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Case Report

A Completely Digital Workflow of an Interim Complete Arch Fixed Implant Prosthesis Using a Novel High-Performance 3D Printed Polymer

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Abstract: The advent of osseointegration has offered a quantum shift in treatment planning patients with missing teeth. Patients with a terminal dentition or edentulous arch have become candidates for a fixed rehabilitation with immediate function. A striking limitation of this modality, however, has been the mechanical failure rate of the reconstructions, especially the interim prostheses. This clinical report describes a completely digital workflow and additive manufacturing of an interim complete arch fixed implant prosthesis, immediately placed after extraction. The prosthesis is supported by four immediately loaded implants on the maxillary arch, using stackable guides and the use of a novel 3D printed high-performance UDMA to improve precision, efficiency, and prosthetic stability.

Keywords: digital workflow; dental implants; novel polymer; prosthetic stability; immediate load; immediate placement; interim prosthesis

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Citation: Sadowsky, S.J.; Stansbury, J.W. A CompletelyDigital Workflow of an Interim Complete Arch Fixed Implant Prosthesis Using a Novel High-Performance 3D Printed Polymer. *Oral* **2023**, *3*, 477–486. https://doi.org/10.3390/oral3040038

Academic Editor: Riccardo Nucera

Received: 5 September 2023
Revised: 26 September 2023
Accepted: 3 October 2023
Published: 9 October 2023

1. Introduction

Since the introduction of osseointegration to North America over 40 years ago, there have been continual permutations in surface modification, applications, diagnostic and treatment workflows, design, materials, as well as manufacturing [1–5]. Despite this progress, the discovery of a high-performance prosthetic material that is economical and efficiently manufactured has eluded the field for the implant restoration of the completely edentulous patient. The lack of long-term prosthetic success in complete arch fixed implant prostheses (CAFIP) is well documented. Purcell et al. evaluated patients with a mandibular complete arch fixed prosthesis opposing a complete denture and noted after 5 years it was 50× times more likely to need posterior tooth replacement than at 2 years and 25% of those prostheses also demonstrated a tooth or veneer fracture [6]. Papaspyridakos et al. reported the cumulative rates for CAFIP free of minor and major technical complications (predominantly wear and fracture, respectively) at 10 years were 8.9% and 30.1% [7]. In an effort to address this chronic maintenance problem, zirconia has been employed with a subtractive manufacturing process. However, there are limitations with this material. It may be cost-prohibitive for the patient, it is difficult to repair, long-term studies are lacking, patients complain of audible sounds on contact, and subtractive manufacturing is more cost and time-intensive compared with additive manufacturing [8–11]. In addition, zirconia cannot be used for the interim prosthesis in the All-on-4 treatment concept, while methyl methacrylate has been reported to be plagued with a 60% fracture rate [12].

In an attempt to find a high-strength 3D-printed photopolymerized polymer for the implant interim prosthesis, urethane dimethacrylates (UDMA) have been loaded with surfactant-modified glass fillers. While hardness and elastic modulus may improve, increased flexural strength and diametral tensile strength were not proportional to filler content [13]. Instead, a novel approach has been to formulate UDMA with acidic and

hydrophobic comonomers, resulting in an extended urethane-urethane hydrogen bonding, favorably affecting polymerization reactivity and mechanical properties [14]. The superiority in flexural strength and elastic modulus compared to conventional, additive and subtractive manufactured polymers is due to the complex based on noncovalent bonds, between the imino groups of UDMA and the carboxyl groups of the acidic monomers [15,16]. It is of note that these critical non-covalent acid-urethane interactions can survive in water (Figure 1). In addition, high-wear resistance of photopolymer was corroborated in an independent study (Figure 2). The polymer has been marketed under the name of Trusana.

