Evaluation of Two Noninvasive Repositioning Systems for Computer-Assisted Oral Implant Surgery in Oral Cancer Patients

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Purpose: Reconstructive surgery in oral cancer patients uses thick flaps, which may render the placement of miniscrews for stabilizing radiosurgical templates difficult. The realization of noninvasive systems for the repositioning of surgical templates has been proposed. The present study aimed to assess the clinical usefulness of these noninvasive repositioning systems. ***Materials and Methods:*** Two noninvasive (ie, without osseous anchorage) repositioning systems (one intraoral, one intra- and extraoral) were tested. They were coupled with a computer-aided system for oral implantation. The criteria for evaluation were: accuracy, cost, time for placement and removal, and six additional subjective criteria (ease of use and production, bulk of the device, patient comfort, stability during surgery, and ergonomics). ***Results:*** Nine edentulous patients undergoing surgery to the oral cavity, oropharynx, or pharynx; external radiotherapy of the mandible; or microvascular flap reconstruction were included. Twenty-seven implants were placed in the mandibles of seven patients. For the extraoral system, the angular deviation between planned and achieved position was 6.04 degrees, with differences of 2.14 mm at the tip and 2.16 mm at the base. For the intraoral system, deviations were 5.05 degrees, 1.13 mm, and 1.82 mm, respectively. Subjective criteria were consistent with expected values, especially ease of use, comfort, and ergonomics. ***Conclusions:*** Noninvasive systems remain less accurate than templates stabilized by miniscrews and should be reserved for treating arches in which miniscrews cannot be placed. These methods may be unacceptable in areas where vital structures may be damaged by a misguided implant, and further studies are required. More satisfactory results should be obtained in partially edentulous patients. *Int J Prosthodont 2010;23:463–468.*

Computer-assisted surgery has been used recently in oral cancer patients. In spite of good results in terms of accuracy, current methods remain invasive because they involve the use of miniscrews or extensive bone exposure to fit the guide. The risk of osteoradionecrosis caused by surgical trauma persists throughout life. Therefore, mucosal or osseous trauma should be reduced to a minimum.

Reconstructive surgery uses thick flaps, which often remain mobile relative to the bone. Thus, the placement of miniscrews for stabilizing radiosurgical templates is sometimes difficult and may lead to local inflammation during the interval between computed tomography (CT) scanning and surgery. The realization of noninvasive systems for the repositioning of surgical templates has been proposed. The aim of the present study, therefore, was to assess the clinical usefulness of these noninvasive repositioning systems.

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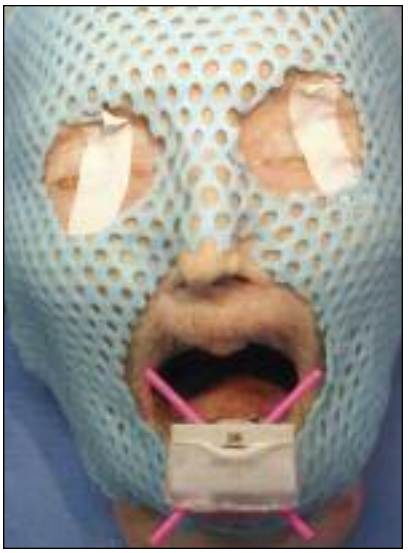

Fig 1 Extraoral repositioning system final testing on a human cadaver. The mask was placed and readjusted and the guide was connected to the cube through a fastening box.

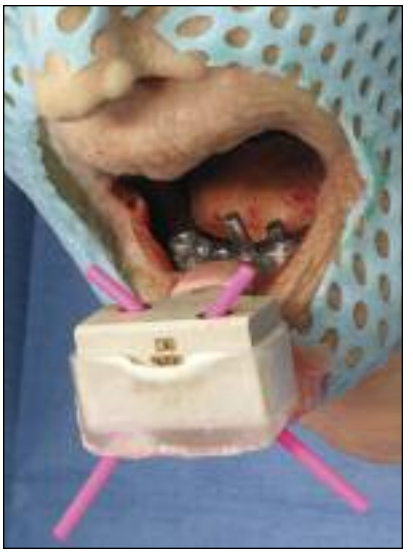

Fig 2 Detail of the fastening box and the cube. Parallelizing gauges were inserted to show the placement of the implants.

Fig 3 Intraoral repositioning system: splint molded on the maxilla, resin supports, and guide.

Materials and Methods

Nine completely edentulous patients undergoing surgery of the oral cavity, the oropharynx, or the pharynx; external radiotherapy to the mandible; or free fibula flap reconstruction and who were candidates for oral implantation were proposed to participate in this study.

The image-guided system used was the EasyGuide system (Keystone Dental). Its method includes creating a template custom made to the design of the future prosthesis. The prosthesis was then planned based on the number of teeth to be replaced, the contours of the prosthesis, and whether it would be fixed or removable. A fiducial marker (X-cube) was fixed on the template to allow precise alignment of the drilling machine with the planned position on the template. A CT scan was performed with the system in place, and preparatory planning was done using the EasyGuide software. The template was drilled mechanically following preplanning instructions. The precision of the drilling machine was evaluated to 0.2 mm in translation and 1.1 degrees in rotation.[1] Surgery was then performed guided by the holes and the digital surgical treatment plan. Patients were randomized into two groups: treatment with the extraoral repositioning system and treatment with the intraoral repositioning system.

