

Article

Implant-Prosthetic Rehabilitation of the Agenesis of Maxillary Lateral Incisors: A 2-Year Prospective Clinical Study with Full Digital Workflow

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Abstract: The main objectives of the present prospective clinical study were to evaluate the survival and success rates of implant-supported zirconia single crowns fabricated with a full digital workflow for the rehabilitation of mono- and bilateral agenesis of maxillary lateral incisors after 2 years of clinical function; biological and technical parameters affecting the prosthetic restorations were recorded, as well as the patient-satisfaction score. Twenty-two patients showing mono- or bilateral agenesis of the maxillary lateral incisors were included in this study, and a total of 30 narrow-diameter implants were inserted. Thirty screw-retained monolithic cubic zirconia single crowns with internal connections were fabricated. Objective outcome evaluations were performed by means of the Functional Implant Prosthodontic Score, whereas the patient-satisfaction score was evaluated using Visual Analog Scales. Descriptive statistics were performed and the Kaplan–Meier analysis was run to analyze time-to-event data. After 2 years of clinical function, the overall FIPS found in the present study was 9.2, whereas the average patient-satisfaction score was 8.7. The Kaplan–Meier analysis at the 2-year follow-up reported a cumulative survival rate of 100% and a cumulative success rate of 93.3%. The implant-prosthetic rehabilitation with a full digital workflow proved to be an effective and reliable procedure for the functional and aesthetic treatment of the agenesis of maxillary lateral incisors in the short-term. Clinical investigations with wider sample populations and longer observational follow-ups could be useful to validate, in the long-term, the clinical outcomes of the present prospective clinical study.

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1. Introduction

Dental agenesis is defined as the absence or failure of formation of a tooth, and permanent maxillary lateral incisors have been reported to be the teeth most likely to be missing [1,2]. This condition can affect the Oral Health Related Quality of Life (OHRQoL) of patients, as it represents peoples' subjective perspectives regarding various experiences and symptoms related to oral functions, aesthetic perceptions, and psychological comfort and self-esteem.

In the literature, the prevalences of maxillary lateral incisor agenesis varied across population on the basis of race and sex [2,3].

This anomaly was reported to be frequently bilateral and often associated with tooth ectopias and/or other abnormal dental conditions, such as smaller or peg-shaped teeth on the contralateral side [2–4].

In particular, smiles showing agenesis of maxillary lateral incisors were ranked as less attractive by patients and laypeople, probably because of anatomical differences between the lateral incisors and canines [5]. The presence of canines, which are more conical, and the absence of lateral incisors, which are smaller and flat-faced, were considered disharmonious aspects that were seen as less pleasant in a smile by evaluators [5]. The lack of maxillary lateral incisors was referred to as a reason of concern to patients for both functional and aesthetic reasons; therefore, several options were proposed for the rehabilitation of this condition [5]. The chosen treatment should be the less invasive option that could satisfy both the functional issues and the aesthetic expectations of patients. Careful interdisciplinary treatment planning is always advisable, keeping in mind that improper patient selection could result in unsatisfactory clinical outcomes [4].

If the deciduous maxillary lateral incisors are present in the arch, then a short-term conservative approach consists of only an esthetic reshaping of the deciduous teeth with composite resins [6]. Alternatively, canine substitution can be performed by carrying out a coronal reshaping and resin composite camouflage of the canine to be transformed in a lateral incisor; however, such a solution may not be completely satisfactory from both the functional and esthetic point of views. Removable partial dentures (RPDs) are usually considered interim restorations whereas more invasive prosthetic approaches are based on adhesive bridges (i.e., Maryland or Rochette bridge), cantilevered restorations, or fixed dental prostheses (metal-ceramic or all-ceramic FDPs) sustained by the central incisor and the canine so as to replace the missing maxillary lateral incisor [7].

Nevertheless, according to the literature, patients seem to prefer an interdisciplinary treatment based on an orthodontic approach to close the edentulous space or conversely to open it and carry out an implant-prosthetic treatment, as no tooth preparation is required [8,9]; these can be considered the most conservative and widespread treatments [10], and the present study focused on this specific treatment option.

As regards implant-prosthetic treatment, narrow-diameter implants were found to be comparable to standard fixtures in the anterior zone, with users reporting satisfactory cumulative success rates ranging from 84.2% to 100% (mean: 95.2%) [11–13]. Implant-prosthetic rehabilitations can be performed by means of either conventional or digital workflows.

