Implant Provisionals Utilizing a Novel Abutment: Assessing Quality, Efficiency and Stability

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***Abstract*—This study assessed the efficacy of a novel cost-effective provisional abutment and technique to fabricate an implant-supported crown, and compared the process to titanium and thermoplastic provisional abutments *in vitro*. Three mandibular and maxillary dentoform casts were fixed onto bone analogues. Dental implants were then placed into the analogues. Thermoplastic, titanium and Tempcap provisional abutments were utilized and a temporary implant-supported crown was fabricated. The quality of the provisional crown, implant stability quotient (ISQ) pre- and post-temporization, and average provisional time were measured. Among the three different abutment methods, Tempcap increased provisional crown quality and reduced the time required to fabricate the provisional crown for mandibular implant sites. Furthermore, the Tempcap group showed the lowest ISQ changes pre- to post-temporization, however differences between abutment groups were not statistically significant. Provisional crowns utilizing the Tempcap abutment could be potentially efficient in increasing provisional quality, reducing fabrication time, and minimizing changes in implant stability pre- to post-fabrication. Further investigation is necessary to assess the clinical relevance of the Tempcap abutment.**

***Keywords*— Clinical implantology, medical device, provisional prostheses.**

I. INTRODUCTION

Implant-supported restorations are a well-recognized esthetic and functional solution for partially edentulous patients [1],[2]. In the interim phase of treatment, provisional restorations are used to restore gingival health [2],[3], while providing psychological benefits to the patient [1]. Despite these advantages, the use of provisional abutments can present a challenging situation. With high potential for clinical failure [2],[4],[5] and a demand for optimal esthetics [6], considerable scientific interest has been focused on refining the components and processes for predictable implant provisionals.

A number of biomechanical and biological factors contribute to the success of implants [2],[7],[8]. Studies suggests that implant survival is dependent on the existing quality and quantity of host bone [2],[8],[9], minimizing the forces exerted on the implant body [6], meticulously managing the gingival architecture to prevent contamination of the surgical site [10] and allowing sufficient time for the process of osseointegration [11]. The latter, defined as the structural and functional connection between bone and the surface of a load-carrying implant [12], is underscored as the primary measure of implant stability and implant success [8],[9],[13].

Although many factors influence osseointegration, implant design is particularly important in determining the success of an implant [2], [7], [14], [15]. Literature suggests that reducing the magnitude of stress between bone and implant has a significant impact on the healing of soft tissue. This is related to the remodeling of the gingival architecture according to the implant's capacity to withstand functional loading [2], [15]. Despite this knowledge, Cho and colleagues [14] report that

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many marketed provisional prostheses apply external stressors that initiate soft-tissue inflammation and inhibit osseointegration. Removable partial denture or flipper provisionals, that are not properly fabricated, can induce undesired pressure on the healing cap/cover screw and/or implant body. This approach also involves additional costs, and may result in poor patient acceptance due to bulkiness and speech impediments. Similarly, use of conventional provisional abutments (titanium/thermoplastic) could compromise the success of the implant surgery and overall success. Preparation of a thermoplastic (Peek) abutment transfers micro-vibrations and heat to the implant body. The intraoral preparation of the acrylic abutment may also contaminate the surgical field, increasing the risk of post-surgical infections. In both cases, the frequency of bond failure remains relatively high [14].

Research Driven Inc. (Ontario, Canada) has developed a novel abutment, combining a healing cap/cover screw and provisional abutment, termed the Tempcap (U.S. Patent No. 12/668832, 2016) [16]. This novel abutment and process for temporization addresses the functional, esthetic, and financial disadvantages of many mainstay provisional prosthetics. The titanium construct of Tempcap would allow for optimal gingival healing and sulcus formation around the implant neck, and minimizes the transfer of micro-vibrations and heat associated with the fabrication of plastic abutments. Moreover, sheaths are used to fit the provisional crown, such that shaping and polishing may be performed outside the patient's mouth, minimizing contamination of the surgical field. The pin projections are used to retain the provisional. Emergence profile, marginal fit and occlusion are optimized by unlimited removal and reseating of the provisional. This minimizes the effort and time required to make alterations. Ultimately, the Tempcap may be an alternative for removable prostheses.

