Congruency of Stereo Lithographically Produced Surgical Guide Bases Made from the Same CBCT File: A Pilot Study

Lambert J. Stumpel, DDS*

ABSTRACT

Purpose: This is a pilot study evaluating the effect of the algorithms and production processes of four commercial manufacturers of stereolithographically produced surgical guide.

Materials and Methods: A singular Dicom file was used to produce six distinct duplicate dentures, which function as the base for surgical guides. The duplicate dentures were repeatedly fitted ($n = 10$) into an impression of the occlusal surface of the original scan appliance. The gaps between the incisal edge of teeth #8 and #9 and the corresponding imprints in the vinyl polysiloxane impression were photographed, digitally recorded, and measured in a blinded fashion.

Results: Nobel Biocare mean was 0.56 mm (range 0.49–0.65), I-dent mean was 0.57 mm (range 0.31–0.74), Materialise II mean was 1.12 mm (range 0.90–1.40), Blue Sky Bio II mean was 1.13 mm (range 0.93–1.35), Materialise I mean was 1.43 mm (range 1.21–1.86), and Blue Sky Bio I mean was 2.17 mm (range 2.06–2.34). The difference between the fit of the Nobel Biocare and the I-dent guide bases and the guide bases from Materialise and Blue Sky Bio is statistically significant ($p < .05$).

Conclusion: The algorithms and production processes of the different manufactures do influence the congruency outcome of the produced surgical guide bases. Within the limits of this study, we were unable to produce a perfect fit, although some duplicate dentures showed minimal errors. The implications of the discrepancies need further study.

KEY WORDS: deformation, stereolithography, surgical guides

INTRODUCTION

Implant placement is directed by biological and prosthetic parameters. The implant requires intimate bone contact, cannot interfere with biological structures, and must adequately serve as a foundation for a prosthetic reconstruction. The three-dimensional positioning of a dental implant during surgery must fulfill all of the above-mentioned criteria. Traditionally, implants have been placed freehand or with the assistance of a variety of surgical guides.[1–8] The increased access to computerized tomography (CT) and cone beam CT (CBCT) technologies in recent years has led to the development of a multitude of specialized planning software systems. To transfer the planning information to the surgical field, there are two main technological solutions: navigated systems and surgical guide stent based systems. In navigated surgery, the drill position, as determined by the previously planned osteotomy site, is followed live as the surgeon advances the surgical instrumentation.[9–14] With surgical guide stent-based systems, the surgeon follows the planning information encoded in the surgical guide, directed by a guide sleeve embedded in the surgical guide stent itself. Then with dedicated instruments, the osteotomy is made through the guide sleeves, after which the placement of the implant may be guided as well.[15–17]

Computer assisted machining (CAM) for surgical guides is divided by subtractive and additive technologies. The subtracting process is called numerically controlled milling. Most commercial systems will modify an oral device that was worn during the scanning process. As the scan guide and the surgical guide are similar, duplicating the position of the appliance during the scan with the position of the appliance during the surgery is facilitated.[18,19] Stereolithography (SLA) represents the most popular additive process.[20] In stereolithography, a basin of light polymerizing resin is illuminated with a laser, polymerizing small areas at a time, much like an

*Private practice, San Francisco, CA, USA

Reprint requests: Lambert J. Stumpel, DDS, 450 Sutter Street, Suite 2530, San Francisco, CA 94108, USA; e-mail: lambertstumpel@pacbell.net

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inkjet printer deposits ink on paper. The basin is then moved down over a small distance and the laser travels over the field again. This process is repeated over a period of time, slowly building the object. In contrast to the previously mentioned numerically controlled manufacturing technique, the base and, for that, the whole of the surgical guide with the SLA technique is newly fabricated, and the fit of which has not been verified. It is evident that the objective of computer-aided implant placement is to transfer the planning information to the clinical outcome with minimal deviation. Clinically, this has been challenging. The most recent systematic review by Schneider and colleagues indicates that a 1.5- to 2-mm deviation at the apex should be considered.[21] Better results have been reported by Vasak and colleagues,[22] indicating the influence of many factors and combination of factors. One of those factors, as described by Stumpel,[23] is the possibility of deformation of the SLA-produced surgical guide based on CBCT data resulting from the incorrect International Organization for Standardization (ISO) settings used in a planning software program. Weitz and colleagues[24] show 1.5- to 3.0-mm discrepancies for templates manufactured via rapid prototyping based on Dicom sets produced by a low-dose CBCT machine, concluding that the deployed technique is inadequate for the surgical transfer in dental implant guided surgeries. Based on the above-referenced publications, a safety margin around implants of 1.5 mm, as is often found in planning software, should be considered an optimistic minimum. The discrepancy between planned position and actual position is of course a result of the accumulation of errors throughout the full process. Aside from errors in production, deformation of the guide itself will create a discrepancy between the planned position and the actual placement. A premade provisional bridge fabricated, based on this incorrect guide, will fit the implants and the occlusion will be correct. If, however, such surgical guide is repositioned incorrectly, as might be caused by a discrepancy between the occlusal surface and the bite index, then the premade bridge will still fit the implants, but now the occlusion will be incorrect.