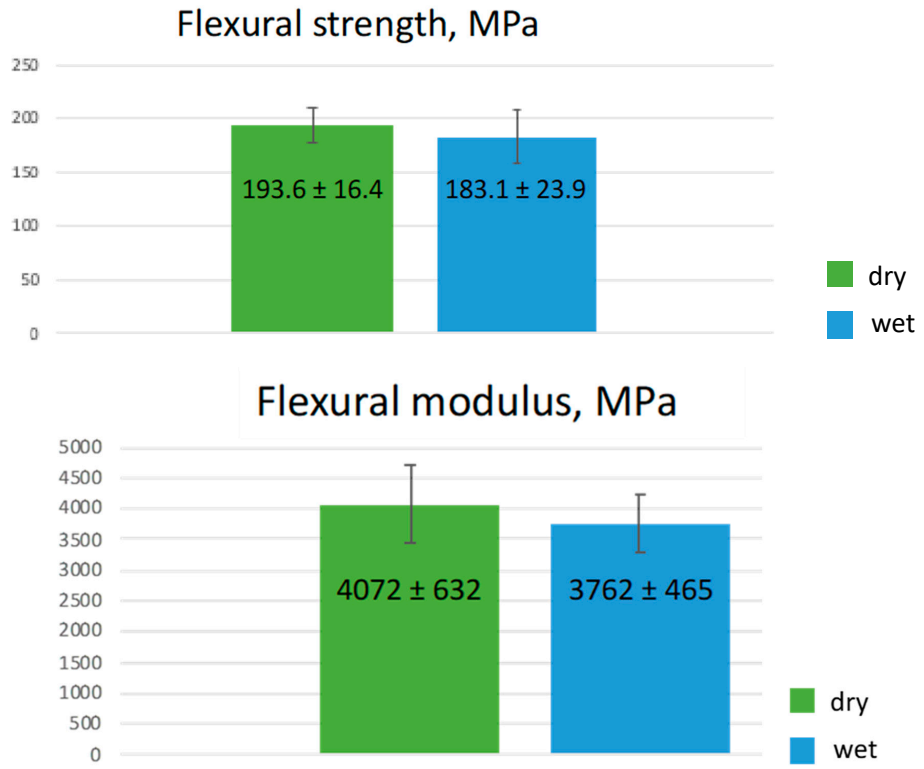


Figure 1. Flexural strength and modulus of Trusana under dry (green) and wet (blue) conditions. Tested by Dr. Jeff Stansbury, Senior Associate Dean for Research, University of Colorado.

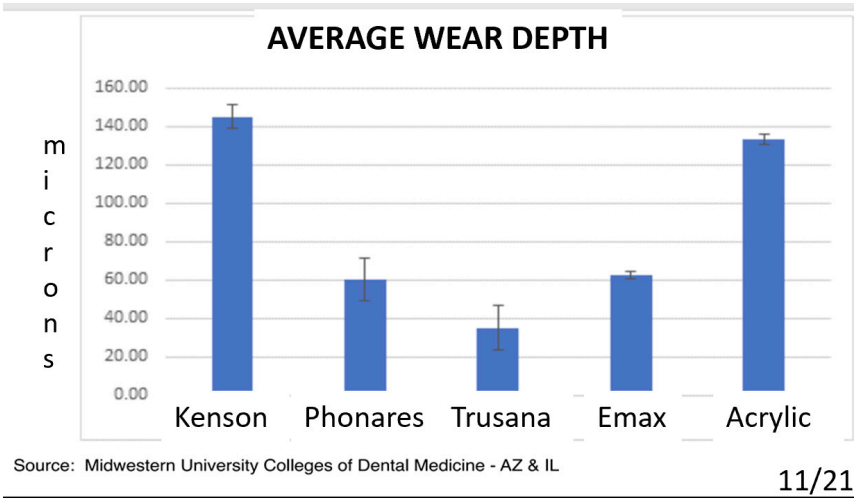


Figure 2. Mean maximum wear depth of Kenson and Phonares II denture teeth, lithium disilicate, and methyl methacrylate compared with Trusana samples. Conducted by Dr. John Mitchell, Associate Dean, Midwestern University using a zirconia antagonist on a Mechatronik Testing System for the Linearly Reciprocating Ball-on-Flat Sliding Wear 30.000 times (ASTM G133-95).