This pilot study aims to compare the average provisional quality score, change in the implant stability quotient (ISQ), and temporization time of Tempcap to titanium and thermoplastic abutments. This experiment was conducted using dental implants placed in bone analogous as a simulated exercise. It is hypothesized that the Tempcap abutment and technique will *1*) create a higher quality provisional *2*) provide minimal changes to the ISQ, and *3*) decrease provisional fabrication time.

II. MATERIAL AND METHODS

Neither human nor animal subjects were featured in this study. Therefore, ethics approval was not required due to the *in vitro* design of the study.

Preparation of the Tempcap Abutment

The implant used in this study was a AB dental implant (Ashdod, Israel) made of commercially pure-grade titanium alloy Ti-6A1-4V ELI. The Tempcap abutment (Research Driven Inc., Ontario, Canada) is a titanium healing cap and provisional abutment combined into one unit. Specifically, the Tempcap abutment was fabricated to fit the AB I2 Screw Type Groovy Implant and consists of two to three, 3mm retentive pins projecting from the abutment. Tempcap abutments may be manufactured to be compatible with any dental implant system and existing instrumentation.

Laboratory Procedure

Alginate impressions were taken of dentoforms with a single missing tooth at select sites (tooth numbers: 12, 22, 36, and 46). The impressions were poured with Jade stone (Whip Mix, Louisville, Kentucky). Eight tactile bone analogues (two per bone density) were prepared from oak (D1), pine (D2), balsa (D3), and Styrofoam (D4) (Fig. 1A). D4 was not utilized due to the poor quality of implant stabilization. The casts were fixated to the bone analogues using epoxy cement. Osteotomies were performed on bone analogues according to standard surgical protocols [17] (Fig. 1B).