The present pilot study was designed to further study the effect of various software programs on the computer aided design/CAM product of a singular CBCT-generated Dicom file. The null hypothesis was that all surgical guides made by four manufactures from the same CBCT file would be similar.

MATERIALS AND METHODS

A 51-year-old male presented with full edentulism in the maxilla, desiring implant-supported reconstruction. After the fabrication of a new removable full denture, eight gutta percha markers were placed in a zigzag pattern on the buccal flanges and palate. The markers are about 1 mm3 in volume. The patient was scanned in a CBCT scanner (Newtom VGI, AFP Imaging Corporation, Elmsford, NY, USA) while wearing the scan prosthesis. Then the scan prosthesis was scanned individually, generating two distinct Dicom files: one is the individual prosthesis, while the second is the combination of the patient and the prosthesis. Nobelguide (Nobel Biocare, Göteborg, Sweden) is a commercially available specialized software product that allows the importation of CT and CBCT data, the planning of implant therapy, and the subsequent production of a SLA-produced surgical guide. To improve the congruency of the produced SLA guides with the original scan appliance, Nobel Biocare has developed a calibration procedure. A dedicated polymer disc with known dimensions, the calibration object, is scanned separately with the same CBCT unit used on the treated patient. This step creates a separate Dicom file that entered compared with the software with known dimensions of the calibration object. The software evaluates how this specific CBCT machine at this specific moment in time images the calibration object. If, for example, the Dicom file would indicate a 5% enlargement compared with the actual size of the calibration disc, then the software will have to shrink the output of the CBCT machine with 5% to get the correct dimensions. The same percentage will then be applied to the Dicom data from the scan appliance. By changing the ISO value, the software can shrink or expand the output that will produce the SLA guide. The manufacturer advises the use of a new calibration file for a specific machine, every 6 months or after maintenance on the machine. The calibration set for the used CBCT unit computes an ISO value, which will be used in processing the patient specific information. The patient/scan appliance and the scan appliance file are introduced in the software according to the set ISO value. Implants are virtually planned, and a surgical guide designed. This design will then be outputted in a Standard Tessellation Language (STL) file, which will be used in an SLA process to produce a surgical guide. It is also possible to create a duplicate of the scan appliance, the so-called duplicate denture. The surgical guide is essentially similar to the duplicate denture with the exception of cavities, in which metal cylinders are glued. Excess material is often removed to improve access during surgery. For actual patient treatment and our study, one surgical guide and one duplicate denture were ordered and received.

The same Dicom file of the scan prosthesis only was sent to three other manufacturers of SLA-produced surgical guides with the request to fabricate duplicate dentures. No additional surgical guides were ordered.

I-dent (iDent Imaging Inc., Foster City, CA, USA) produced one duplicate denture. Materialise (Materialise Dental, Leuven, Belgium) and Blue Sky Bio (Blue Sky Bio, LLC, Grayslake, IL, USA) each produced two duplicate dentures. Each of these last three manufacturers has a proprietary calibration method, for which no details are available, preventing further descriptions of the individual calibration procedures.

A verification method previously described elsewhere,[23] stiff vinyl polysiloxane (VPS) material (Blu-Mousse, Parkell Inc., Edgewood, NY, USA), was used to make a dedicated impression of the occlusal aspect of the scan denture. VPS material was extruded onto a flat surface, and the occlusal and incisal edges of the prosthesis were lowered into the soft material. Upon setting, the material was cut back as in to expose the incisal edges and cusp tips.

A separate impression was made with VPS of the intaglio of the scan denture (Figures 1 and 2).

