		

668 **Table V** Detailed description of PES/WES needed restorations (n tot =10). PES: pink
669 aesthetic score, WES: white aesthetic score, SD: standard deviation
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PES	Mesial papilla (mean±SD)	Distal papilla (mean±SD)	Level of soft-tissue margin (mean±SD)	Soft-tissue contour (mean±SD)	Alveolar process (mean±SD)	Soft-tissue color (mean±SD)	Soft-tissue texture (mean±SD)	**Total PES Score (mean±SD)**
1 year	1,7±0,67	1,3±0,67	2,0±0,0	1,4±0,52	1,3±0,48	1,8±0,42	1,8±0,42	11,30±1,49
2 years	1,7±0,67	1,20±0,79	1,80±0,63	1,90±0,31	1,60±0,52	1,70±0,48	1,70±0,48	11,60±1,50
WES	Tooth form (mean±SD)	Tooth volume/outline (mean±SD)	Color (hue/value) (mean±SD)	Surface texture (mean±SD)	Translucency (mean±SD)			**Total WES Score (mean±SD)**
1 year	1,80±0,42	1,90±0,32	1,40±0,52	1,30±0,48	2,0±0,0			8,4±1,07
2 years	2,0±0,0	2,0±0,0	1,80±0,42	1,50±0,53	1,90±0,32			9,2±0,79

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Table VI Duration of each step of the 1T1T protocol and total time needed

Procedure step	Minutes (mean±SD)
Implant placement	15,70±4,7
Digital impression	14,5±4,3
Crown manufacturing	105,1±40,8
Placement and occlusal adjustments	40,4±18,1
TOTAL	**175,7±60,66**

Table VII: PROMs as measured using a 10-point Likert scale. NA: Not Applicable

Score	Intervention (mean±SD)	1 week (mean±SD)	1 year (mean±SD)	2 years (mean±SD)
Comfort during surgery	9,3±0,87	NA	NA	NA
Comfort during prosthodontic procedure	9,5±0,73	NA	NA	NA
Aesthetic perception	9,5±0,53	NA	NA	NA
General satisfaction	NA	9,4±1,01	9,3±1,0	9,8±0,44
Would recommend to a friend	NA	100%	100%	100%

FIGURES

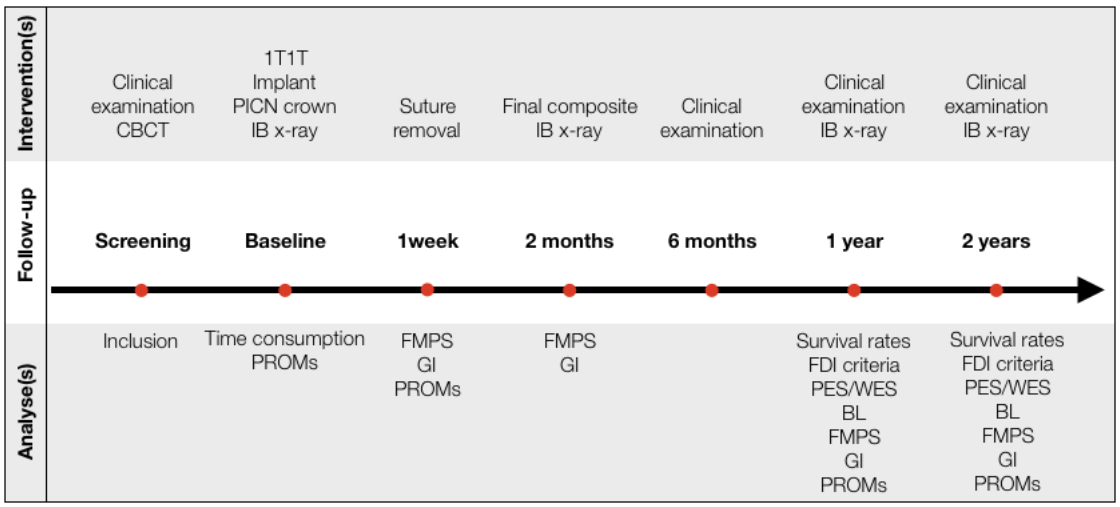

Figure 1: Timeline including interventions and analyses performed at each timepoint.

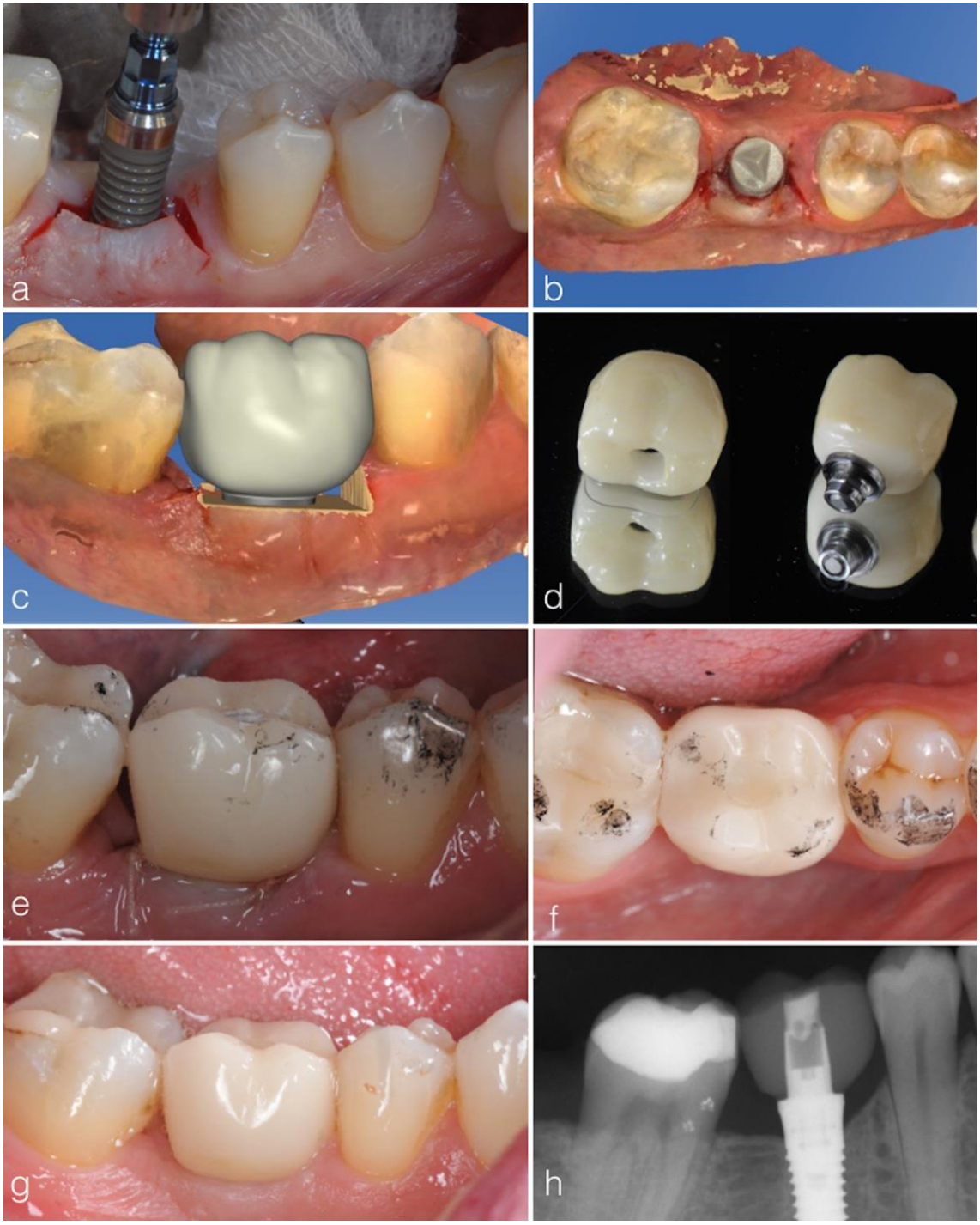

Figure 2 (a) Implant placement (TE implant, Straumann Group, Switzerland), using a minimally invasive surgical approach. (b) Digital image of IOS with the scan body placed on the Variobase. (c) Digital setup of the crown. (d) Crown just after the chair-side manufacturing cemented on a titanium base (Variobase, Straumann Group, Switzerland). Note the emergence profile. (e) Final CAD/CAM crown made of PICN placed a couple of hours after the surgical procedure. (f) Occlusal

view two months after the placement of the crown. Note the occlusal contact areas. (g) Clinical outcome after one year. (h) Intra-oral X-ray after one-year follow-up.