The polymer was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test consisting of L-929 mouse fibroblast cells. This study was conducted following the guidelines of ISO 10993-5, biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity. The test article extract showed no evidence of causing cell lysis or toxicity extract and met the requirements of the test since the grade was less than a grade 2 (Table 1). These in vitro test results completed the requirements, along with comparisons with predicate devices, for FDA compliance for the use of this photopolymer, intraorally. Distribution followed the approval of the Clinical Evaluation Report (Trusana, Schein Dental, Henry Schein, Mellville, NY, USA).

Table 1. Cytotoxicity Test Scoring of Trusana.

Grade	Reactivity	Conditions of All Cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observed.
3	Moderate	Not more than 70% of cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed.
4	Severe	Nearly complete or complete destruction of the cell layers.

This nonclinical laboratory study was conducted in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58.

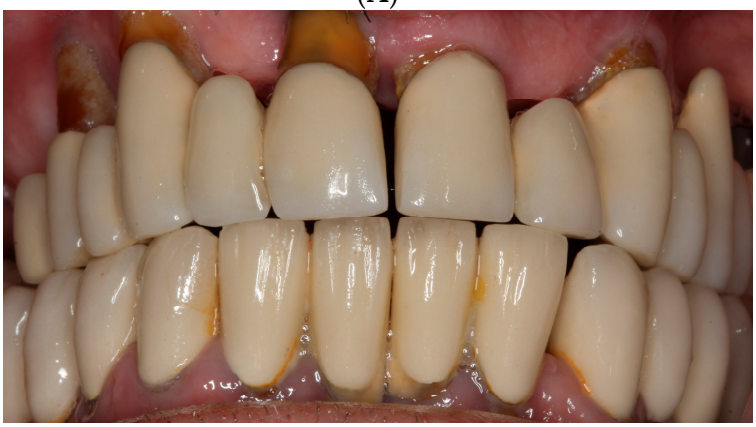
2. Case Report

A 59-year-old male, in excellent health and taking no medications, presented with a chief complaint of discomfort and mobility of his maxillary teeth. A comprehensive extraoral and intraoral examination was conducted (Figure 3A–D). Extraoral examination disclosed sufficient interocclusal space between vertical dimension of rest and occlusion. The patient presented with a Class I skeletal class relationship and was completely restored with porcelain fused to metal crowns and fixed dental prostheses. A complete full mouth series of periapical and bite-wing radiographs was taken (Figure 3E). The patient was assessed to have severe periodontitis on the maxillary arch with Class 3 mobility, and mild to severe periodontitis on the mandibular arch with localized periapical lesions. There were no active carious lesions on the mandibular arch. The patient desired a fixed prosthetic rehabilitation. An immediately loaded CAFIP was recommended after immediate implant placement for the maxillary arch and the risks, benefits and alternatives were elucidated in detail. Long-term follow-up of immediately loaded implants on the maxillary arch up to 15 years, with 90.7% implant survival, was reviewed with the patient [17]. The advantages of immediate versus delayed loading were discussed in terms of facilitating a fixed restoration on day 1 of surgery, and the fact that less marginal bone loss around immediately loaded implants has been recorded over a 6-year follow-up [18]. Immediate placement of implants in the edentulous patient has been shown over a 7-year period to be equally as effective as delayed placement [19]. The patient elected to proceed with an interim CAFIP on the maxilla during osseointegration healing. Scaling and curettage was planned for the mandible, prior to a periodontal reassessment and selective endodontic treatment. The occlusal plane on the mandible was deemed acceptable.