The VPS impression of the occlusal aspect was marked at points below the imprint of the incisal edge of teeth #8 and #9. Each duplicate denture was positioned and stabilized freehand in a best fit relationship with the tuberosity area of the prosthesis and the impression. The

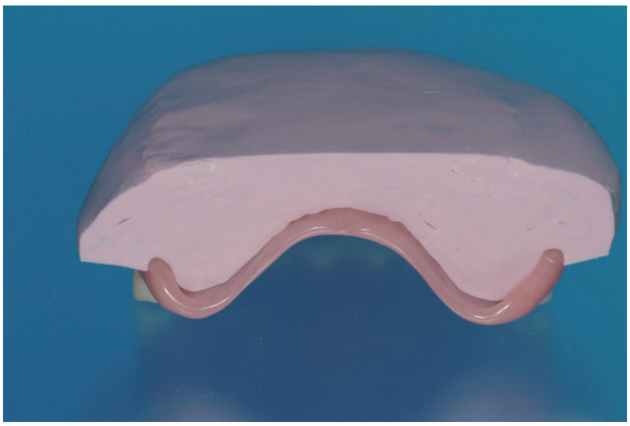

Figure 1 Intaglio vinyl polysiloxane impression.

Figure 2 Occlusal aspect vinyl polysiloxane impression.

flat surfaces of the tuberosities were chosen, as they seemed to experience the least deformation and allowing the most consistent repositioning. The relationship between the anterior teeth #8 and #9 and the VPS impression was photographed at a 1:1 ratio of a 105-mm macrolens and digitally recorded. The duplicate denture was removed from the VPS impression and repositioned as described, and the gap was again photographed and recorded. This was repeated for a total of 10 recordings per duplicate denture, totaling 60 measurement photographs. In addition, 3:1 photographs were made as overview images of each duplicate denture positioned into the VPS impression. Although not quantifiably used for this study, the VPS impression that was made of the intaglio of the original full scan denture was fitted into each duplicate denture and photographed once per duplicate denture at 3:1 ratio of the 105-mm macrolens.

To allow calibration of the image measurement program, a photograph was made of a digital caliper (Electronic caliper 721A, Starrett Co, Athol, MA, USA), set at 10.00 mm, with the same 1:1 ratio settings of the camera used to photograph the samples.

First, the calibration photograph was introduced in an image manipulation program (Photoshop CS3, Adobe Systems Incorporated, San Jose, CA, USA). The gap between the prongs of the caliper was measured with the measurement tool from the software. The tool indicated a number of 14.00, which coincided with the actual space of 10.00 mm. The resulting magnification factor of 0.71429 was used to calculate the gap space from the Photoshop measurements to millimeters. A blinded collaborator (SP), unfamiliar with the appearance of the individual guides, performed the measurements of the photographs, which were not identifiable beyond numbering.

TABLE 1 Deviation Measurements

	MAT2		NB		I-Dent		MAT1		BSK1		BSK2	
	#8	#9	#8	#9	#8	#9	#8	#9	#8	#9	#8	#9
1	1.26	1.22	0.50	0.51	0.31	0.32	1.27	1.26	2.10	2.15	0.98	1.04
2	1.40	1.38	0.53	0.54	0.32	0.39	1.24	1.21	2.15	2.12	1.08	1.18
3	1.22	1.18	0.57	0.58	0.50	0.58	1.29	1.21	2.25	2.28	0.93	1.02
4	1.16	1.09	0.65	0.60	0.59	0.67	1.33	1.34	2.21	2.20	1.02	1.07
5	1.00	1.00	0.58	0.60	0.54	0.63	1.60	1.60	2.09	2.09	0.98	1.04
6	1.18	1.11	0.62	0.61	0.63	0.74	1.48	1.44	2.11	2.14	1.14	1.24
7	1.00	0.93	0.60	0.60	0.55	0.6	1.61	1.53	2.06	2.07	1.22	1.35
8	1.00	0.92	0.49	0.52	0.61	0.71	1.86	1.84	2.13	2.16	1.15	1.27
9	1.00	0.90	0.49	0.50	0.62	0.68	1.45	1.42	2.21	2.18	1.14	1.26
10	1.20	1.18	0.57	0.55	0.61	0.69	1.35	1.35	2.34	2.29	1.15	1.24
Mean	1.14	1.09	0.56	0.56	0.53	0.60	1.45	1.42	2.17	2.17	1.08	1.17
Mean 2	1.12		0.56		0.57		1.43		2.17		1.13	

BSK1 = Blue Sky Bio I; BSK2 = Blue Sky Bio II; MAT1 = Materialise I; MAT2 = Materialise II; NB = Nobel Biocare.