The use of a digital workflow in daily dental practice is increasing, allowing clinicians to optimize chair time and, simultaneously, improving the patients' comfort and compliance [14–17]. A full digital workflow involves several aspects such as 3D radiographic acquisition, optical impressions by means of intraoral scanners (IOSs), digital smile planning and CAD-CAM fabrication of the prostheses by means of milling or 3D printing. Nowadays, the advantages of digital technologies are well known, including offering a 3D pre-visualization and planning of the region of interest and reducing working time, according to the skill and experience of clinical operators [14–16]. Patients seem to prefer optical impressions, in terms of anxiety, nausea, taste, and discomfort related to the conventional impression-taking procedure. Furthermore, the digital workflow allows the avoidance of possible distortions associated with conventional impression materials, offering the possibility to re-scan a defective area with better acceptance by patients [14–17].

Recent investigations reported satisfactory clinical outcomes in esthetic areas when implant-prosthetic rehabilitations were carried out following a digital workflow, although more clinical prospective studies are needed to establish valid protocols [18–20].

The present prospective clinical study was designed to evaluate the 2-year survival and success rates of implant-supported zirconia single crowns produced with a digital workflow for the rehabilitation of mono- and bilateral agenesis of maxillary lateral incisors. Biological (i.e., marginal bone levels and peri-implant soft-tissue conditions) and

technical parameters (i.e., mechanical complications) possibly affecting the prosthetic restorations were recorded, as well as the patients' satisfaction scores.

2. Materials and Methods

The present study was designed as a 2-year prospective clinical study, following the international guidelines STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) and respecting the Declaration of Helsinki (2013) or comparable ethical standards reviewed and approved by the hosting institution. Digital data collected from patients were protected by means of a password and the access was limited to clinicians who performed the present study. This study was performed by expert prosthodontists from the Scientific Unit of Digital Dentistry (SUDD) at the Department of Prosthodontics of the University "Federico II" of Napoli (Italy) and was authorized by the Institutional Review Board of the University "Federico II".

The recruitment of patients was carried out between April and June 2020 according to the following inclusion criteria established by the literature for implant-supported prostheses:

- minimum age: 18 years (proven completion of facial growth);
- single edentulous space (mono- or bilateral agenesis of maxillary lateral incisors);
- presence of at least 10 pairs of opposing teeth;
- intact adjacent teeth, restored with functionally and esthetically congruous reconstructions or restored with prostheses precluding the possibility of adding missing teeth;
- refusal of alternative treatments (i.e., canine replacement, removable prosthesis, adhesive prosthesis, conventional or cantilevered fixed dental prostheses).

In addition, the following exclusion criteria were used:

- symptomatic temporo-mandibular dysfunctions;
- inability to undergo surgical procedures;
- pregnancy or breastfeeding;
- abuse of medication and/or drugs;
- psychosis and/or dysmorphophobia;
- unachievable esthetic expectations;
- poor bone quantity and/or quality (i.e., D3 or D4) or unsatisfactory conditions of the implant site (as highlighted by clinical and X-ray examinations);
- bone volume in the implant site not sufficient to position a 3.3 mm × 10 mm narrow-diameter implant;
- mouth opening and/or space between the dental arches insufficient for implant components (>4 cm);
- incomplete facial growth and/or tooth eruption.

Subjects recruited for this study had to meet all of the inclusion criteria; the meeting of one or more exclusion criteria made the subject not suitable for this study population. The included subjects received exhaustive explanations about treatment risks, therapeutic alternatives, and study aims and design; they expressed their willingness to participate by signing a written informed consent form.

This study was performed according to the following timeline:

- 0–3 months: patient recruitment;
- 4–10 months: periodontal and orthodontic preparation (if necessary) and implant surgery;
- 11–12 months: prosthetic finalization and baseline control (T0);
- 24 months: 1-year follow-up;
- 36 months: 2-year follow-up.

Based on the inclusion and exclusion criteria, 22 patients were recruited for the present study (15 women and 7 men), aged between 18 and 37 years.

Of the subjects recruited for this study, 14 presented monolateral agenesis whereas 8 showed bilateral agenesis of the maxillary lateral incisors (Figure 1).



Figure 1. Pre-operative intraoral view.