An intraoral scan (CEREC Omnicam, Henry Schein Dental, Melville, NY, USA) and a cone-beam computed tomography of the patient was completed. The Digital Imaging and Communications in Medicine files (DICOM) were merged for diagnostic purposes to facilitate 3 dimensional planning of the implant and prosthesis placement (Figure 4) [20].

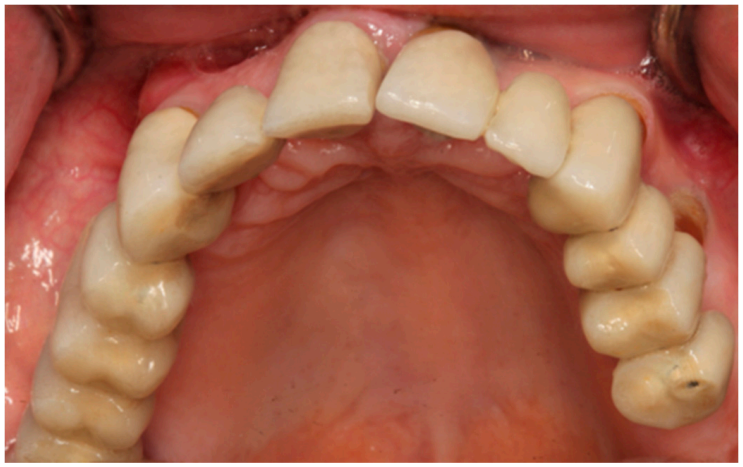
The existing crowns created a template for the position of the implants, mindful of the need for 15 mm interocclusal space for the prosthesis [21]. A Zoom conference was set up for the oral surgeon and prosthodontist to view together the merged files for optimal implant placement considering the bony compartment and restorative constraints. An All-on-4 prototype using Trusana was selected for the interim prosthesis with a shortened dental arch design [22]. The patient desired an occlusal table with at least first molar support in the definitive prosthesis. Sinus augmentation was planned at the time of the initial placement of 4 implants anterior to the antra. Four months after healing, an implant in the first molar site would be placed bilaterally after healing of the graft [23]. A definitive All-on-6 CAFIP will be fabricated with metal reinforcement following four more months of osseointegration in the antra.

(**A**)



(**B**)

Figure 3. *Cont.*



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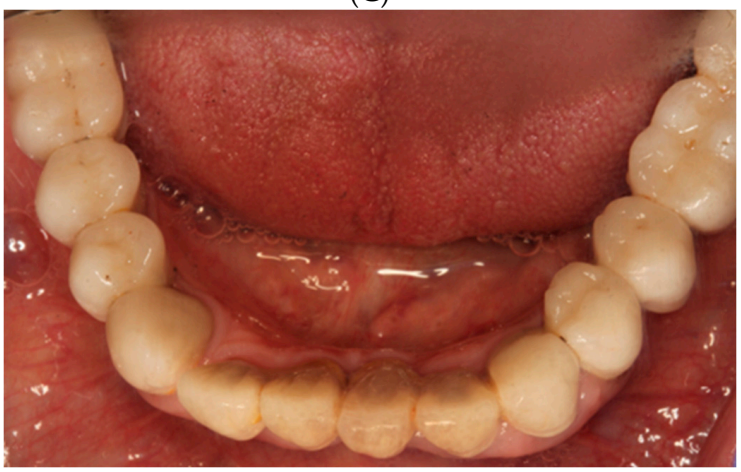