The 60 measurement photographs were loaded into the Photoshop software, and the gap between the incisal edge of teeth #8 and #9 and the corresponding area of the VPS impression was recorded above the middle of the markings on the VPS impression for a total of 120 measurements.

RESULTS

Nobel Biocare mean = 0.56 mm (range 0.49–0.65 mm), I-dent mean = 0.57 mm (range 0.31–0.74 mm), Materialise II mean = 1.12 mm (range 0.90–1.40 mm), Blue Sky Bio II mean = 1.13 mm (range 0.93–1.35 mm), Materialise I mean = 1.43 mm (range 1.21–1.86 mm), and Blue Sky Bio I mean = 2.17 mm (range 2.06–2.34 mm) (Table 1). The difference between the fit of the Nobel and the I-dent guide bases and the guide bases from Materialise and Blue Sky Bio is statistically significant ($p < .05$) (Figures 3–11).

DISCUSSION

The objective of computer-generated surgical guides is to transfer the digital planning to the clinical reality with a minimal error. Every error within the process will add to any discrepancies in the final outcome and thus controlling the individual errors is of importance for the end result. CT machines can be calibrated, whereas cone beam technology does not allow a similarly precise calibration. The output from a given type and brand of CT

Figure 4 Nobel Biocare.

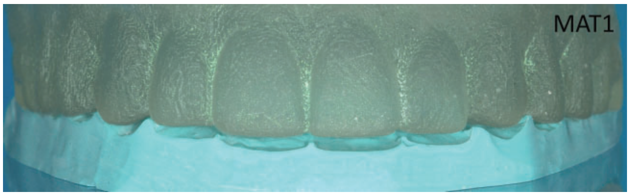

Figure 5 Materialise I.

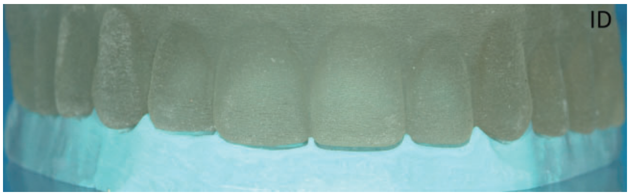

Figure 3 I-Dent.

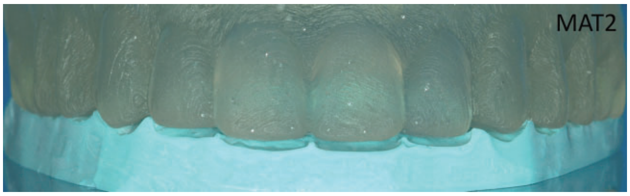

Figure 6 Materialise II.

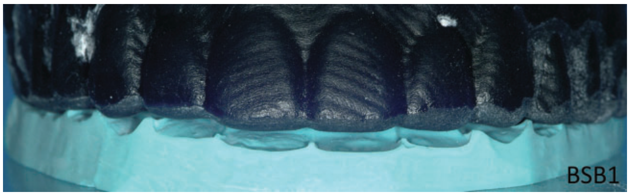

Figure 7 Blue Sky Bio I.

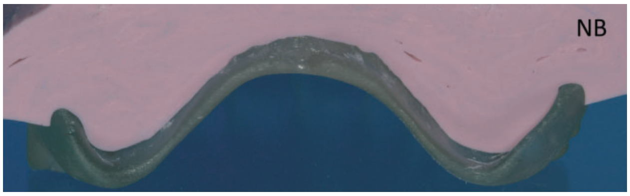

Figure 10 Intaglio fit Nobel Biocare.

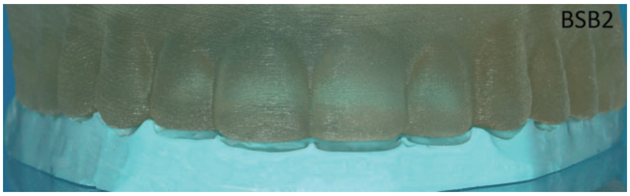

Figure 8 Blue Sky Bio II.

machine is known to a surgical guide base manufacturer. The outcome of each individual CBCT machine, even from the same manufacturer, does differ. As the initial experience of the surgical guide manufacturers was with calibrated CT machines, it was not until recent years that the understanding grew that the output from CBCT machines is less predictable for the guide manufacturers. In a previous publication, it was described[23] that SLA-produced surgical guides based on CBCT imaging can be dissimilar to the scan appliance it mimics.