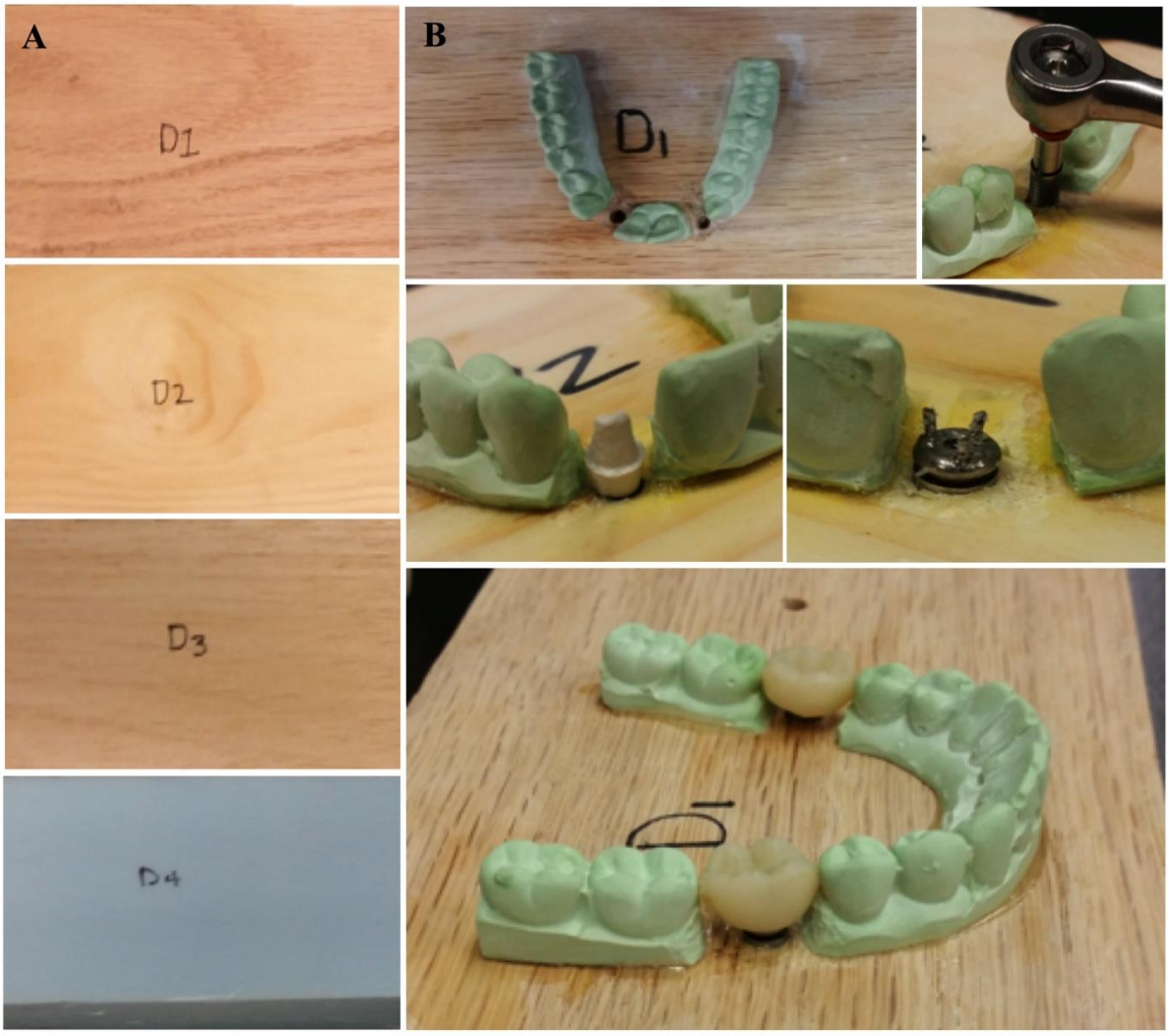

Figure 1.Methodology of the Tempcap abutment. A) Preparation of bone analogues**.** Tactile bone analogues (*n*=8) were prepared from oak wood (D1), pinewood (D2), bulsa wood (D3), and Styrofoam (D4). B) Tempcap and Peek abutment placement on D1 bone analogue in maxillary implant sites. A dentoform cast impression was mounted onto bone analogues and Tempcap and Peek abutments were placed onto implants that were placed following a simulated standard surgical procedure. Styrofoam was eliminated from the study due to poor implant stability

The Tempcap provisional was fabricated by the following technique. Following simulated surgery, the Tempcap (Fig. 2A) was placed into the implant body (Fig. 2B) and tightened to specification with a standard driver (Fig. 2C). Impression sheaths were placed over the retentive pins to allow for the removal and re-seating of the provisional (Fig. 2D). A vinyl polysiloxane (VPS) template was used for temporization and automixedbis-acrylic provisional material, such as Protemp Plus (3M ESPE, Saint Paul, Minnesota), was loaded into the prefabricated VPS impression to create the temporary crown (Fig. 2E). The VPS and dual-cured acrylic material was positioned over the Tempcap abutment and held for 60 s (Fig. 2F). The VPS matrix was then removed, followed by removal of the temporary crown from the VPS matrix. Once out of the oral cavity, the preliminary crown was light-cured for 30s and then shaped and polished (Fig. 2G). The emergence profile, marginal fit, occlusion and esthetics were evaluated by re-seating the crown on the Tempcap. Additional adjustments were made externally. Provisional Temp-Bond cement (Kerr, Orange, California) was applied to the temporary crown (Fig. 2H) and cemented onto the Tempcap abutment (Fig. 2I).