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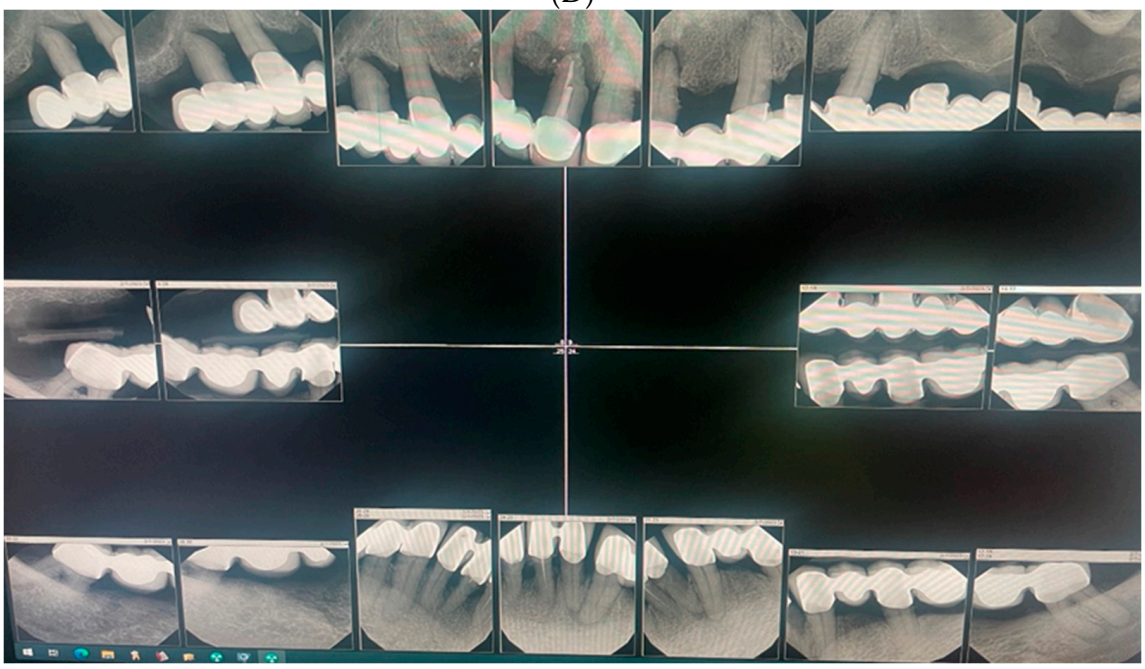

(**E**)

Figure 3. (**A**). Preoperative frontal image. (**B**). Intraoral image of teeth in centric occlusion. (**C**). Occlusal image of maxillary teeth. (**D**). Occlusal image of mandibular teeth. (**E**). Full mouth radiographs.