The ISO value as set in the guide base manufacturer software was determined to be critical in this fabrication process but might not be singularly responsible. The manufacturer (Nobel Biocare) of the surgical guide base in this publication has changed the setting of the ISO value in their software from a manual process to an automated process as previously discussed. Based on the findings in the pilot study, this calibration procedure has greatly improved the outcome when CBCT data are utilized. The reader is reminded that the manufacturer has control over the ISO values as set in their planning software. The ISO values set in the (CB)CT is out of control of the surgical guide manufacturer. Assuring the calibration and appropriate settings of the (CB)CT is of paramount importance to create a Dicom data set which most closely represents the patient's anatomy.

To test the processes of four commercial SLA-produced surgical guide manufactures, the same Dicom file was introduced into their system. The null hypothesis was that the input of the same Dicom file would create a similar output from all processes and manufacturers. As the starting point is the same, the variables were the individual software algorithms and the SLA fabrication process employed by the manufacturers. Only the Nobel Biocare duplicate denture was made in a normal production fashion. The three other manufactures had to individualize the process as no surgical guides were ordered, but just duplicate dentures. This required deviation from the standard operating protocol and it created an error in the first process of Materialise I. An incorrect software version was used, creating clipping of the histogram and a less desirable outcome. Materialise II was made with the correct settings. Blue Sky Bio also wanted to fabricate a second duplicate denture, with adjusted ISO settings in their software and a different SLA object producer. In this instance, through changes made internally in the individual manufacturer's production processes, the outcomes differed.

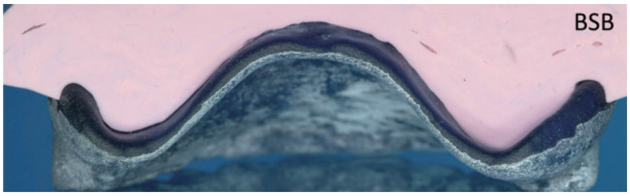

Figure 9 Intaglio fit Blue Sky Bio.

Figure 11 Measurement image 1:1 ratio.

The outcomes of measurements made at fixed points vary considerably. The measurement method can be criticized as it relies on hand positioning to a best fit of a surface, which to some extent will be arbitrary. Another method would be to scan the dentures in a three-dimensional surface scanner and then apply a best algorithmic fit of the files. This will show where the discrepancies are; colors will indicate the magnitude.

The VPS impression is similar to the clinical bite registration method and, although low tech, might be closer to the clinical reality. Because of the limitation in the measuring method, it warrants to not see these numbers as absolutes, but as a relative comparison of the different processes. Although not quantified, it was recognized that the intaglio surface of all guides differed minimally as measured by the impression of the intaglio surface. Most of the discrepancy appears to be at the occlusal surfaces. Although the reason remains unknown, this indicated that the surgical guides do not exhibit uniform deformation. Possible factors might be that the density of denture teeth differs from the density of the acrylic base or burnout artifacts of the occlusal/incisal surfaces by the x-ray beam. Future investigation into this would possibly disclose a difference between a uniform all acrylic scan prosthesis versus an actual full prosthesis fabricated with denture teeth and acrylic. It must be noted that all mentioned manufactures at this time use a (CB)CT image of a scan prosthesis to fabricate the base of their surgical guide in fully edentulous cases. This differs markedly from partially edentulous cases where many manufactures employ surface scanning of dental casts or direct intraoral scanning to develop the STL file used to produce a surgical guide via the SLA process.

The null hypothesis was rejected as there were considerable differences between the manufactured duplicate dentures.

CONCLUSION

The SLA fabrication method based on CBCT data is one commonly used in the fabrication of surgical guides. Within the limits of this study, it was not possible to create a base for a surgical guide which was similar to the scan appliance it mimicked, although some duplicate dentures showed minimal errors. There are differences in congruency outcomes between manufacturers and processes employed by manufacturers. The clinical implication and magnitude needs further study.