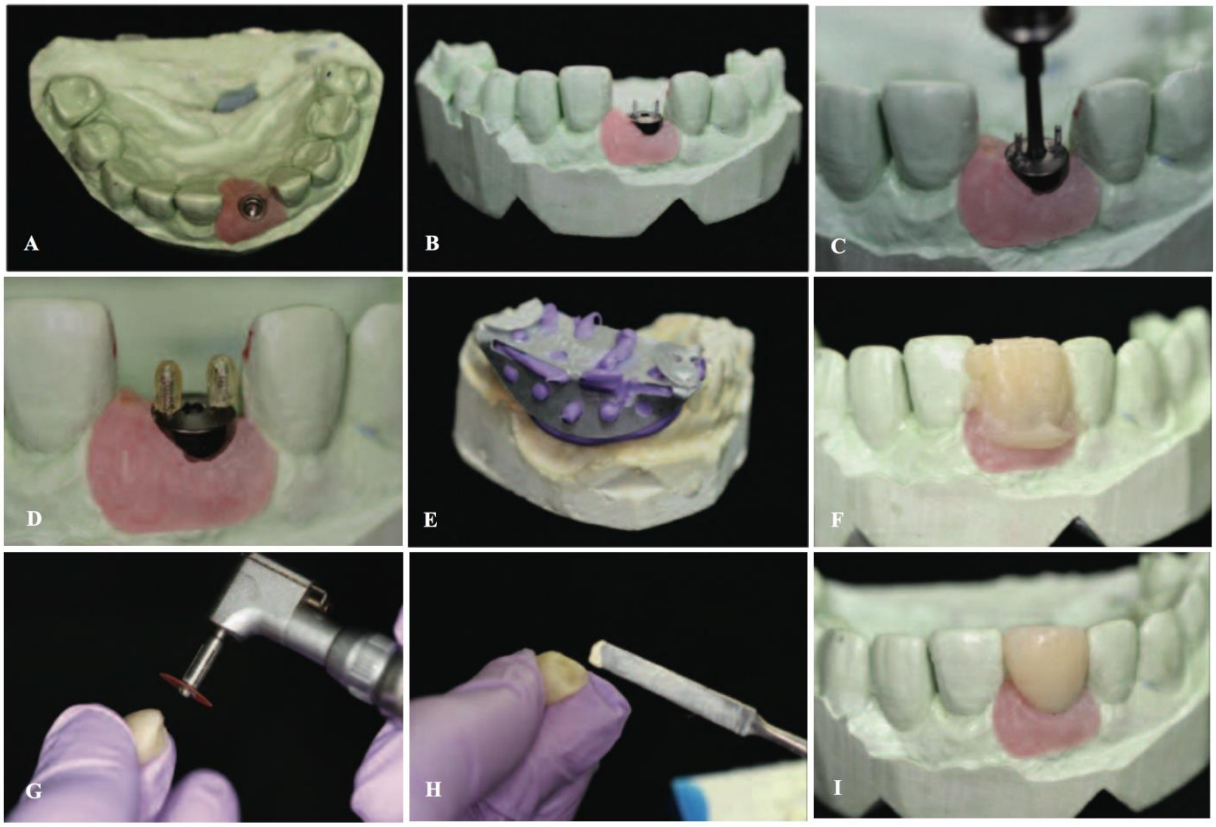

Figure 2.Temporization of the Tempcap abutment into the implant body: A step-wise protocol. A and B) The Tempcap abutment was placed on the master cast and C) tightened with a driver to specification. D) Impression sheaths placed on the retentive pin projections. E) A temporary matrix loaded with bis-acrylic provisional material and placed over the Tempcap, creating a F) preliminary temporary crown. G) The temporary crown is shaped and polished out of the oral cavity. H) Temporary cement is applied into the temporary crown. I) The polished temporary crown is seated onto the Tempcap abutment.

Similarly, titanium and thermoplastic abutments were placed into the implants and torqued to specification. The abutments were shaped on the implant to facilitate the fabrication of a provisional crown. Provisionals were fabricated in the same fashion as the Tempcap and cemented with Tempbond. The Tempcap was compared to standard titanium abutments in the posterior mandible (sites 36 and 46) and to the thermoplastic abutments in the anterior maxillae (sites 12 and 22).