The extraoral repositioning system consisted of a thermoplastic face mask similar to those used for patient immobilization during external radiotherapy (Fig 1). The mask was modeled with an open mouth, and particular care was given to the tracking of facial convexities and concavities. Since all implants were placed under general anesthesia, the mask was modified not to interfere with the care of the patient during anesthesia (the nostrils and eyes were cut out of the mask). The mask and the X-cube were connected by a fastening box and methyl methacrylate resin (Fig 2).

The intraoral repositioning appliance included a thermoplastic splint molded to the shape of the maxilla. Two vertical resin supports were added between the splint and the template of the EasyGuide system to immobilize the patient with his or her mouth wide open. Indentations were made on the splint to lock both the template and splint in predetermined positions (Fig 3). The vertical resin supports were fixed on the upper splint.

The agreement between implant planning and actual placement was assessed by postimplantation CT scans with the repositioning systems in place. For each implant, differences were calculated at the tip and at the base of the implant. The angular deviation was also evaluated (Fig 4). The cost and time for placement and removal were calculated for each system.

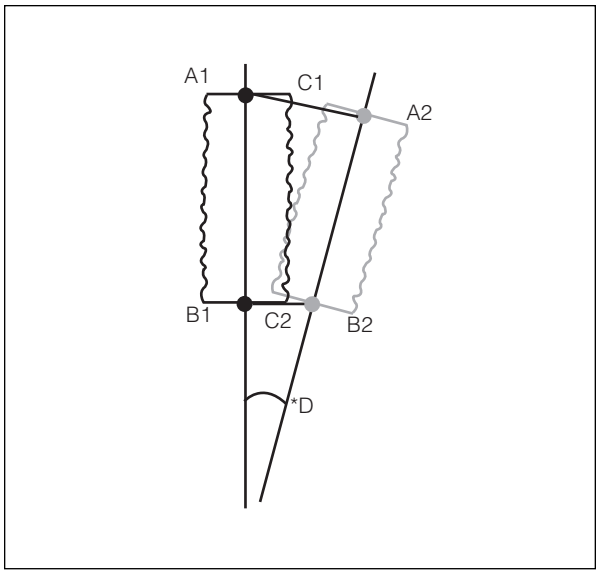

Fig 4 Pre- and postoperative matching. A1 = top of the implant planned; A2 = top of the implant placed; B1 = tip of the implant planned; B2 = tip of the implant placed; C1 = error at the top; C2 = error at the tip; D = angular deviation.

Table 1 Age, Sex, Site of the Initial Tumor, and Treatment for Each Patient Included

Patient	Device	Age (y)/sex	Site of the tumor	Treatment
1	Extraoral	68/M	Oropharynx	Surgery + ERT (60 Gy)
2	Not treated (intercurrent disease)	55/M	Tonsil	Surgery + fibula + ERT (62 Gy)
3	Extraoral	51/M	Right mandible	Surgery + fibula + ERT (60 Gy)
4	Extraoral	61/M	Oropharynx	Surgery + ERT (60 Gy)
5	Not treated (dead)	72/M	Pharyngolarynx	Surgery + ERT (66 Gy) + CDDP
6	Intraoral	56/M	Anterior floor of the mouth	Surgery + ERT (60 Gy)
7	Extraoral	57/M	Anterior floor of the mouth	Surgery + FAMM flap + ERT (58 Gy)
8	Intraoral	59/M	Pharyngolarynx	Surgery + ERT (62 Gy)
9	Intraoral	54/M	Anterior floor of the mouth	Surgery + FAMM flap + ERT (54 Gy) + CDDP

M = male; ERT = external radiography; CDDP = concomitant chemotherapy; FAMM = facial artery musculomucosal.

Subjective criteria such as ease of use and production, patient comfort, ergonomics, bulk of the device, and stability during surgery were scored from 1 to 4 (1 = very easy or excellent, 2 = fairly easy or good, 3 = difficult or bad, 4 = very difficult or bad). Comfort was graded by the patients themselves after CT scanning. Ergonomics included compatibility with the operating room. Bulk corresponded to the place occupied by the system in the operative field, which led to a restriction of the surgeon's movements, and was evaluated subjectively by the surgeon during surgery.

Results

Nine patients were included but only seven were available for postimplantation analysis; four were treated with the extraoral system and three with the intraoral system (Table 1). Of the other two patients, one died before implantation and one did not undergo postimplantation CT scanning because of intercurrent disease. Four patients received implants in native mandibular bone, two in a facial artery musculomucosal (FAMM) flap, and one in a fibula. One patient with native bone and one with a fibula flap did not complete the postimplantation analysis. Twenty-nine implants were planned for the eight patients. Of these, 27 were placed and 2 (1 for each system) were not. All placed implants were inserted interforaminally.