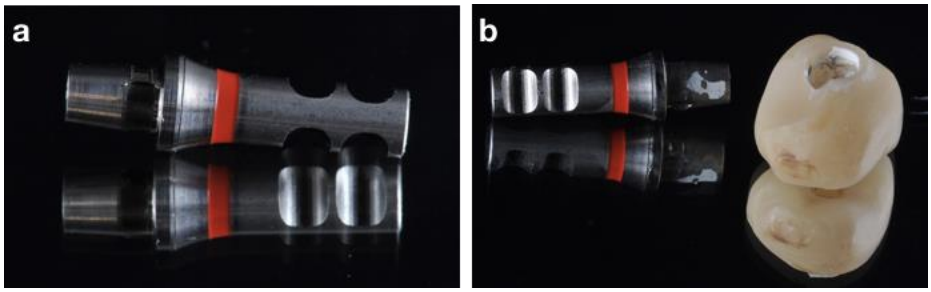

Figure 3: (a) Titanium Variobase design at baseline, before it was sandblasted. (b) Bonding failure after 2 years (the crown was moving, the PICN cohesive fracture occurred when trying to totally remove the crown). The debonding occurred at the interface between titanium and resin cement. A more retentive design for the titanium base would probably be more appropriate. A new crown was immediately placed within the same appointment, using the original file in the CEREC system and without the need to take a new optical impression.

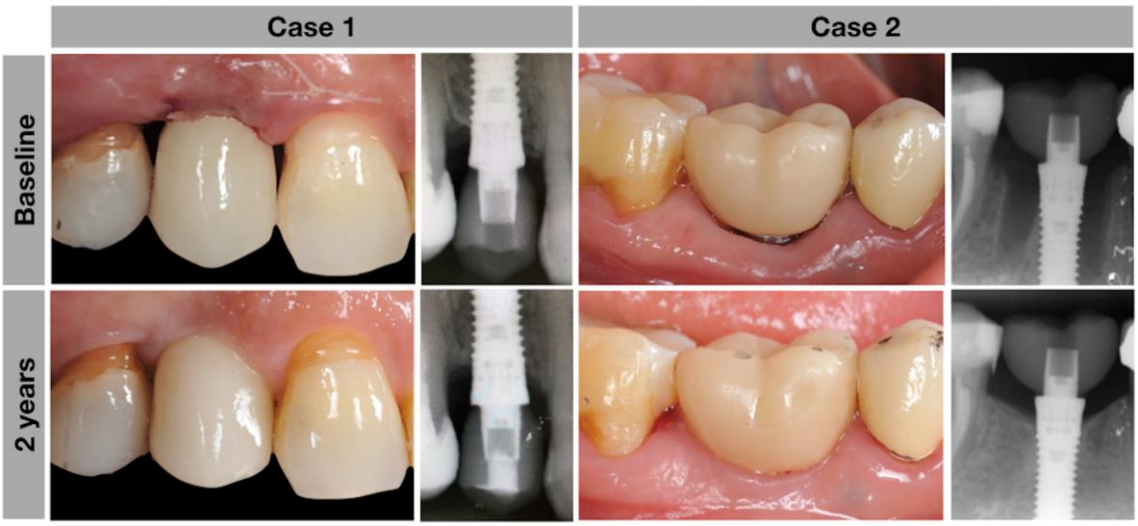

Figure 4 In these two cases, PICN crowns placed with the 1T1T protocol at baseline and two-year follow-up. We note the improvement of the peri-implant soft-tissue contours over time as well as an acceptable peri-implant bone-level stability from baseline to two years.

One tooth-One time (1T1T), immediate loading of posterior single implants with the final crown: Two-year results of a case series.

ABSTRACT

AIMS: The aim of this study was to evaluate the two-year outcomes of the One Tooth-One Time (1T1T) completely digital workflow, allowing the immediate loading of a single implant in the posterior region with a final CAD-CAM crown made of a polymer-infiltrated ceramic network (PICN).

MATERIALS AND METHODS: A series of 10 implants were placed, and an intra-oral scan was taken after the surgery. A final screw-retained PICN crown was manufactured chair-side and placed the same day in full occlusion. Marginal peri-implant bone changes and soft-tissue health were evaluated, as well as restoration performance using World Dental Federation criteria and Pink and White Esthetic Scores. Patient-related outcome measures (PROMs) and time consumption data were collected.

RESULTS: After two years, the implant survival rate was 100%. The debonding of one crown from its Titanium Base led to a 90% prosthodontic survival rate and the remaining crowns were all considered successful. The mean marginal peri-implant bone changes yielded 0.87 (SD: 0.96) and 0.55 (SD: 0.53) mm after one and two years, respectively. Mild or no inflammation of peri-implant soft tissue was observed in most implants. The overall treatment time reached 175 min and PROMs displayed high patient satisfaction.

CONCLUSIONS: This study constitutes the first report considering immediate loading of a single implant in the posterior region with a final crown in occlusion. In this case-series, the two-year outcomes of the 1T1T protocol seem rather promising and fulfil patient expectations. However,

those preliminary results need to be confirmed by randomized control trials and patient selection is probably a key factor in this procedure success.

CONFLICT OF INTEREST: The implants materials were kindly provided by Straumann Belgium.

INTRODUCTION

In today's world, things are going increasingly fast, mainly due to the impact of digital technologies. The trend is similar in the dental field: digital workflows are increasingly used, especially for single-unit restorations, and a recent systematic review concluded that patients tend to prefer digital over conventional techniques [1]. In particular, advances in computer-aided design and manufacturing (CAD-CAM) materials and chair-side CAD-CAM systems offer a new landscape for implant dentistry and a complete virtual environment without any physical model situations [2]. These new developments can contribute to improvement in patients' expectations and satisfaction in offering straightforward and cost-efficient protocols, but those breakthroughs should not reduce treatment quality and prognosis.

The reliability of immediate loading on single implants in the posterior mandible, using provisional crowns, has been demonstrated in several reports; the evidence is weaker for the posterior maxilla [3-6]. In the reports describing immediate restoration in the posterior regions, non-occlusal immediate loading using resin-based provisional is often described, and the final crowns would be realized several weeks after implant placement once the osseointegration was achieved [7]. Although such protocols may improve patient satisfaction, several appointments and a significant contribution by the dentist and the lab technician are required, which affects the overall treatment cost [8].

On the other hand CAD-CAM composites, particularly of polymer-infiltrated ceramic network (PICN), also called hybrid ceramics (Vita Enamic, Vita Zahnfabrik, BadSackingen, Germany), now constitute an alternative to ceramics for definitive, single-unit restorations[9]. They exhibit some advantages over ceramics, such as their better machinability (faster and with lower-thickness milling, with less edge chipping) [10, 11], the absence of post-milling firing and the ease of in-mouth adjustments. Most of all, the material's stiffness (elastic modulus value between enamel and dentin,

whereas ceramics are stiffer than enamel) and damping effect ability may make them potential candidates for implant restorations [12, 13], particularly for immediate loading.

Intraoral scanning (IOS) of single-unit implants directly after surgery and the chair-side manufacture of a PICN crown enable the delivery of a final restoration within the same visit. Such a protocol was previously introduced, describing two pilot cases, as the One-tooth One-time (1T1T) approach [14]. However, clinical research remains to be developed to validate this approach.

The aim of the present study was to evaluate the clinical and radiographic outcomes prospectively after a two-year follow-up of 10 single implants placed according to the 1T1T protocol. In addition, the time necessary to perform the procedures and the patients' reported outcome measures (PROMs) were assessed.