Provisional Quality Score

The provisional implant supported crowns were evaluated blindly by a full-time faculty member using a 4-point grading system (1-low quality, 4-high quality) in accordance with the preclinical marking criteria at the Schulich School of Medicine and Dentistry at Western University (Appendix Table I). The score was averaged for each abutment at each site.

Implant Stability Change

A non-invasive intraoral technique for evaluating implant stability has been previously described [9], [12], [18]. Briefly, bone anchorage around an implant is evaluated using resonance frequency analysis (RFA) of a transducer attached to an implant. Data gathered from Osstell ISQ instrument (Gothenburg, Sweden) yields an ISQ value from 0 to 100, where a larger ISQ indicates higher stability. In this study, a SmartPeg was positioned on the implants, tightened and the RFA was measured immediately following initial implant placement (simulated surgery) and after the fabrication of the provisional crowns, once the crowns and abutments were removed. Differences

between initial and final ISQ values were used to assess the average change in implant stability following temporization.

Time to Temporization

The time required for the fabrication of the provisional crown was measured from the time of the placement of the provisional abutment to the cementation of the provisional crown.

Statistical Analysis

Statistical analysis was performed between implant groups using student's *t*-tests. Data are reported as mean ± SD. Data is considered significant when $p<0.05$.

III. RESULTS

Provisional quality

The results were analyzed and presented as a percent value of provisional quality. As shown in Fig. 3, provisional crowns with the Tempcap abutment in the mandible displayed statistically significant increases in quality compared to the provisional crowns with titanium abutments ($p<0.001$). The values measured were 91.67 ± 0.02% and 83.33 ± 0.02%, respectively. However, no significant differences were evident between the provisional crowns with the Tempcap and thermoplastic abutments at maxillary implant sites (Fig. 3).

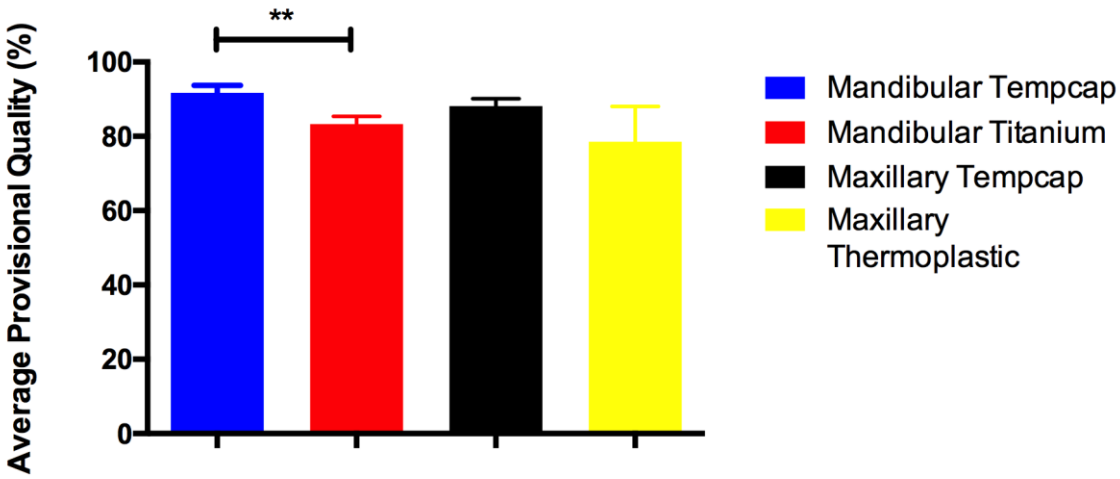

Figure 3.Analysis of provisional quality score of mandibular and maxillary implants. Provisional quality scores were evaluated using a 4-point grading scale following provisional fabrication. Single measurements were corrected averaged to yield an average percent quality score. Results are presented as mean ± SD for percent quality. $^{**}p<0.001$

ISQ Change

The ISQ change of the three bone analogues (D1, D2, and D3) is presented in Fig. 4. Differences in stability change of the provisional crowns using the Tempcap abutment compared to the provisional crowns on titanium and thermoplastic abutments approached significance in both the mandibular ($p=0.0918$) and the maxillary implant sites ($p=0.0647$), but were not statistically significant.