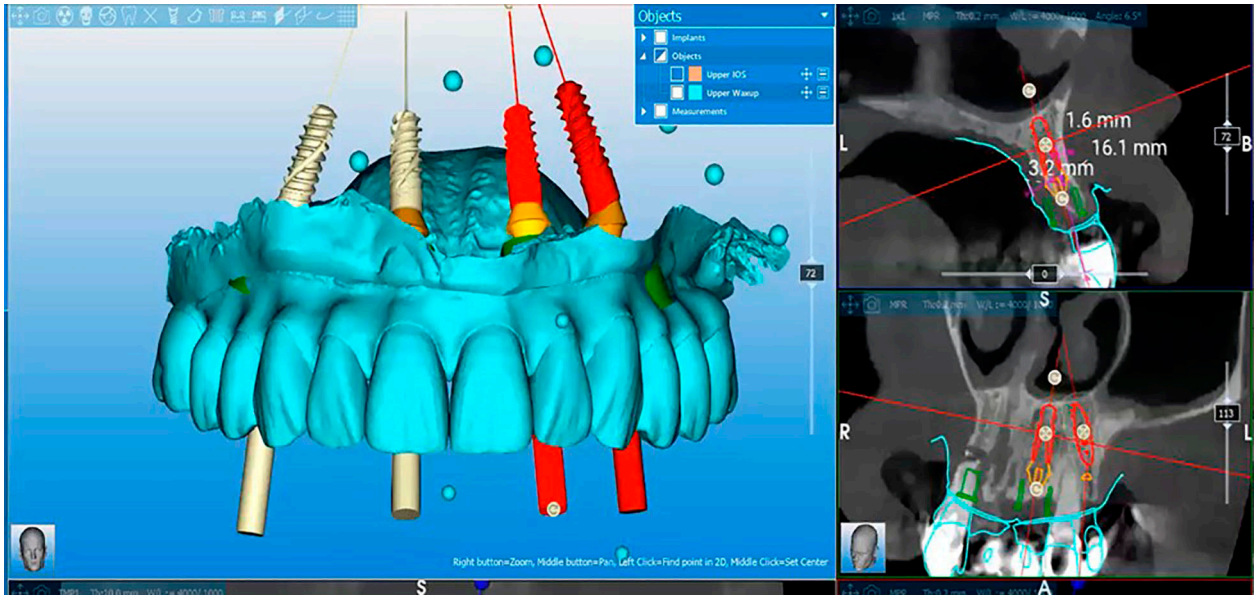

Figure 4. Merged DICOM files from intraoral scan and CBCT (frontal view of prosthetic template).

Additive manufactured stackable guides were fabricated to facilitate a close fidelity between planned and actual osteotomies, as well as position of the prosthesis (Masters Dental Arch, Phoenix, AZ, USA) [24,25]. After administering conscious sedation with Propofol (Fresenius Kabi, Lake Zurich, IL, USA) and local anesthetic intraorally on the maxilla with Marcaine 1:200,000 epinepherine (Pfizer, New York City, NY, USA) and Septocaine 1:100,000 epinepherine (Henry Schein, Melville, NY, USA), using standardized sterile protocols, the maxillary teeth were extracted in preparation for implant placement (Courtesy of Dr. J. Reed Rayher). The foundational guide was referenced to the nasal floor with retentive hooks. This design is preferred when the teeth are mobile and cannot be used reliably for the placement of the three horizontal stabilizing cross pins (Figure 5A). Once the foundational guide was secured, bone reduction of 6 mm was provided based on the spatial requirements of the implant prosthesis. The second interlocking surgical guide directed the placement of 2 narrow platform implants (3.5 mm × 10 mm BLX; Straumann, Basel, Switzerland) in the #8 and #10 position and 2 narrow diameter implants (3.5 mm × 12 mm BLX; Straumann) in the #5 and #12 positions (Figure 5B,C). Before final placement, trajectories of the four implants were evaluated with the prosthetic stackable guide (Figure 5D). Primary stability was achieved in all sites with >35 Ncm. Multi-unit abutments (0^0 for #8, #10; Straumann, 17° for #5, #8; Straumann) were torqued to 35 Ncm. Four non-engaging temporary titanium abutments were placed and torqued to 15 Ncm (Figure 5E). At this juncture, a Caldwell-Luc procedure was performed to place a deproteinized bovine mineral and platelet-rich fibrin in the maxillary sinus, bilaterally [26]. The incisions were sutured, and primary closure was achieved.

A stereolithographic file (STL) was generated from the merged DICOM files detailing the prosthetic design, adding the mortise and tenon attachments for the stackable guide placement (Figure 5F). This prosthesis was fabricated using Trusana UDMA material processed by additive manufacturing with the Asiga Max printer (Kris Schermerhorn, CDT, Northern Virginia Dental Laboratory). The steps involved in the 3D printing process include (a) STL file manipulation, (b) position appliance with occlusal aspect facing build plate at 20° (c) add supports (d) calibrate the printer (e) mix resin (f) commence printing (g) remove build plate and place in isopropyl alcohol bath for 2 min, (h) place in clean bath for 1 min, (i) remove supports and post-cure.