Once recruited for this study, the patients underwent periodontal preparation through professional oral hygiene and motivation to maintain correct oral hygiene at home with the help of a dental hygienist. According to the interdisciplinary treatment plan, 9 patients underwent orthodontic therapy preparatory to implant surgery. At the end of the periodontal and/or orthodontic preparation, the local anatomical conditions were carefully re-evaluated before proceeding with the surgical placement of the implants.

The surgical and prosthetic planning of the cases were carried out after acquiring the volumes of the loco-regional anatomy by means of 3D CBCT radiographs and detecting the morphology of the dental and mucous tissues adjacent to the implant site by means of intraoral digital optical scans with an IOS system (Trios 4, 3Shape, Copenhagen, Denmark). The relative DICOM and STL files were imported into specific software that allowed us to superimpose the digital images, obtaining high fidelity 3D models. These models were used to create printed surgical templates for the guided surgical positioning of non-submerged implants.

Thirty non-submerged implants with a narrow diameter of 3.3 mm and a length of 10 mm (NC Bone Level, Straumann, Basel, Switzerland) were inserted by the same experienced oral surgeon. Peri-implant-tissue profile designers (Iphysio, LYRA ETK, Salanches, France) were used as healing abutments to provide an initial peripheral conditioning of the transmucosal path (Figures 2 and 3).



Figure 2. Buccal view of profile designers used as healing abutments and scan bodies for digital impression making with IOS to fabricate the temporary prostheses.

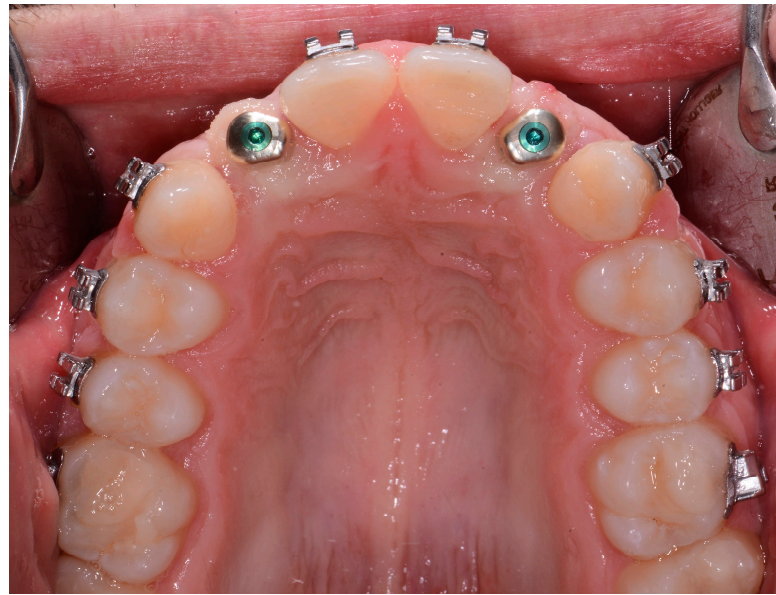


Figure 3. Occlusal view of profile designers used as healing abutments and scan bodies for digital impression making with IOS to fabricate the temporary prostheses.

Depending on the surgical procedures performed and the local conditions of each case, the healing and osseointegration period lasted from 3 to 6 months before proceeding to the prosthetic rehabilitation.

After the healing period, proper osseointegration was checked by means of either clinical and radiographic examinations; individual X-ray trays were made for each implant site to standardize radiographic examinations, and they were used in the same position at each follow-up appointment.

The same experienced prosthodontist performed all of the prosthetic procedures. The same profile designers that were employed as healing abutments were used as scan bodies to make digital impressions by means of an IOS system (Figure 4).