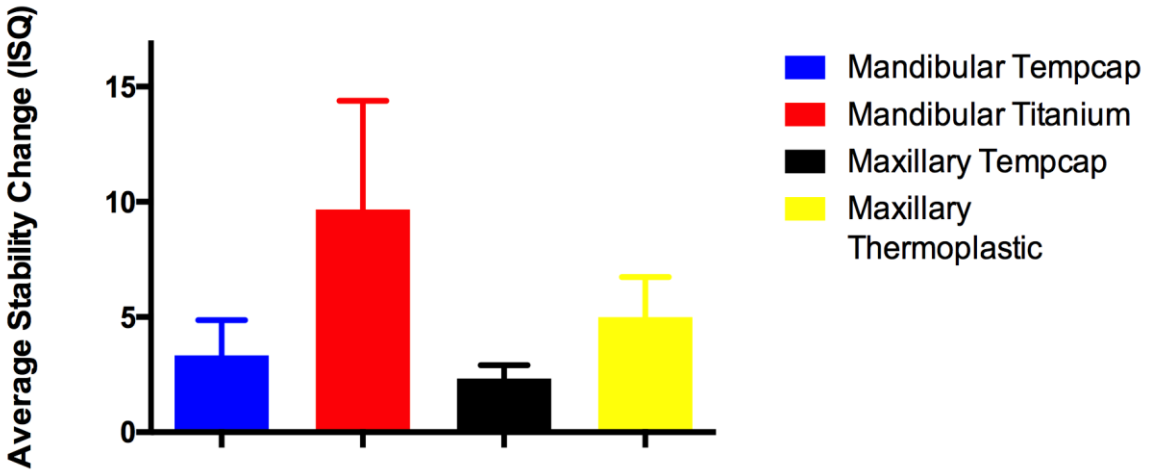

Figure 4.Analysis of stability change of mandibular and maxillary implants. Resonance frequency was measured immediately following initial implant placement and after subsequent removal of provisionals. Single stability readings were quantified using Osstell instrumentation to yield an ISQ value. Initial and final ISQ's were subtracted to calculate the average stability change between provisionals in maxillary and mandibular sites. Results are presented mean ± SD for stability change. ISQ, implant stability quotient.

Elapsed Time

The average time to fabricate a provisional implant-supported crown is displayed in Fig. 5. In the posterior implant site, the temporization time was significantly lower for provisional crowns utilizing Tempcap abutments compared to provisional crowns utilizing titanium abutments (p<0.0001). This corresponds to an average provisional time of 7.64 ± 0.43 min for Tempcap and 23.41 ± 1.05 min for titanium abutments. Time of provisional crown fabrication between the Tempcap abutment and thermoplastic abutment in the maxilla were not statistically significant.