MATERIALS AND METHODS

Regulatory approvals, screening and consent

The study was approved by the Ethical Committee of Liège University Hospital and was conducted in accordance with the Declaration of Helsinki Helsinki of 1975, as revised in 2000 and all applicable local regulations and standards (file: B707201629113, approved on 18/08/2016). Participants complying with the inclusion criteria were provided with written information about the study, advising them of the study requirements and possible risks. Enrolled patients signed the informed consent form according to local regulations.

Study Design

The present study was designed as a single-centre prospective case series of nine consecutive patients presenting one or several maxillary or mandibular single missing teeth in the posterior region. Patients were treated in the Dental Department of the University Hospital of Liège and recruited between June 2016 and September 2016. Both surgical and prosthodontic procedures were performed by a single periodontist and a single prosthodontist, respectively. The patients were followed for a period of two years. At each follow-up visit, the implant and prosthodontic data were collected **(Figure 1)**. In addition, possible patient dropouts and withdrawals, as well as adverse events, were carefully monitored during the entire investigation period.

Patient selection

Inclusion criteria

- Voluntarily signed the informed consent form before any study-related action
- Age: at least 18, with one or two missing teeth in the posterior area, seeking for implant therapy
- In good systemic health (ASA I/II)
- Healed alveolar crest (at least 12 weeks post-extraction)
- Bone volume allowing the placement of an implant of at least 10 mm in length and 4.1 mm in diameter in a straight position in the axes of the future restoration.

Exclusion criteria

- Medical conditions contraindicating implant placement
- Smokers
- Full-mouth plaque score (FMPI) lower than or equal to 25%

- Sites treated with socket preservation or bone reconstruction techniques
- Presence of intraoral infection (periodontitis, caries and so on)
- Absence of antagonistic fixed teeth
- Less than 4 mm of keratinised gingival tissue in the implant site (2 mm in buccal and 2 mm in lingual)

Clinical procedure (Figure 2)

The patients were treated according to the previously described 1T1T protocol [14]. They were subjected to a cone-beam computed tomography (CBCT) scan to evaluate the bone dimensions in the area of interest and to confirm that they comply with the inclusion criteria. All subjects received preoperative antibiotics (amoxicillin 2 g or, if allergic, clindamycin, 600 mg) one hour before the surgery. After local anaesthesia, minimally invasive incisions were made. The drilling sequence and implant insertion was carried out according to the protocol of the manufacturer for the placement of a tapered-effect (TE) implant, (Straumann Group, Switzerland) of at least 10 mm in length and 4.1 mm in diameter. Implants were included in the present study only if a primary stability of at least 35 Ncm was achieved. The implant, displaying a 1.8 mm transgingival smooth neck, was vertically positioned in order to place the limit between the rough and smooth surface adjacent to bone level. The implant stability was measured using the wrench key and recorded in N/cm. The loading procedure was considered only if the insertion torque was higher than or equal to 35 N/cm. The implants were covered with healing abutments before suturing with a resorbable suture (Vicryl, 5/0).

Directly after the surgery, titanium Variobase abutments (Straumann Group, Basel, Switzerland) and a CEREC plastic scan body were placed on the implant in order to take an IOS (Omnicam

camera, CEREC System, Sirona, Salzburg, Austria) of the upper and lower jaws as well as of bite registration, according to manufacturer recommendations. Healing abutments were placed during the chair-side crown manufacturing process. Screw-retained implant restorations were designed with CEREC 4 software and manufactured with the CEREC MCXL (CEREC System), using the dedicated PICN blocks, with a pre-shaped hole fitting the titanium base (Vita Enamic IS-16L, Vita Zahnfabrik, Bad Säckingen, Germany). The restorations were designed with a convex emergence profile in order to mimic the shape of a natural tooth and support the peri-implant soft tissues. The PICN crown intaglio was etched with hydrofluoric acid for 60 seconds, subsequently cleaned in a 90% ethanol ultrasonic bath for five minutes and recovered by a primer layer (Monobond Plus, Ivoclar Vivadent, Schaan, Lichtenstein), which was applied using a microbrush and left for 60 seconds and then air dried for 10 seconds. The Variobase abutment was screwed onto an implant replica to facilitate handling. After neck protection with a silicone impression material, the abutment was sandblasted (50-μm alumina particles, two bars), cleaned and recovered by a primer layer in the same way as the crown intaglio. After screw head protection with Teflon, the crown was cemented on the abutment with a resin composite cement (Multilink Hybrid Abutment, Ivoclar Vivadent), according to the manufacturer's recommendations.

Finally, if needed for aesthetic purposes, the restoration was stained with a light-cured nano-filled composite coating agent (GC Optiglaze colour, GC Corporation, Tokyo, Japan), according to the manufacturer's recommendation and after crown etching and silanisation, as performed for bonding. The final crown was subsequently polished with dedicated instruments (Vita Enamic Polishing set). Before placement, the crowns were cleaned for 2 min in three consecutive ultrasonic baths (cleaning agent, sterile water and then 90 °C ethanol). Once manufactured and cleaned, the PICN definitive crowns were directly placed on the freshly placed implants. In case of overcontact or in the absence of passive fit, the crowns were subjected to occlusal or proximal contact areas

adjustments and were screwed with a torque of 15 N/cm. The access channels were filled with Teflon and temporary filling material (Cavit, 3M ESPE, St. Paul, MN, USA), and X-rays were taken for baseline radiologic data. Chlorhexidine spray (0.12%) was prescribed twice daily on the surgical sites for seven days; ibuprofen, 600 mg TID, was prescribed for 4–5 days according to the patient's need. Patients were advised to avoid tooth brushing at the implant site for seven days and food such as nuts or grain food was not recommended for a period of 2 months.

Follow-up and data collection

Patients were followed up at seven days, two months, six months, one year and two years. In case of any complications, the patients were asked to contact one of the study dentists directly. After two months, the osseointegration was verified with a radiograph and a clinical assessment. The restorations were torqued at 35 N/cm and the access channel filled Teflon and then a light-cured composite (Els Extra Low Shrinkage® Saremco, Rebstein, Switzerland).

At six months, one year and two years, the patients were recalled to evaluate both implant and prosthodontic outcomes, and patient-reported outcome measures were collected.

Occlusal risk factors

Occlusal relationships were classified based on the clinical examination of two independent evaluators. Class I, class II.1, class II.2 or class III as well as malocclusion, anterior or posterior crossbite, edge to edge or open bite were identified. The presence of bruxism was recorded if the patient fulfilled at least two criteria: A) reporting of tooth grinding during the night or day; or B) the presence of at least one clinical sign among the following: abnormal attrition wear facets on the teeth; transitory pain or fatigue on waking felt in the jaw muscles; temporal headaches on waking;

and jaw locking on waking related to teeth grinding during sleep [15]. The use of an occlusal nightguard was noted.

Marginal peri-implant bone changes and soft-tissue health

Marginal peri-implant bone changes of the mesial and distal bone levels were assessed based on intra-oral X-rays, using the parallel technique performed immediately after surgery and 1 and 2 years after the procedures. The degree of physiological remodeling after implant placement was determined as the crestal bone level changes from baseline to one year. Any further bone loss beyond the crestal bone level changes resulting from initial bone remodeling was considered as pathologic.

Marginal bone changes were measured using the Image J64 (National Institutes of Health, Bethesda, MD, USA) image processing software. The peri-implant soft-tissue health was also assessed by scoring peri-implant bleeding on probing (BOP) using the Silness and Loe index on each implant [16]. Gingival index scores below or equal to one were considered healthy peri-implant soft tissues. Moreover, at each follow-up visit, a full-mouth plaque score was collected using the O'Leary plaque index [17].

Clinical evaluation of PICN screw-retained restorations

At each follow-up visit, clinical pictures of the restorations were taken, and two independent evaluators clinically evaluated the restorations, following the criteria of the World Dental Federation (FDI) [18, 19]. Three dimensions, which represented 18 items, were described: aesthetic, functional, and biological. Each item was assessed on a five-point Likert scale, 1 corresponding to an excellent restoration and 5 corresponding to a restoration that needs to be replaced. In cases of discrepancy,

an agreement was found between evaluators to determine the final score. Scores 4 and 5 were considered failure.