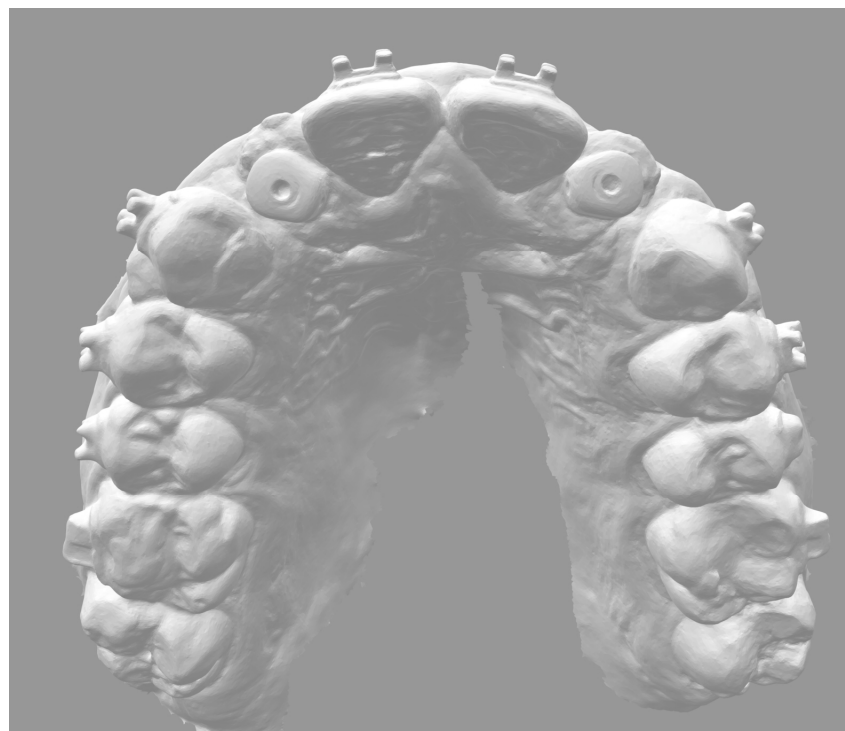


Figure 4. Digital scanning performed using profile designers.

By means of CAD-CAM manufacturing, temporary screw-retained single crowns in polymethylmetacrylate (PMMA) were fabricated to test occlusion, esthetics, and phonetics and to customize the peri-implant emergence profiles. When necessary, the temporary restorations were modified by relining with composite resin, in order to optimize the 3D morphology of the transmucosal path and obtain an optimal emergence profile of the restorations. After achieving proper shape and volume of the transmucosal paths and waiting for the maturation and stabilization of peri-implant soft tissues, the triple scan technique (i.e., temporary in situ, temporary extraoral, scanbody) was used for final digital impression making with an IOS system as previously described, in order to detect both the 3D position of the implant and the architecture of the soft tissues as conditioned by the morphology of the temporary prosthesis (Figures 5 and 6).



Figure 5. Occlusal view of peri-implant emergence profiles conditioned by means of screw-retained temporary single crowns.



Figure 6. Buccal view of scan bodies for digital impression making with IOS to fabricate the final prostheses.

As for the temporary prostheses, CAD-CAM manufacturing was used to fabricate 30 monolithic cubic zirconia crowns (5Y-TZP; GC Initial Zirconia Disks, GC Co., Tokyo, Japan) that were cemented onto screw-retained implant Ti-bases with internal connection. Micro-layering with veneering ceramics was made only onto the buccal surfaces, leaving all of the functional areas (i.e., transmucosal, interproximal, palatal, and incisal) in polished zirconia, in order to promote epithelial attachment and avoid any possible chipping (Figure 7).



Figure 7. Final screw-retained zirconia single crowns.

The restorations were tried on intraorally, carefully verifying the occlusal and interproximal contacts as well as the coupling of the implant-prosthetic components using standardized intraoral radiographs. After possible occlusal adjustments, the final crowns were screwed onto the implants with a torque wrench at 25 Ncm and the screw channels were sealed with teflon tapes and resin composites (Figures 8 and 9).



Figure 8. Post-operative intraoral view.



Figure 9. Post-operative extraoral view.

At the baseline and follow-up assessments, the levels of the marginal bone tissues were recorded clinically by means of peri-implant probing with plastic periodontal probes in order to damage neither the zirconia of the prosthetic crowns nor the titanium of the implant necks; moreover, standardized periapical radiographs were taken as previously described to record the marginal bone levels radiographically (Figure 10) and to use software allowing overlapping of the radiographic images and collection of the relative measurements over time.