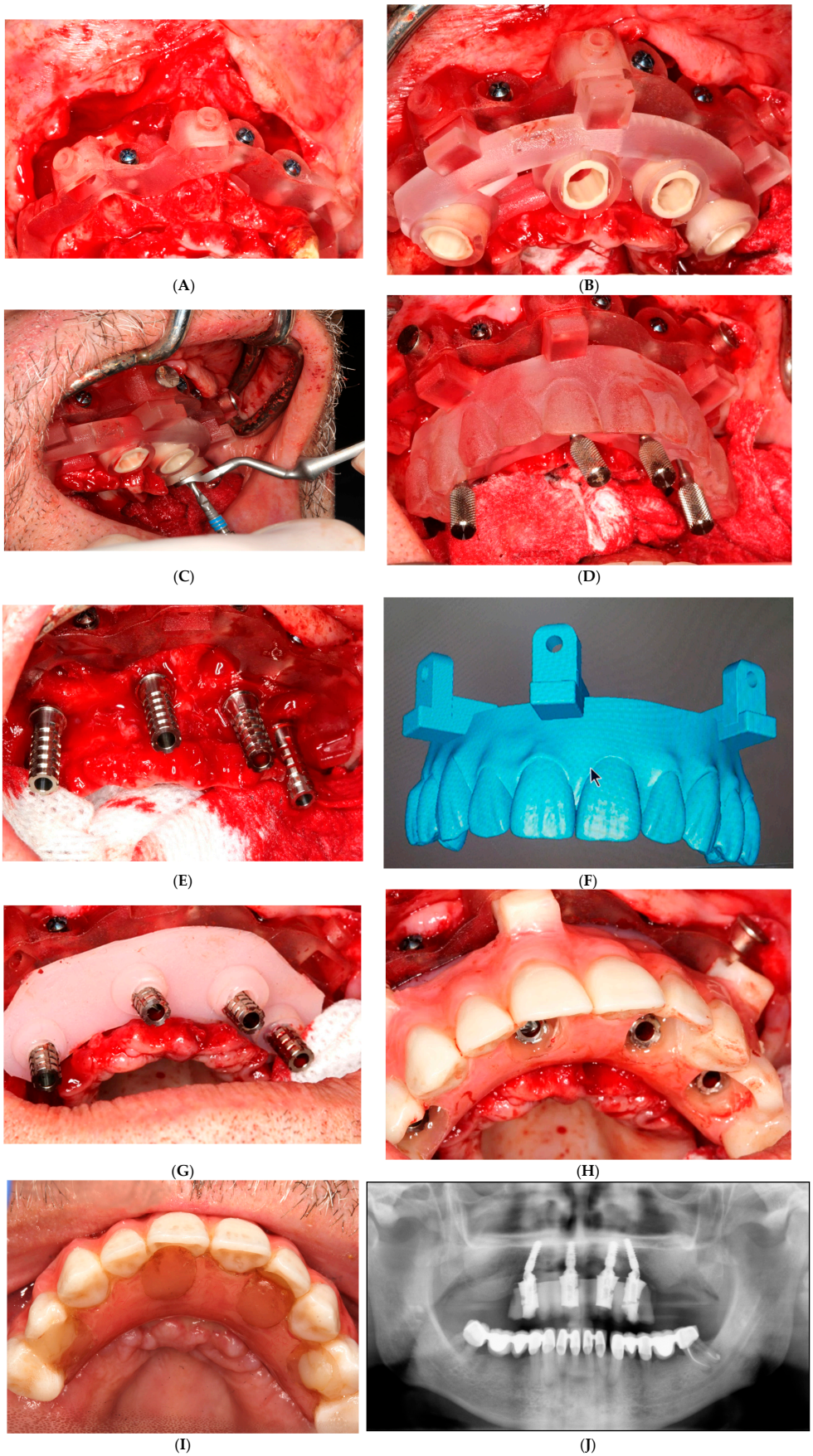

Figure 5. *Cont.*

(**K**)