Aesthetic outcomes (PES-WES)

Although it was initially described to evaluate the esthetic outcomes in the anterior region, the pink aesthetic score/white aesthetic score (PES/WES) index was used in this case in the posterior region as previously described [20]. A score of 2, 1, or 0 was assigned to each PES/WES parameter. Hence, the highest possible score was 14 for the PES according to Furhauser et al. [21] and 10 for the WES according to Belser et al. [22], which represented, respectively, a close match of the peri-implant soft-tissue conditions and the clinical single-tooth crown compared to the respective features present at the contralateral natural tooth site.

Time

The time necessary for each step of the clinical procedures and chair-side manufacturing (respectively, implant placement, IOS, chair-side manufacturing and restoration placement) were recorded in minutes. Patient installation and patients cares before and after the technical procedures were not taken considered. In addition, the overall time necessary to perform the 1T1T procedure was calculated by summing up the time necessary for each of these steps.

Patient Reported Outcomes Measures

The patients received satisfaction questionnaires related to the procedure, the function and the aesthetics of their crown(s) following the intervention as well as at the one-week, one-year and two-year follow-ups. The questionnaire included items that score the level of patient satisfaction related to the global appearance of the crown (1), crown colour (2), crown structure (3) and crown position

(4). Each item was evaluated using a visual analogue scale (VAS-10-point Likert scale). Additionally, patients were asked whether they would recommend the procedure to a friend (5) and whether they would undergo the treatment again (6).

Statistical analyses

Results were expressed as means ± standard deviations (SDs) or medians for quantitative variables, whereas frequencies and proportions (%) were used for categorical variables. Statistics are only descriptive, because there was no failure. Calculations were always carried out with the maximum amount of data available.

Missing data was not replaced. Data analysis was carried out using GraphPad Prism (GraphPad Software, San Diego, CA).

RESULTS

Patients' and site characteristics

A total of 10 implants were placed in nine patients; four were female and five were male, with a mean age of 45.7 years (ranging from 30 to 62 years). No patients dropped out during the follow-up of the study. Patient-related parameters, including occlusal risk factors, are detailed in **Table I**. The presence of clinical signs of bruxism, and consequently high occlusal stress, was suspected in six patients out of nine, and only one patient wore a nightguard (on the treated jaw) for this reason. The mean bucco-lingual bone thickness of the future implant site at baseline was 8.1 (SD: 1.1).

Implant survival rates

All implants reached a primary stability of at least 35 N/cm and all were immediately loaded with the final crown. No implants failed over the two-year follow-up period, leading to an implant survival rate of 100%.

Marginal peri-implant bone changes and soft-tissue health

The mean crestal bone remodelling from baseline to one year (physiological bone remodelling) was 0.87 (SD: 0.96) mm. After two years, no further bone loss was observed as a mean peri-implant bone gain of 0.32 (SD: 0.53) mm was actually observed. Most of the implants (80%) showed no or mild inflammation on probing, whereas more severe BOP was found on two implants at both one and two years, respectively. Full-mouth plaque scores above 15% were observed in two and four patients, respectively, at the one- and two-year follow-ups. Details related to survival rates and clinical parameters are displayed in **Tables II and III**.

Clinical evaluation of PICN screw-retained restorations

All crowns could be successfully manufactured and placed. Only minor occlusal or interproximal adjustments were necessary. The most frequent complication was crown unscrewing, which occurred in half of the crowns within two months after the procedure. These restorations were then torqued at 35 Ncm and no further unscrewing occurred. In addition, at the two-year recall in a single case, the PICN crown appeared to be slightly moving. In fact, it was debonded from the titanium Variobase and the crown was immediately replaced with a new one within the same appointment, using the original file in the CEREC system, that is, without taking a new optical impression **(Figure 3)**. The replacement of this crown led to a prosthodontic survival rate of 90%. Aesthetic, functional and biological properties related to the remaining original restorations (nine out of 10) were

sufficient to excellent, according to the FDI rating. Details are presented in **Table IV**. No complications were detected on antagonistic teeth.

PES/WES

The mean global PES score yielded 11.6 out of 14 after two years. The lowest values were found for the 'alveolar process' and the 'presence of the distal papilla'. The mean global WES reached 9.2 out of 10 after two years, and the lower value was found for the surface texture. Details for the PES/WES scores appear in **Table V.**

Time

The mean overall net treatment time, including clinical and chair-side procedures, reached 175.7 ± 60.7 minutes. The mean necessary time, respectively, for the surgery, the prosthodontic steps and the manufacturing process were 15.7, 54.9 and 105.1 minutes. Details appear in **Table VI.**

PROMs

The general satisfaction related to the overall treatment and the aesthetic perception of the crown both reached a score of 9.5. The scores for comfort during the surgery and the prosthodontic procedures were, respectively, 9.3 and 9.5. All patients said that they would do the treatment again and that they would recommend it to a friend. PROMs-related data is available in **Table VII**.

DISCUSSION

According to the present preliminary study, the innovative 1T1T protocol displayed rather successful outcomes after a two-year follow-up. To our knowledge, this is the first report

288 considering data of an immediately loaded single implant in the posterior region with a final crown
289 in occlusion, using a fully digital workflow without the use of physical models.
290 The present implant survival rates are encouraging; however, it is important to emphasise that
291 several key diagnostic factors, as described by Bahat et al., were taken into account and may have
292 positively influenced the results [23]. First, the patients were carefully selected regarding bone volume
293 and quality; all sites were healed, and the bone availability allowed placement of regular-diameter
294 implants of 10 and 12 mm. Moreover, smoking patients were excluded from the study. Although
295 tobacco use was not considered a risk for early implant failure in immediately loaded implants, it
296 seems to influence long-term peri-implant bone changes and therefore implant success [24, 25]. Yet,
297 it must be noted that patients exhibiting clinical signs of bruxism were not excluded. Consequently,
298 the majority of implants (70%) were probably submitted to high occlusal load, which could have
299 negatively influenced the treatment prognosis.
300 The choice of implant may have also influenced the present results. Tissue-level, tapered implants
301 with a highly hydrophilic surface were used to implement, respectively, the primary and secondary
302 implant stability and to respect soft-tissue integration. Indeed, as demonstrated by some authors,
303 it is preferable to insert single implants with a medium (>35 N/cm) to high (80 N/cm) insertion to
304 minimise early implant failures when loading them immediately [26]. In vitro and clinical studies have
305 emphasised the relevance of tapered implant design as employed in the present study to ensure
306 primary stability [27-29]. Highly hydrophilic implant surfaces have been shown to benefit
307 osseointegration [30-32]. Reaching faster secondary implant stability is, in principle, an argument for
308 an immediate loading protocol because the total stability of the implant would not drop in the first
309 weeks after implantation; therefore, such a hydrophilic implant surface was chosen for the 1T1T
310 protocol.

311 The choice of a PICN CAD/CAM restorative material characterised by a lower elasticity modulus
312 than ceramics [33] and, most of all, an ability to absorb occlusal stress by reversible deformation [34]
313 was also considered by the authors to be a key aspect of the procedure to have a restoration with
314 a damping effect. Because of their specific microstructure, PICN materials resulting from the
315 infiltration of a partially sintered glass–ceramic block secondarily infiltrated by monomers may
316 positively influence the biomechanics of immediately loaded implants and therefore the
317 osseointegration process. Although it was not demonstrated yet, the mechanical properties of this
318 material may also play a role on peri-implant bone stability and would therefore be an advantage
319 in the long-term outcomes of implants.
320 After two years of loading, a 100% implant survival rate was yielded and the marginal peri-implant
321 bone changes were comparable to what is described in the literature when using tissue-level
322 implants in a classic loading procedure [35] and can therefore be consider as physiological
323 remodeling, especially with tissues level implant in which the smooth surface may have been
324 potentially placed slightly sub-gingival in order to optimize the transgingival profile [36]. It is worth to
325 mentioned that the x-rays to measure bone level changes were not standardized and this may
326 explain the bone gain observed from 1 to 2 years. Although, the parallel technique was used in
327 order to minimize distortions, it remains a limitation of the present study.
328 As suggested by recent European Federation of Periodontology (EFP) consensus statements, peri-
329 implant soft-tissue health is an important criterion for implant success [37], and bleeding on probing
330 may be the first indicator of peri-implant disease such as mucositis or peri-implantitis [32, 38-40]. In the
331 present study, after two years of loading, 80% of the implants displayed no or mild peri-implant
332 soft-tissue inflammation, whereas some implants exhibited signs of mucositis with moderate
333 bleeding on probing (20%) [41]. Recently, experimental PICNs have been shown to exhibit
334 biocompatibility properties comparable to lithium disilicate and no monomer release, due to the