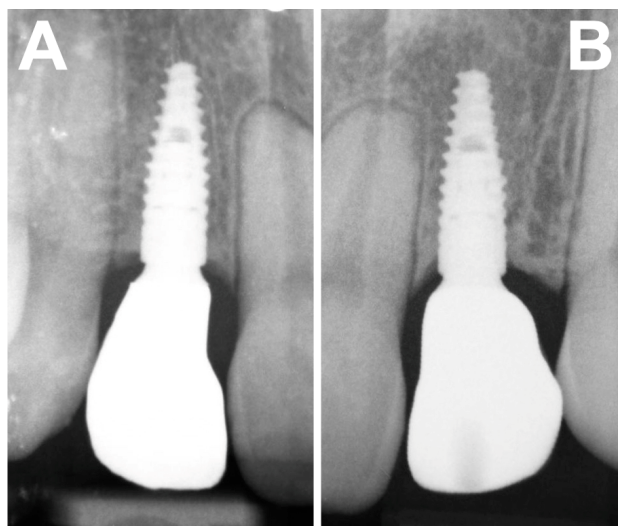


Figure 10. Standardized periapical radiographs in a case of bilateral agenesis at the baseline. (A) tooth 12 and (B) tooth 22.

The conditions of the peri-implant soft tissues were evaluated qualitatively and quantitatively from a clinical point of view by the same expert periodontist.

Any possible mechanical or biological complications affecting implants, crowns, or peri-implant tissues were recorded. The clinical variables affecting the outcome of restorations were subjected to an objective evaluation by means of the Functional Implant Prosthodontic Score (FIPS) [21]. This score can vary from 0 to 10, attributing a numerical value from 0 (worst) to 2 (best) to 5 clinical parameters as follows (Table 1):

- interproximal conditions (contact areas and papillae);
- occlusion (static and dynamic);
- appearance of the crown (margin and color);
- peri-implant soft tissues (quantity and quality);
- marginal bone tissue (radiographic evaluation).

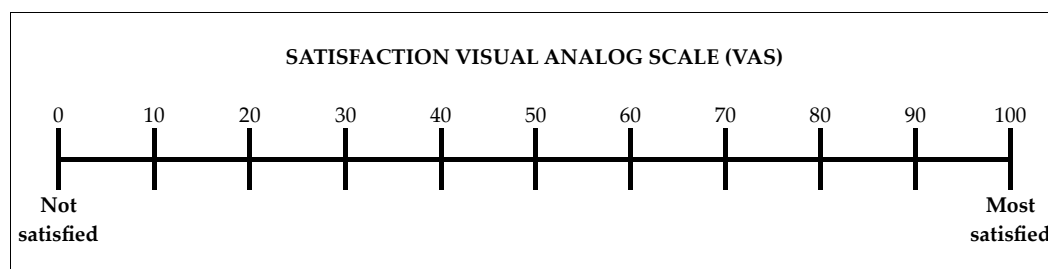
Table 1. Variables for the objective evaluation of FIPS (Functional Implant Prosthodontic Score) [21].

Variable	0	1	2
Interproximal conditions (contact areas and papillae)	Major discrepancies (2x incomplete)	Minor discrepancies (1x incomplete)	No discrepancy (2x complete)
Occlusion (static and dynamic)	Major discrepancies (precontact)	Minor discrepancies (infraocclusion)	No discrepancy
Appearance of the crown (margin and color)	Major discrepancies (margin)	Minor discrepancies (color)	No discrepancy
Peri-implant soft tissues (quantity and quality)	Non-keratinized, non-adherent	Non-keratinized, adherent	Keratinized, adherent
Marginal bone tissue (RX)	Marginal resorption > 1.5 mm	Marginal resorption < 1.5 mm	No marginal resorption

Furthermore, the above-mentioned clinical variables were subjectively evaluated by patients using Visual Analog Scales (VASs) to rank the degree of patients' satisfaction [22]; such scales allowed patients to express an opinion on the clinical experience and satisfaction with the restorations received, expressing a vote from 0 (worst) to 10 (best) (Table 2).

Data produced using the VAS and FIPS scales were collected by the same expert prosthodontist and periodontist who performed this study.

Table 2. VAS scale for the subjective assessment of the degree of patients' satisfaction.



Patients were monitored for a minimum follow-up period of 24 months; controls were performed at T0, 7 days, 1 month, 3 months, 6 months, 1 year and 2 years.

The recordings of the study variables using FIPS and VASs were carried out at T0 and at the periodic follow-up controls at 1 and 2 years. The values obtained were statistically analyzed and cumulative 2-year survival and success rates were calculated according to the Kaplan–Meier analysis. Two independent curves were analyzed separately. Dedicated software (SPSS 17, SPSS Inc., Chicago, IL, USA) was used to perform statistical analyses.