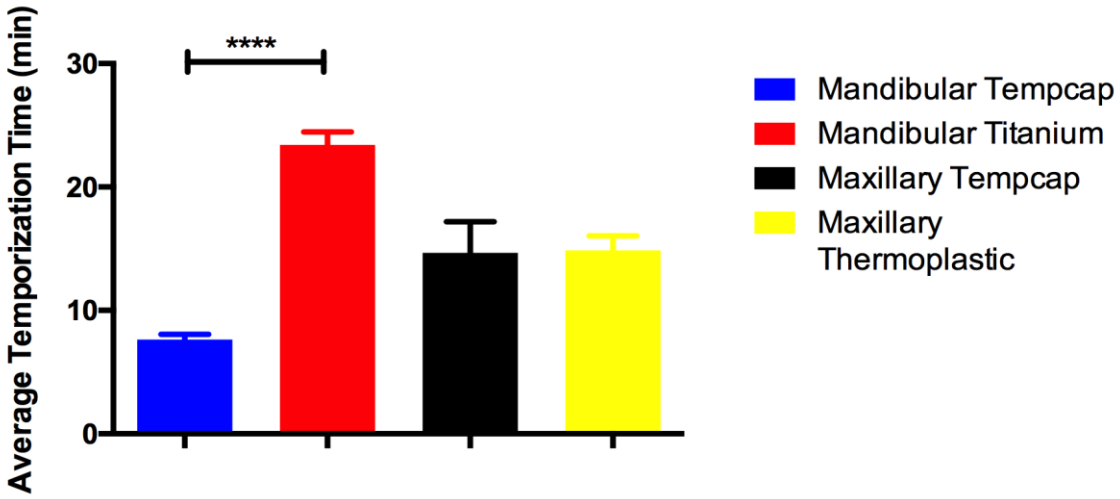

Figure 5. Average time elapsed to temporize mandibular and maxillary implant-supported provisional crowns. Times for implant temporization in all bone analogues were averaged to yield a single measurement. Elapsed time to temporization was recorded as mean ± SD in minutes. ****p<0.0001

IV. DISCUSSION

The objective of this pilot study was to evaluate the efficacy of the Tempcap abutment and technique for the temporization of a dental implant. Using several bone analogues, Tempcap, titanium, and thermoplastic abutments were placed in identical implant sites, and compared using measures of provisional quality, ISQ change, and provisional fabrication time. A comparison

between Tempcap, titanium, and thermoplastic abutments and the process to develop the provisional crown found a significant difference in the provisional quality score and total time of fabrication for implants placed in the posterior mandible. Furthermore, ISQ values changed the least when fabricating a provisional crown utilizing the Tempcap abutment in both anterior and posterior sites. Although there is not enough statistical evidence to validate these findings, the data are indicative of a trend in favour of the Tempcap treatment group. These outcomes suggest that this approach may be more effective and efficient than current temporization techniques Further investigation, with a larger sample size and clinical assessment, is warranted to validate these preliminary findings.

The provisional phase of treatment is one of the most critical and challenging phases of implant dentistry. Several temporary prosthetic approaches are used today which have been documented to be predictable treatment options for ensuring the long-term success of an implant [14]. The most common techniques include the use of removable dentures and provisional (titanium/thermoplastic) abutments. As suggested by previous authors, the complications associated with these approaches are two-fold: mechanical and biological. According to Agustin-Panadero and colleagues [19], mechanical complications often present as stress fractures and deformation to the implant body. In many cases, these may lead to implant failure or the loss of the vital osseointegration union between the implant body and bone, respectively. In cases where biological complications arise, patients can incur soft tissue inflammation initiated by undesired pressure transmitted to the implant and subsequently to the site of surgical healing [14], [19]. Combined with the esthetic demands of the patient, the cost of the provisional, and overall chair-side time, patient satisfaction is often difficult to achieve [14].

Tempcap provides an attractive approach for clinicians because it can be adequately secured into different implant bodies, with various thread designs, theoretically providing a predictable and clinical outcome. The simplicity of the design combines the healing cap and temporization abutment, eliminating the use of multiple implant components. Given the evidence between implant micro-movement and bone-tissue healing [20], [21], this design may prove to be valuable in accelerating the healing process and promoting greater patient acceptance. Similar to the anatomical PEEK healing/temporary abutment manufactured by Nobel Biocare (Gothenburg, Sweden), the Tempcap can also be used to support any superstructure, from a morphologically accurate crown to a sulcus-forming projection. This customizes the superstructure to guide gingival healing. The Tempcap can be applied as either a standard healing cap or customizable temporization abutment, depending on the clinical situation.