335 original polymerisation process involving high temperature and high pressure [42, 43]. Even if those
336 properties are not as good as zirconia or titanium, which constitute the gold standard [42, 43], they can
337 contribute to the acceptable peri-implant soft-tissue health found in the present study.
338
339 The aesthetic results of implant restorations are also a critical parameter for treatment success,
340 especially because patient expectations tend to increase even in the posterior region in the maxilla
341 when they show up to the first molar. Although the PES/WES scores were described for the anterior
342 region, it is the only index proven to be very reliable and reproducible for implant-supported single
343 crowns [44] and it was therefore used in the present study. The PES was rather good, and the variable
344 with the lowest score was generally the 'alveolar process resorption', which is related to buccal
345 bone resorption after extraction [45]. Indeed, the study criteria excluded previous ridge preservation
346 techniques or extraction and immediate implants that may have limited this buccal bone remodeling
347 [46-48]. Also, the score related to the papilla depends on the anatomy of the adjacent tooth bone level
348 and anatomy [49, 50]. These parameters are not only related to the materials or protocol used in the
349 present study; therefore, this data should be interpreted cautiously. The PES scores may have also
350 been influenced by the immediate placement of the final crown with the ideal emergence profile
351 allowing prosthesis-driven soft-tissue healing. This aspect is a potential additional benefit of the
352 1T1T protocol **(Figure 4)**.
353 Regarding aesthetic properties of the PICN restorations, both WES and FDI evaluation at two years
354 displayed very good results; excellent or good scores were found for all crowns regarding luster,
355 staining and anatomical form; for color match and translucency, only one crown was scored as
356 sufficient, whereas the others were good or excellent (**Table IV)**. Moreover, the FDI results did not
357 change after two years, which is promising regarding material ageing. The FDI evaluation and
358 PROMs also highlighted high patient satisfaction from the aesthetic point of view. Patients were

shown to be totally satisfied with the result in this posterior area. Luster was noted as good and not excellent when the material was just polished and not glazed, but future perspectives include the development of more aesthetic PICN materials, which should show higher luster after polishing [34].

Over the two-year follow-up, crown unscrewing occurred only within the two months after the procedures in 50% of the crowns. The restorations were initially screwed with a torque of 15 Ncm, which does not seem enough considering that the single crowns were in full occlusion. Because primary implant stability of 35 Ncm was required to apply the 1T1T protocol, we recommend torqueing the restoration at 35 Ncm from the first day. Indeed, in cases of unscrewing, the crowns were tight to 35 Ncm and no further complication of that type occurred.

It must be noted that no material fracture was observed, despite the presence of high occlusal stress in the majority of patients, which was previously shown to promote chipping of zirconia-based restorations [51]. This can be attributed to the monolithic restoration design and the material's ability to absorb occlusal stress by reversible deformation. No antagonistic tooth complication was detected. The PICN material was easy to manufacture and to adjust on occlusal and interproximal contact areas. Those occlusal contact areas were shown to be able to evolve from one evaluation time to the other (**Figure 2**), which indicates that the material can adapt to occlusal relationships by a slight wear process, which could reduce the risk of occlusal contact area interference compared to harder materials. Indeed, PICN are composite materials: they are less wear-resistant than ceramics but their wear resistance was shown to be satisfactory and superior to other CAD-CAM composites with dispersed filler, while they are more antagonist-friendly than ceramics [52-55]. The only observed failure was related to a PICN crown debonding from the titanium Variobase at two years while proper surface pre-treatments were performed. The failure was located at the interface between the resin cement and the titanium base, and the resin cement was still present

on the PICN surface. Indeed, the PICNs were shown to exhibit very good bonding properties, significantly higher than other CAD-CAM composites and similar to lithium disilicate glass–ceramics, which are considered the gold-standard [34]. Consequently, it seems that the typical design of the used titanium base, which is round and short, could be improved to promote a better crown retention.

Finally, the 1T1T protocol is performed in a single day, compared to the conventional approach that would require three or more appointments. Overall, the procedure took about three net hours. However, the times to welcome the patients, install and uninstall them in the operation room as well as the breaks in between were not taken into account. It is fair to say that it takes half a day and that the learning curve may improve the results found in this case series. All in all, it may take the same time as a conventional approach, with the main difference that the patient has only one treatment visit, which in certain cases is seen as a strong benefit from the patient's side, and the technical needs are reduced. At this stage, time efficiency and cost-effectiveness are difficult to extrapolate from the present study design, and further controlled randomised trials are necessary. Patient-reported outcome measures are becoming important aspects in assessing the outcomes of implant therapies [56, 57]. Although excellent results related to the overall treatment satisfaction as well as comfort and aesthetic perception of patients were found, the data should be interpreted cautiously because, as already suggested by some authors, the perception of new technologies may have influenced the figures [58]. Moreover, in the absence of validated tools to assess PROMs for single-tooth replacement, the satisfaction questionnaires used in the present study might be discussable. However, according to the collected information, the 1T1T procedures seemed highly appreciated by the patients, particularly the single-visit characteristic, which is easier to manage

406 with their own professional activity and can decrease global stress related to the procedure of tooth
407 replacement.
408
409 **CONCLUSION**
410
411 Despite the limitation of the present study, this is the first report considering single implant
412 immediate loading in the posterior region with a final crown in occlusion. These 2-year outcomes
413 of the 1T1T protocol, using a fully digital workflow, seem rather promising. The straightforward
414 technique provides immediate results, allows prosthesis-driven soft-tissue healing, is free of
415 substantial complications and highly appreciated by the patients. However, patient selection is
416 probably a key factor for the success of this procedure. Further clinical research is needed,
417 including randomised controlled trials (RCTs) comparing this new protocol to conventional
418 procedures.
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TABLES

Table I Patients and implant-related data

Patients (n tot= 9)	% (n)
Tobacco use	
Yes	0 (0)
No	100 (9)
Occlusal relationships	
Class I, II1	55,6 (5)
Class II2	11,1 (1)
Class III	0 (0)
Crossbite	11,1 (1)
Edge to edge	22,2 (2)
Guidance	
Group	55,6 (5)
Canine	44,4 (4)
Occlusal stress	
Yes	66,7 (6)
No	33,3 (3)
Nightguard	
Yes	11,1 (1)
No	88,9 (8)
Implants (n tot = 10)	**% (n)**
Location	
Maxillary premolar	20 (2)
Maxillary molar	20 (2)
Mandibular premolar	0 (0)
Mandibular molar	60 (6)
Implant lengths	
10mm	60 (6)
12mm	40 (4)

649 **Table II** Survival rates and peri-implant bone changes
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	Baseline -1Year	Baseline - 2 Years
Implant survival rate (n tot = 10)	100%	100%
Peri-implant bone loss (mean±SD)	0.87 ± 0.96mm	0.55 ± 0.53mm
Prosthodontic survival rate (n tot = 10)	100%	90%

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	Baseline -1Year	1Year - 2 Years
Implant survival rate (n tot = 10)	100%	100%
Peri-implant bone changes (mean±SD)	-0.87 ± 0.96mm	+0.32 ± 0.53mm
Prosthodontic survival rate (n tot = 10)	100%	90%

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Table III Plaque and gingival indexes

Full-mouth plaque score	**1 week**		**2 months**		**6 months**		**1 year**		**2 years**	
	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)	<15% (n)	>15% (n)
Patients (n tot = 9)	8	1	2	7	5	4	7	2	5	4
Gingival index	**1 week**		**2 months**		**6 months**		**1 year**		**2 years**	
	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)	0-1 (n)	≥2 (n)
Implants (n tot = 10)	9	1	9	1	9	1	8	2	8	2