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REFERENCES

1. Quinlan P, Richardson CR, Hall EE. A multipurpose template for implant placement. Implant Dent 1998; 7:113–121.
2. Weinberg LA, Kruger B. Three-dimensional guidance system for implant insertion: Part I. Implant Dent 1998; 7:81–93.
3. Atsu SS. A surgical guide for dental implant placement in edentulous posterior regions. J Prosthet Dent 2006; 96:129–133.
4. Shotwell JL, Billy EJ, Wang HL, Oh TJ. Implant surgical guide fabrication for partially edentulous patients. J Prosthet Dent 2005; 93:294–297.
5. Meitner SW, Tallents RH. Surgical templates for prosthetically guided implant placement. J Prosthet Dent 2004; 92: 569–574.
6. Windhorn RJ. Fabrication and use of a simple implant placement guide. J Prosthet Dent 2004; 92:196–199.
7. Tsuchida F, Hosoi T, Imanaka M, Kobayashi K. A technique for making a diagnostic and surgical template. J Prosthet Dent 2004; 91:395–397.
8. Stumpel L. Cast based guided implant placement; a novel technique. J Prosthet Dent 2008; 100:61–69.
9. Wanschitz F, Birkfellner W, Watzinger F, et al. Evaluation of accuracy of computer-aided intraoperative positioning of endosseous oral implants in the edentulous mandible. Clin Oral Implants Res 2002; 13:59–64.
10. Wittwer G, Adeyemo WL, Schicho K, Birkfellner W, Enislidis G. Prospective randomized clinical comparison of 2 dental implant navigation systems. Int J Oral Maxillofac Implants 2007; 22:785–790.
11. Wittwer G, Adeyemo WL, Schicho K, Gigovic N, Turhani D, Enislidis G. Computer-guided flapless transmucosal implant placement in the mandible: a new combination of two innovative techniques. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2006; 101:718–723.
12. Casap N, Tarazi E, Wexler A, Sonnenfeld U, Lustmann J. Intraoperative computerized navigation for flapless implant surgery and immediate loading in the edentulous mandible. Int J Oral Maxillofac Implants 2005; 20:92–98.
13. Kramer FJ, Baethge C, Swennen G, Rosahl S. Navigated vs. conventional implant insertion for maxillary single tooth replacement. Clin Oral Implants Res 2005; 16:60–68.
14. Casap N, Wexler A, Lustmann J. Image-guided navigation system for placing dental implants. Compend Contin Educ Dent 2004; 25:783–784.

15. Di Giacomo GA, Cury PR, de Araujo NS, Sendyk WR, Sendyk CL. Clinical application of stereolithographic surgical guides for implant placement: preliminary results. J Periodontol 2005; 76:503–507.
16. Van Steenberghe D, Malevez C, Van Cleynenbreugel J, et al. Accuracy of drilling guides for transfer from three-dimensional CT-based planning to placement of zygoma implants in human cadavers. Clin Oral Implants Res 2003; 14:131–136.
17. Terzioğlu H, Akkaya M, Ozan O. The use of a computerized tomography-based software program with a flapless surgical technique in implant dentistry: a case report. Int J Oral Maxillofac Implants 2009; 24:137–142.
18. Fortin T, Isidori M, Blanchet E, Perriat M, Bouchet H, Coudert JL. An image-guided system-drilled surgical template and trephine guide pin to make treatment of completely edentulous patients easier: a clinical report on immediate loading. Clin Implant Dent Relat Res 2004; 6:111–119.
19. Fortin T, Champleboux G, Bianchi S, Buatois H, Coudert JL. Precision of transfer of preoperative planning for oral implants based on cone-beam CT-scan images through a robotic drilling machine. Clin Oral Implants Res 2002; 13:651–656.
20. Sarment DP, Al-Shammari K, Kazor CE. Stereolithographic surgical templates for placement of dental implants in complex cases. Int J Periodontics Restorative Dent 2003; 23:287–295.
21. Schneider D, Marquardt P, Zwahlen M, Jung RE. A systematic review on the accuracy and the clinical outcome of computer-guided template-based implant dentistry. Clin Oral Implants Res 2009; 20:73–86.
22. Vasak C, Watzak G, Gahleitner A, Strbac G, Schemper M, Zechner W. Computed tomography-based evaluation of template (NobelGuide™)-guided implant positions: a prospective radiological study. Clin Oral Implants Res 2011; 23:1157–1163.
23. Stumpel LJ. Deformation of stereolithographically produced surgical guides: an observational case series report. Clin Implant Dent Relat Res 2010. DOI: 10.1111/j.1708-8208.2010.00268.x.
24. Weitz J, Deppe H, Stopp S, Lueth T, Mueller S, Hohlweg-Majert B. Accuracy of templates for navigated implantation made by rapid prototyping with DICOM datasets of cone beam computer tomography (CBCT). Clin Oral Investig 2011; 15:1001–1006.