Cost of fabrication is one of the most obvious advantages of the Tempcap abutment, and may address the controversial issues associated with the re-use of titanium healing abutments. According to Wadhwani*et al.* [22], the recycling of dental healing abutments for economic convenience is a common approach that needs to be reassessed. Recent evidence suggests that despite thorough cleaning and sterilization, the re-use of abutments degrades product performance and the components required for implant installation [23]; it may cause damage to the implant body, and will always carry some degree of debris or contamination [22], [23], [24]. Presence of such contaminants and mechanical damage are suggested to have both direct and indirect biological and biomechanical effects that promote inflammation at implant-tissue interface, and may complicate abutment retrieval, respectively [22], [24]. This represents a clinical problem, as the tissue reaction prior to placement of a definitive prosthetic is vital for the long-term success of an implant [23]. However, with a cost-effective abutment such as Tempcap, a new healing abutment can be used each time.

V. CONCLUSION

The Tempcap presents a novel approach that may help simplify the restoration process by providing a predictable and cost-effective treatment. Previous studies have also explored the possibly

of the Tempcap as a final abutment [25], [26]. Simplicity of fabrication, quality, and cost of the Tempcap are the greatest advantages associated with this abutment, suggesting a role for Tempcap as an effective alternative option for implant provisionals. Further investigative studies are required to assess the clinical value of this novel treatment modality.

APPENDIX

Table I. Preclinical marking criteria at the Schulich School of Medicine and Dentistry.

Structural Integrity	**Score**
Provisional restoration intact in one piece, no cracks present and removed from dentoform for marking	**4**
Provisional restoration broken or visible cracks present or still seated on dentoform tooth preparation	1
Margins	
Marginal gap closed or scarcely detectable and no over/under extensions vertically or horizontally	**4**
Any over or under extension vertically or horizontally ≤ 0.5 mm	3
Any over or under extension vertically or horizontally > 0.5 mm but <1.0 mm	2
Any over or under extension vertically or horizontally ≥ 1.0 mm	1
Axial Contour	
Embrasures are anatomically contoured	4
Embrasures are slightly over/under contoured ≤ 0.3 mm	3
Embrasures are moderately over/under contoured > 0.3 mm but < 0.5 mm	2
Embrasures are extremely over/under contoured ≥ 0.5 mm	1
Proximal Contacts	
Mesial proximal contact is visually closed; floss contact is comparable to adjacent and contral lateral contacts	**4**
Contact is visually closed, but floss contact is lighter or tighter than other contacts	3
Contact is visually open or so tight that floss shreds	1
Distal proximal contact is visually closed; floss contact is comparable to adjacent and contra lateral contacts	**4**
Contact is visually closed, but floss contact is lighter or tighter than other contacts	3
Contact is visually open or so tight that floss shreds	1
Occlusal Function	
Proper occlusal contacts are present and evident with the use of articulating paper in maximum intercuspation position comparable to adjacent and contra lateral contacts	**4**
Few or light or heavy MI contacts	3
No contacts present or evident with the use of articulating paper	2
Tramatic contacts, i.e. occlusion exclusively on the provisional restoration	1
No working contacts present when excentric movement is executed	**4**
Functional working contacts	3
Interferences in working contacts	1

No balancing contacts present when excentric movement is executed	**4**
Balancing contacts	1
Pontic Contour (FPD Only)	
Light contact between tissue of residual ridge and tissue surface of the pontic determined by visual inspection and floss adaptation to tissue surface	**4**
Tissue contact heavy ≤ 0.3 mm or very light	3
Tissue contact heavy > 0.3 mm but ≤ 0.5 mm	2
Tissue contact absent or indents tissue > 0.5 mm	1
Tissue surface view appropriate design, tissue surface convex and cleansable	**4**
Tissue surface view not convex or cleansable or incorrect design	1
Finish	
Restoration is visually and tactilely smooth	**4**
Restoration presents minor scratches	3
Restoration presents catches and irregularities	2
Restoration presents pit or gouges	1
Surface Finishing corresponds to a high shine finish	**4**
Polished to pumice finish	3
Not polished	1

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