Table IV FDI criteria

1 year (n tot = 10) **2 years (n tot = 9)**	**Clinically excellent**		**Clinically good**		**Clinically sufficient**		**Clinically unsatisfactory**		**Clinically poor**		**Acceptable**		**Unacceptable**	
	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)	1 yr (%)	2 yrs (%)
A. Esthetic properties														
Surface luster	30	30	70	70							100	100		
Staining														
a. surface	70	70	30	30							100	100		
b. margin	80	80	20	20							100	100		
Color match and translucency	40	40	50	50	10	10					100	100		
Anatomical form	80	80	20	20							100	100		
B. Functional properties														
Fracture of material and retention	100	90								10	100	90		10
Approximal anatomical form														
a. contact area	90	80			10	20					100	100		
b. contour	100	100									100	100		
Radiographic examination	100	100									100	100		
Patient's view	90	90	10	10							100	100		
C. Biological properties														
Periodontal response	100	100									100	100		
Adjacent mucosa	100	100									100	100		
Oral and general health	100	100									100	100		

668 **Table V** Detailed description of PES/WES needed restorations (n tot =10). PES: pink
669 aesthetic score, WES: white aesthetic score, SD: standard deviation
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PES	Mesial papilla (mean±SD)	Distal papilla (mean±SD)	Level of soft-tissue margin (mean±SD)	Soft-tissue contour (mean±SD)	Alveolar process (mean±SD)	Soft-tissue color (mean±SD)	Soft-tissue texture (mean±SD)	**Total PES Score (mean±SD)**
1 year	1,7±0,67	1,3±0,67	2,0±0,0	1,4±0,52	1,3±0,48	1,8±0,42	1,8±0,42	11,30±1,49
2 years	1,7±0,67	1,20±0,79	1,80±0,63	1,90±0,31	1,60±0,52	1,70±0,48	1,70±0,48	11,60±1,50
WES	Tooth form (mean±SD)	Tooth volume/outline (mean±SD)	Color (hue/value) (mean±SD)	Surface texture (mean±SD)	Translucency (mean±SD)			**Total WES Score (mean±SD)**
1 year	1,80±0,42	1,90±0,32	1,40±0,52	1,30±0,48	2,0±0,0			8,4±1,07
2 years	2,0±0,0	2,0±0,0	1,80±0,42	1,50±0,53	1,90±0,32			9,2±0,79

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Table VI Duration of each step of the 1T1T protocol and total time needed

Procedure step	Minutes (mean±SD)
Implant placement	15,70±4,7
Digital impression	14,5±4,3
Crown manufacturing	105,1±40,8
Placement and occlusal adjustments	40,4±18,1
TOTAL	**175,7±60,66**

Table VII: PROMs as measured using a 10-point Likert scale. NA: Not Applicable

Score	Intervention (mean±SD)	1 week (mean±SD)	1 year (mean±SD)	2 years (mean±SD)
Comfort during surgery	9,3±0,87	NA	NA	NA
Comfort during prosthodontic procedure	9,5±0,73	NA	NA	NA
Aesthetic perception	9,5±0,53	NA	NA	NA
General satisfaction	NA	9,4±1,01	9,3±1,0	9,8±0,44
Would recommend to a friend	NA	100%	100%	100%

FIGURES

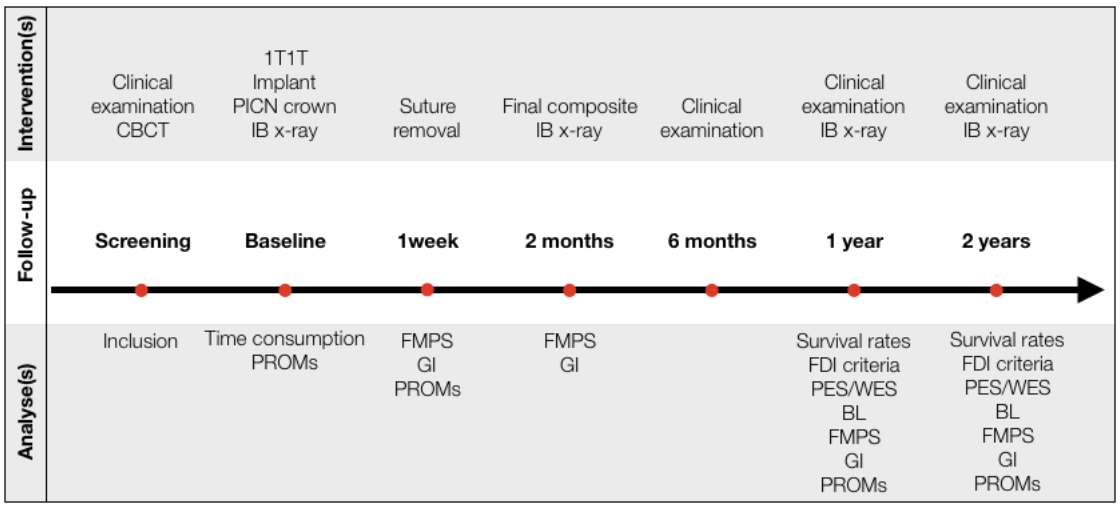


Figure 1: Timeline including interventions and analyses performed at each timepoint.