3. Results

Twenty-two patients were recruited and a total of 30 narrow-diameter implants were inserted. Osseointegration was achieved for all of the implants. At 1- and 2-year follow-ups, non-significant values of marginal bone resorption were found for the implants and optimal qualitative and quantitative conditions of the peri-implant soft tissues were reported.

After 2 years of clinical function, the average recorded FIPS was 9.2 in bilateral agenesis (Table 3) and 9.3 in monolateral agenesis (Table 4), respectively. The overall average FIPS found in the present study was 9.2, showing an optimal functional and esthetic integration of the prosthetic restorations as well as a fully satisfactory short-term stability.

As regards the subjective evaluation of patients, both the function and esthetics of the restorations were considered fully satisfactory; in particular, the following scores were reported according to the VASs evaluation, with an average patient-satisfaction score of 8.7:

- score from 0 to 5: 0 restorations
- score 6: 1 restoration
- score 7: 3 restorations
- score 8: 8 restorations
- score 9: 9 restorations
- score 10: 9 restorations

Table 3. FIPS of restorations of patients affected by bilateral agenesis.

#	INTER PROXIMAL	OCCCLUSION	DESIGN	MUCOSA	BONE	TOTAL
1a	2	2	2	2	2	10
1b	2	2	2	2	2	10
2a	1	1	2	2	2	8
2b	2	1	2	2	2	9
3a	2	2	2	2	2	10
3b	2	2	1	2	1	8
4a	2	2	2	1	2	9
4b	2	2	2	2	2	10
5a	2	1	2	2	2	9
5b	2	2	2	2	2	10
6a	2	2	2	1	1	8
6b	1	2	2	1	1	7
7a	2	2	2	2	2	10
7b	2	2	2	2	2	10
8a	2	2	1	2	2	9
8b	2	2	2	2	2	10

Table 4. FIPS of restorations of patients affected by monolateral agenesis.

#	INTER PROXIMAL	OCCCLUSION	DESIGN	MUCOSA	BONE	TOTAL
9	2	2	2	2	2	10
10	1	2	2	2	2	9
11	2	1	2	2	2	9
12	2	2	1	2	2	9
13	2	2	2	2	2	10
14	2	2	2	0	1	7
15	2	2	2	2	2	10
16	2	1	2	1	2	8
17	2	2	2	2	2	10
18	2	2	2	2	2	10
19	2	2	2	2	2	10
20	2	2	1	2	2	9
21	2	2	2	2	2	10
22	2	2	2	2	1	9

As regards the survival (i.e., permanence in the oral cavity even in the presence of minor complications that do not compromise function) and success (i.e., permanence as delivered in T0) rates of both implants and prosthetic restorations, the Kaplan–Meier analysis at the 2-year follow-up reported a cumulative survival rate of 100% and a cumulative success rate of 93.3% (Figure 11).

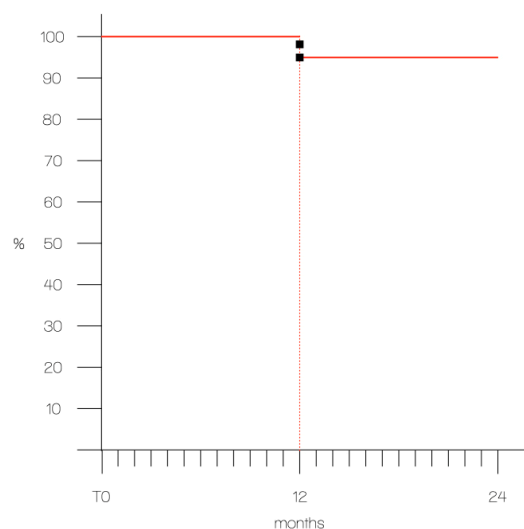


Figure 11. Kaplan–Meier graph showing the cumulative success rate in relation to time.

In particular, after 1 year of clinical function, 1 event of mucositis, and 1 unscrewing of a crown were observed in 2 patients showing bilateral agenesis. No event affected clinical function; the mucositis was resolved, motivating the patient to increase oral hygiene at home, whereas the unscrewing was treated by tightening the restoration again at 25 Ncm.