Figure 5. (**A**). Foundational 3D printed stackable guide engaging the floor of the nose for reference to place 3 cross pins and providing bone reduction guide at inferior border. (**B**). Surgical implant guide placed inferior to foundational guide with mortise and tenon fit. (**C**). Drill handles in place to position the implants. (**D**). Implant trajectories evaluated with stackable prosthetic guide. (**E**). Temporary titanium cylinders in place. (**F**). An STL file of interim prosthesis. (**G**). Silicone barrier placed in preparation for pick-up of prosthesis. (**H**). Luting material placed to engage the titanium temporary cylinders. (**I**). Interim complete arch fixed implant prosthesis. (**J**). Orthopantomogram of interim prosthesis. Note sinus grafting in preparation for implant placement in 4 months. (**K**). Postoperative frontal image.

A silicone barrier was positioned around the temporary abutments (Figure 5G), protecting the soft tissue from the light-polymerized luting material used to attach the interim prosthesis to the titanium cylinders (Chairside Attachment Processing Material; Zest Dental) (Figure 5H). The digitally planned apertures in the interim prosthesis made the conversion to an implant supported prosthesis highly efficient. Once the pick-up was completed, the prosthesis was removed and the mortise and tenon attachments were removed. It was secured intraorally with prosthetic screws at 15 Ncm torque, and teflon tape was placed over the screws and sealed with the Chairside Attachment Processing Material (Figure 5I). A postoperative orthopantomogram was taken demonstrating the position of the 4 implants and xenograft augmentation in the maxillary sinuses (Figure 5J). The patient was pleased with the esthetic and functional result afforded by the interim CAFIP (Figure 5K).

3. Discussion

Full-arch immediate function protocols involving the All-on-4 concept is an invasive surgical procedure but has demonstrated high success rates for both implants and prostheses in a longitudinal follow-up [27]. The synergy of employing a completely digital workflow and a 3D photopolymerizable material with excellent physical properties and wear resistance has offered a seismic change in the durability of the immediately loaded interim CAFIP [28–30]. Merging DICOM files of intraoral scans and CBCTs offers a diagnostic and working template for a digitally generated prosthesis, encouraging a collaborative approach across disciplines. This workflow affords an efficient and economical solution to the limitations of the analogue method. Designing, waxing, and processing a methyl methacrylate interim prosthesis in this way has both, and carries a high maintenance burden. The additive manufacturing of stackable guides has added a level of precision and methodological ease for alveoloplasties, osteotomies, as well as placement and equitable loading of a materially enhanced prosthesis. In addition, the STL file for the interim prosthesis can also be used in planning the definitive CAFIP and for a second interim prosthesis,

if ever needed. The Trusana polymer is also intended for use with titanium reinforcement for the definitive CAFIP.

Branemark's discovery of osseointegration continues to spawn innovative changes to fulfill the promise of a root analogue system that mimics and withstands nature. The literature has revealed the mechanical shortcomings of previous treatment regimens, prompting the need for material advances. The 3D planning and manufacturing of a high-performance polymeric interim CAFIP has indeed added another dimension to rehabilitating our patients with confidence in answer to this unmet need. A limitation of this report is the lack of multiple clinical trials with this novel material. In addition, there are no long-term results. However, its application for an interim CAFIP is intended to demonstrate prosthetic stability for 6 months until the definitive restoration is fabricated. Future research directions should include surface additives for bacterial and fungal inhibition.

4. Conclusions

The implementation of a novel high-performance urethane dimethacrylate polymer with a completely digital workflow is documented for a complete arch implant interim prosthesis to address a long-standing problem of mechanical complications.

5. Patents

Patent US9682018B2 has been filed by the author, in conjunction with Dr. Jeff Stansbury, for this polymer for use in analogue, subtractive and additive manufacturing.

Author Contributions: Conceptualization S.J.S. and J.W.S., Methodology S.J.S., Software S.J.S., Validation S.J.S. and J.W.S. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of University of the Pacific School of Dentistry (IRB 15-41 3).

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

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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