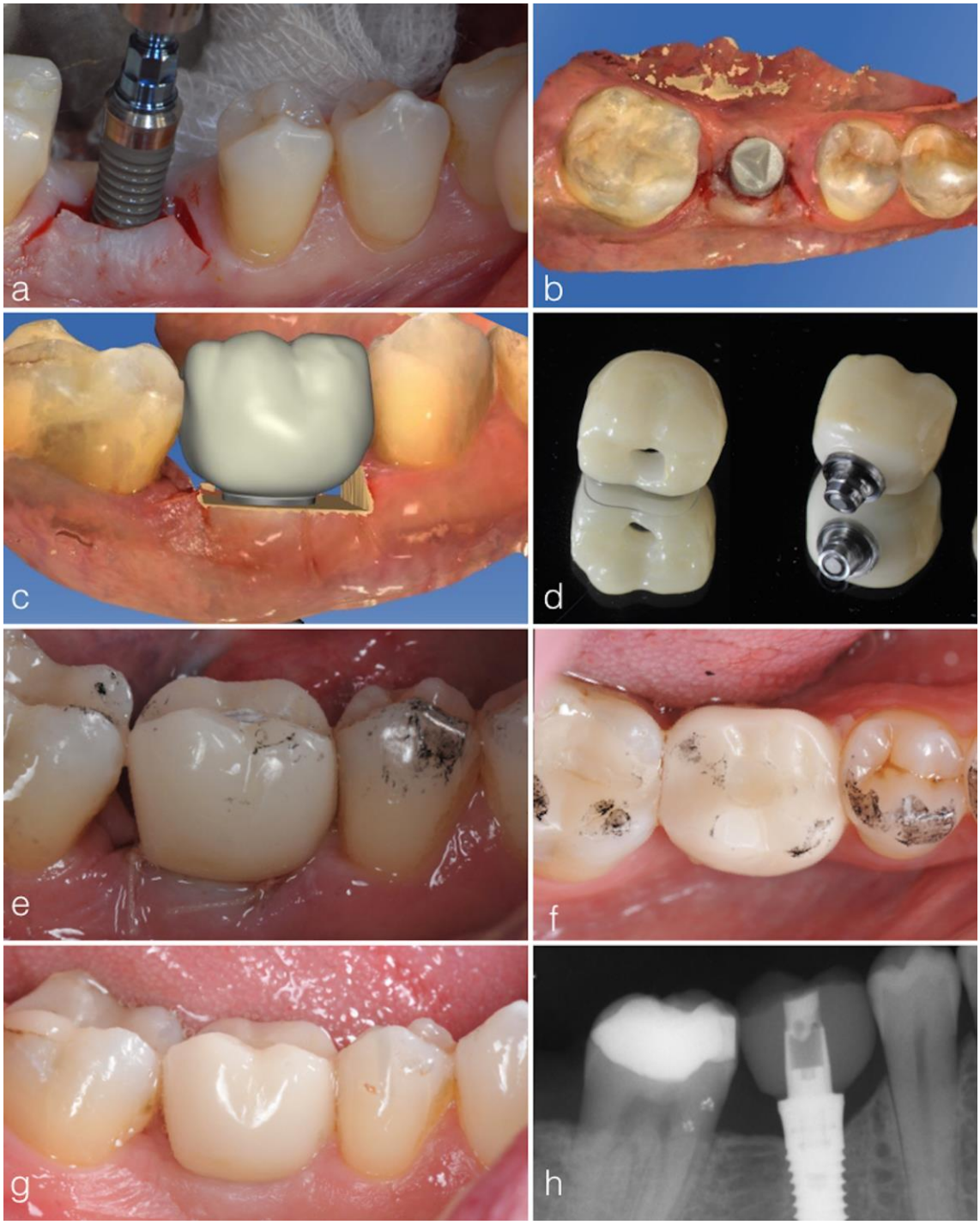


Figure 2 (a) Implant placement (TE implant, Straumann Group, Switzerland), using a minimally invasive surgical approach. (b) Digital image of IOS with the scan body placed on the Variobase. (c) Digital setup of the crown. (d) Crown just after the chair-side manufacturing cemented on a titanium base (Variobase, Straumann Group, Switzerland). Note the emergence profile. (e) Final CAD/CAM crown made of PICN placed a couple of hours after the surgical procedure. (f) Occlusal

view two months after the placement of the crown. Note the occlusal contact areas. (g) Clinical outcome after one year. (h) Intra-oral X-ray after one-year follow-up.

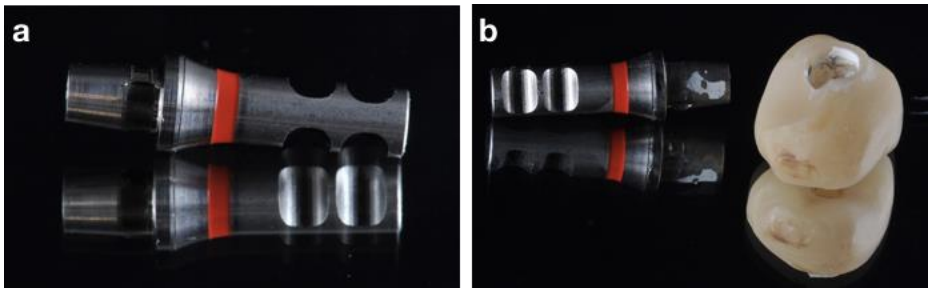


Figure 3: (a) Titanium Variobase design at baseline, before it was sandblasted. (b) Bonding failure after 2 years (the crown was moving, the PICN cohesive fracture occurred when trying to totally remove the crown). The debonding occurred at the interface between titanium and resin cement. A more retentive design for the titanium base would probably be more appropriate. A new crown was immediately placed within the same appointment, using the original file in the CEREC system and without the need to take a new optical impression.

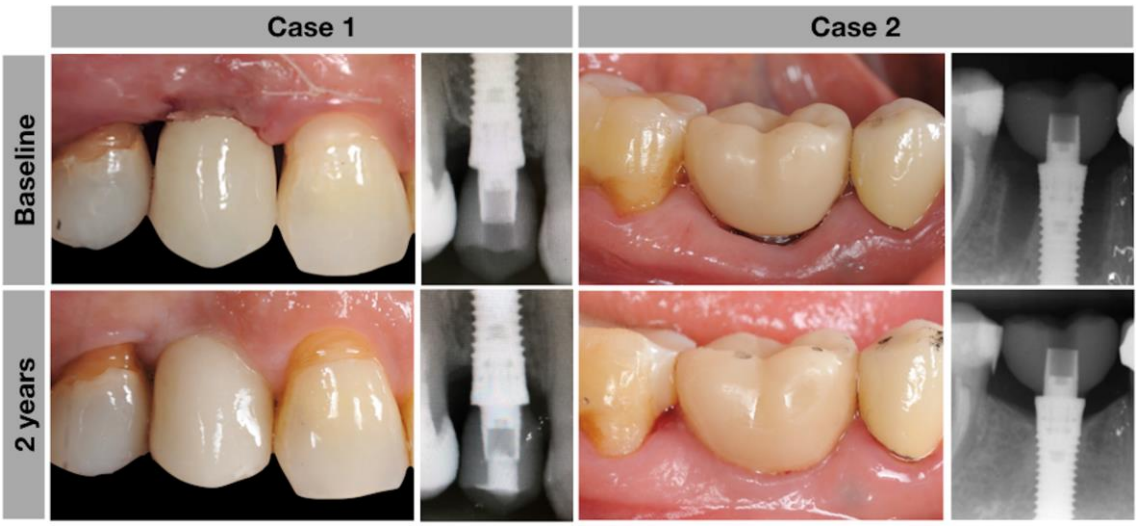
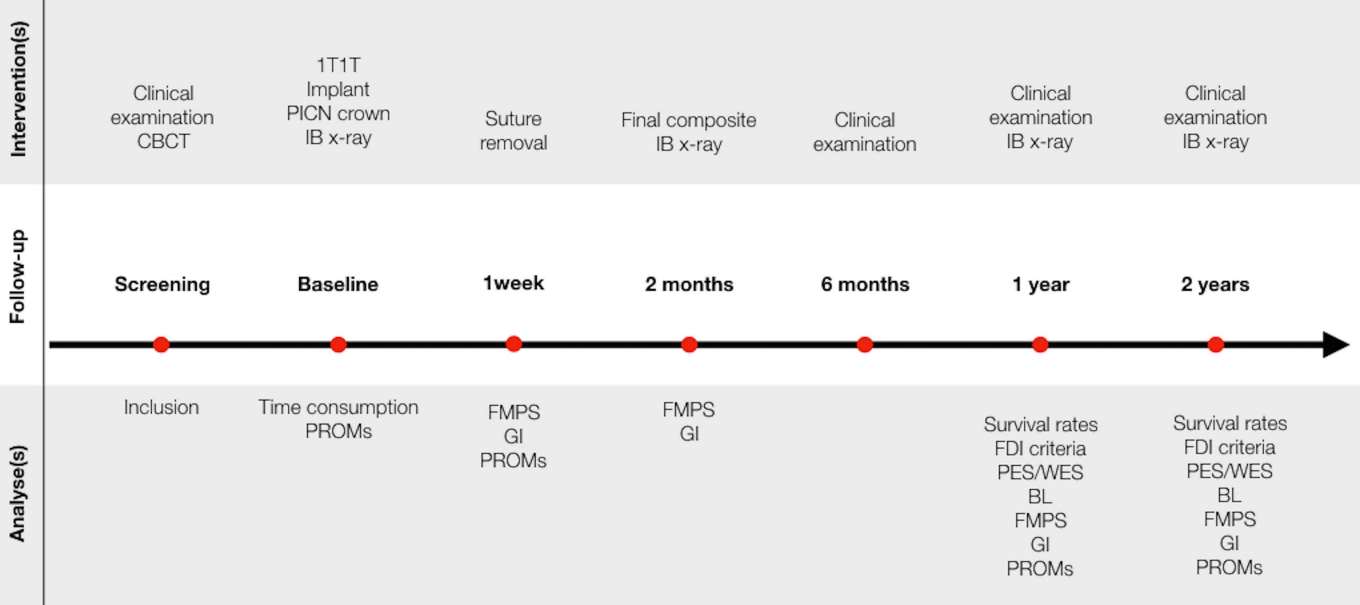
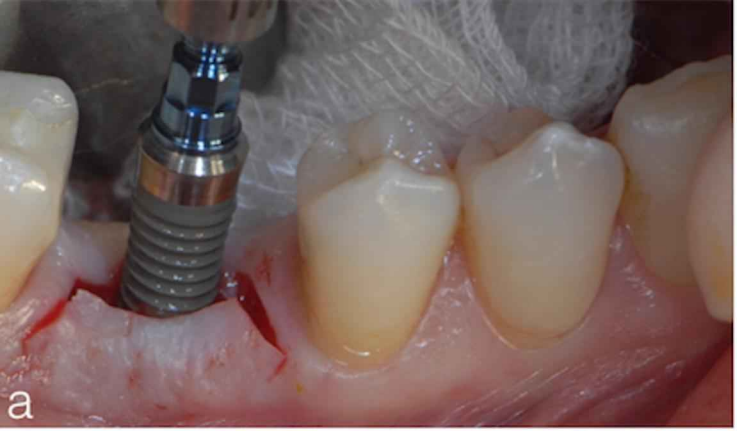


Figure 4 In these two cases, PICN crowns placed with the 1T1T protocol at baseline and two-year follow-up. We note the improvement of the peri-implant soft-tissue contours over time as well as an acceptable peri-implant bone-level stability from baseline to two years.