Both of these drawbacks occurred in patients who did not undergo any orthodontic preparation. Consequently, cumulative survival and success rates of 100% were recorded in orthodontic patients, whereas cumulative survival and success rates of 100% and 93.3%, respectively were recorded in non-orthodontic patients.

4. Discussion

The treatment of maxillary lateral incisor agenesis often requires an interdisciplinary approach. In particular, the implant-prosthetic rehabilitation of this condition is sometimes preceded by an orthodontic treatment that allows patients to achieve the proper surgical space to place an implant and obtain the best functional and esthetic outcomes. Furthermore, the implant-prosthetic approach offers a good cost/benefit ratio and is considered biologically conservative towards the adjacent teeth.

In the present prospective study, all of the implants achieved osseointegration, showing good marginal bone stability and peri-implant soft-tissue response in the short-term.

Previous studies demonstrated satisfactory results in the medium- and long-term for the implant-prosthetic treatment of maxillary lateral incisor agenesis [23–25]. In particular, high cumulative survival (95.7%) and success rates (87.1%) were reported after 16 years of clinical function for implant-supported, all-ceramic cemented crowns used to restore missing maxillary lateral incisors [24].

Although the implant-prosthetic approach is a well-known treatment option, evidence of screw-retained implant-prosthetic restorations used to rehabilitate maxillary lateral incisor agenesis with a full digital workflow are quite scant in the literature.

In the present prospective clinical study, implant-supported, screw-retained cubic zirconia crowns were used to restore maxillary lateral incisor agenesis, showing optimal function, esthetic integration and, at the same time, reducing the risk of periimplantitis related to cementation.

The data collected in the present short-term prospective study confirmed the feasibility of this treatment option as pointed out by previous investigations [23–25], reporting herein high cumulative survival (100%) and success rates (93.3%).

In addition, the high overall FIPS value of 9.2 supported the results of the descriptive statistics, showing the optimal functional and esthetic integration of the implant-supported zirconia crowns in the short-term. Patients enrolled in the present prospective study evaluated as highly satisfactory the clinical experience and the restorations received, reporting an average patient-satisfaction score of 8.7.

These data are consistent with the good objective evaluations obtained using the FIPS and with the findings from other investigations that demonstrated high levels of patient satisfaction when treating maxillary lateral incisor agenesis with implant-prosthetic restorations [26,27]. The authors expect that several factors, such as proper 3D implant positioning, a conservative design of the surgical flaps, and the correct application of temporary acrylic resin restorations may have played an important role in obtaining this result. Furthermore, the use of a digital workflow, in particular for the optical impression, contributed to the reduction of the discomfort of patients in terms of anxiety, nausea, and taste, which are usually related to conventional impression.

As reported by previous studies, a full digital workflow could reduce treatment time, improving each patient's clinical experience and perception of quality as well as their psychological comfort and compliance with the treatment. Nowadays, patients require convenience-oriented treatment timing with reduced chair time and a shortened number of appointments [28].

From a technical point of view, digital workflows help in simplifying the production process, reducing human intervention and overcoming different manual fabrication steps; furthermore the standardization offered by CAD-CAM technologies could contribute to producing high quality and precise prosthetic restorations [29].

Nevertheless, the present prospective clinical study presented some limitations that have to be considered in the interpretation of the obtained clinical data; in particular, the observational period was limited to the short-term (i.e., 2 years), the study population had a limited number of implant-prosthetic study units (i.e., 30), the study lacked a control group, and there were implicit limitations in the scales used (VAS and FIPS). Furthermore, the literature on this topic is quite scant: the present study aimed to provide preliminary short-term data, in the hope of increasing the number of enrolled patients in the future and providing long-term data. Further long-term clinical studies and a larger sample size would be advisable to corroborate the findings of the present clinical investigation and establish validated protocols.

5. Conclusions

Given the limitations of the present prospective clinical study, in accordance with the obtained results, the following conclusions can be drawn:

- in the 2-year short-term, both implants and zirconia crowns did not show significant technical or biological complications, achieving high survival and success rates;
- in standard clinical conditions, the implant-prosthetic rehabilitation can be considered a viable choice option for the treatment of the agenesis of maxillary lateral incisors.
- as regards the subjective evaluation of patients, both the function and esthetics of the restorations were considered fully satisfactory.
- an interdisciplinary approach to the treatment plan represents an essential pre-requisite for achieving functional and esthetic success.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in this study.

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