Intervention(s)
Clinical examination CBCT
1T1T Implant PICN crown IB x-ray
Suture removal
Final composite IB x-ray
Clinical examination
Clinical examination IB x-ray
Clinical examination IB x-ray
Follow-up
Screening
Baseline
1week
2 months
6 months
1 year
2 years
Analyse(s)
Inclusion
Time consumption PROMs
FMPS GI PROMs
FMPS GI
Survival rates FDI criteria PES/WES BL FMPS GI PROMs
Survival rates FDI criteria PES/WES BL FMPS GI PROMs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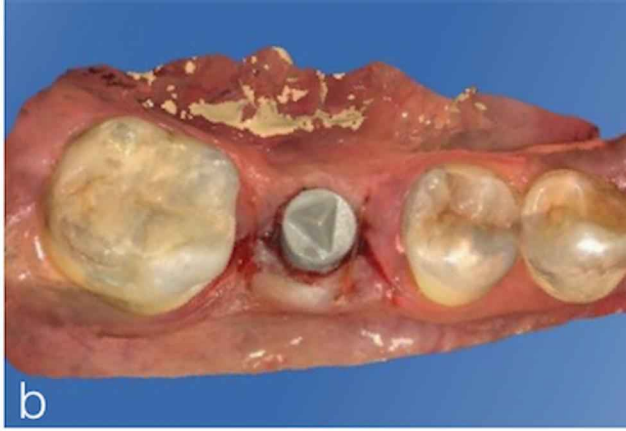
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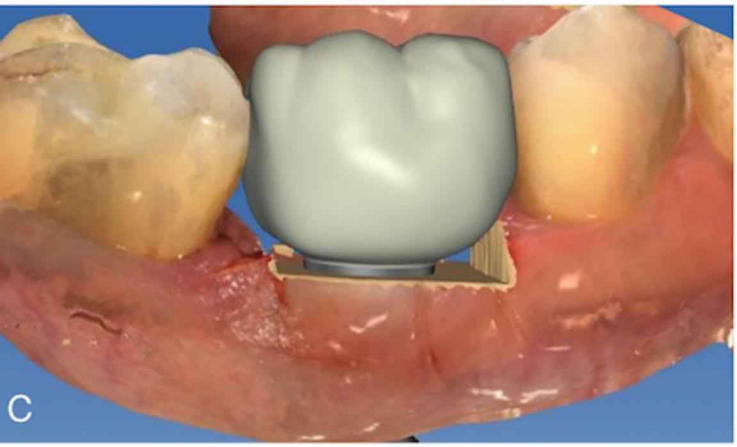
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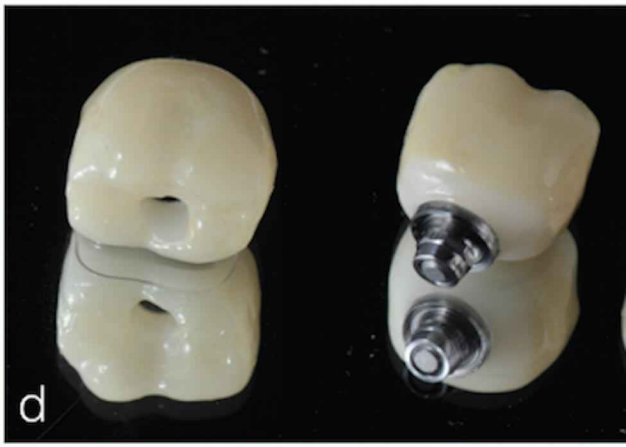
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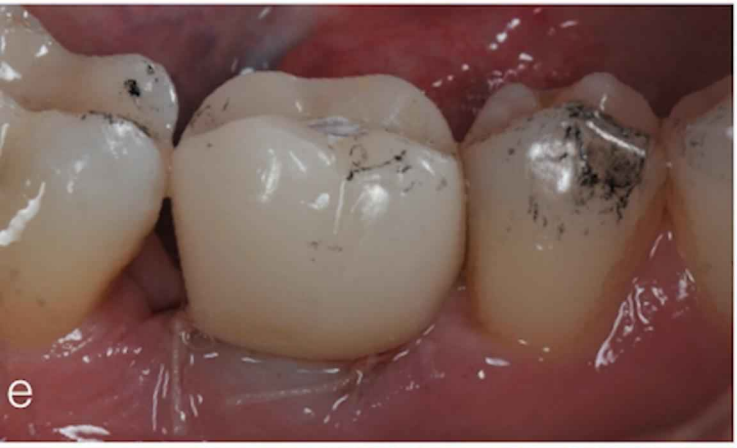
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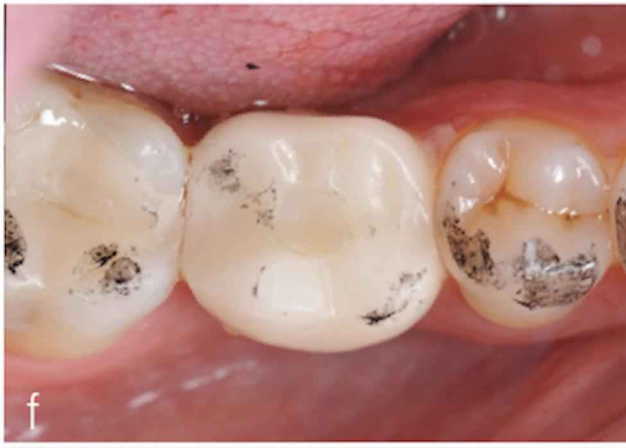
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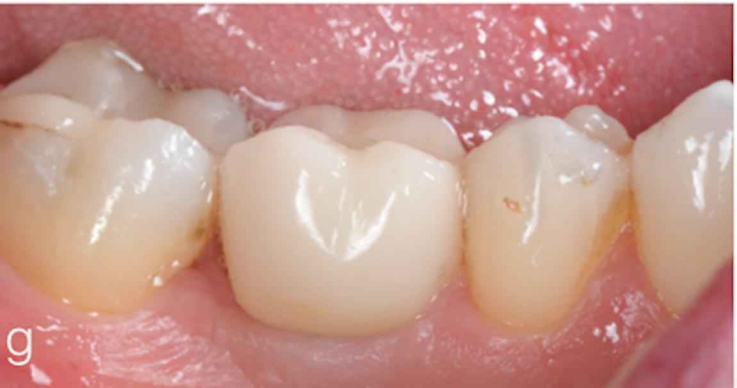
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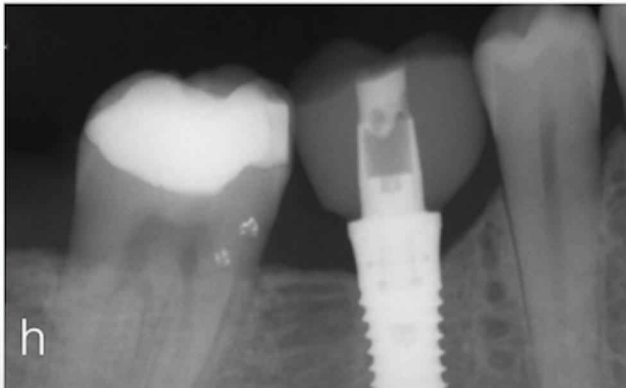
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