Table 2 Implants Placed Using the Extraoral Repositioning System

Patient (site of implantation)/ implant	Difference at the top (mm)	Difference at the tip (mm)	Angular deviation (degrees)
1 (mandible)			
1	2.59	2.28	9.50
2	0.86	1.99	7.10
3	5.86	4.93	7.50
4	2.02	1.11	5.20
3 (fibula flap)			
5	3.74	2.21	3.60
6	2.45	2.56	3.90
7	4.21	3.83	4.50
4 (mandible)			
8	3.75	0.57	3.13
9	0.51	1.02	4.20
10	0.95	0.90	5.40
11	0.4	1.12	6.20
7 (FAMM flap)			
12	1.23	4.45	8.10
13	1.45	2.35	7.30
14	2.02	2.57	7.26
15	1.07	1.25	6.80
16	1.18	1.50	7.10
Mean	2.143125	2.165	6.049375
Variance	2.38082292	1.66524	3.34303292
Standard deviation	1.54299155	1.29044178	1.82839627

Table 3 Subjective Criteria for the Evaluation of the Systems*

	Extraoral system	Intraoral system
Ease of use	2	3
Ease of production	3	2
Ergonomics	1	1
Comfort of the patient	2	2
Bulk of the system	4	2
Stability during surgery	2	2
Total score	14	12

*Range: 1 to 4 (1 = very easy or excellent, 2 = fairly easy or good, 3 = difficult or bad, 4 = very difficult or bad).

Table 4 Implants Placed Using the Intraoral Repositioning System

Patient (site of implantation)/ implant	Difference at the top (mm)	Difference at the tip (mm)	Angular deviation (degrees)
6 (mandible)			
1	0.50	2.16	8.70
2	1.38	1.55	1.55
3	1.20	2.39	6.20
4	0.99	1.18	1.91
8 (mandible)			
5	1.25	1.53	3.95
6	1.52	1.57	4.56
7	1.38	2.02	4.32
9 (FAMM flap)			
8	0.85	1.93	9.50
9	0.98	2.12	2.95
10	1.03	1.63	5.72
11	1.32	1.95	6.21
Mean	1.12727273	1.82090909	5.05181818
Variance	0.08598182	0.12646909	6.47445636
Standard deviation	0.29322656	0.35562493	2.54449531

When using the extraoral system, the difference between planned and placed implants was 6.04 degrees (range: 3.13 to 9.5 degrees) in angular deviation, with 2.14 mm (range: 0.51 to 3.74 mm) deviation at the tip of the implant and 2.16 mm (range: 0.57 to 4.93 mm) at the base (Table 2). On native mandibular bone, the difference was 6.03 degrees, with 2.11 mm deviation at the tip and 1.74 mm at the base. For FAMM and fibula flaps, differences were 7.31 degrees, 2.42 mm, and 1.39 mm and 4.0 degrees, 3.46 mm, and 2.86 mm, respectively. The cost of the repositioning system was evaluated to be 50 EUR. The time for placement and removal was 7.8 minutes (range: 6.8 to 8.5 minutes). The global subjective score was 14: 1 for ergonomics (score: 1 for all patients); 2 for ease of use (range: 1 to 3), comfort (range: 2 to 2), and stability during surgery (range: 1 to 3); 3 for ease of production (range: 1 to 4); and 4 for bulk (range: 3 to 4, Table 3).

When using the intraoral system, the difference was 5.05 degrees (range: 1.55 to 9.5 degrees) in angular deviation, with 1.13 mm (range: 0.5 to 1.38 mm) deviation at the tip of the implant and 1.82 mm (range: 1.18 to 2.39 mm) at the base (Table 4). On native mandibular bone, the difference was 4.46 degrees, with 1.17 mm deviation at the tip and 1.77 at the base; deviations were 6.09 degrees, 1.04 mm, and 1.91 mm on FAMM flaps, respectively. The cost of the repositioning device was evaluated to be 30 EUR. The time for placement and removal was 7.6 minutes (range: 7.2 to 8.0 minutes). The global subjective score was 12: 1 for ergonomics (score: 1 for all patients); 2 for ease of production (range: 1 to 3), comfort (range: 1 to 3), stability during surgery (range: 1 to 3), and bulk (range: 2 to 2); and 3 for ease of use (range: 1 to 4, Table 3).

In all patients, prosthesis placement was achieved as defined by the treatment plan, ie, a removable denture stabilized by implants.

Discussion

Patients who were candidates for implant dentistry using noninvasive repositioning systems were completely edentulous and had been treated by external radiotherapy to the mandible or by microvascular free fibula flaps for mandibular reconstruction. The repositioning system was tested with the mandible in a wide open position and was supported by anatomically reconstructed tissues in three of seven patients (two FAMM flaps and one fibula) and without secondary anchorages such as residual teeth.

Of the 29 implants planned, 2 were not placed because of poor bone density or because of an important bony step between the native mandibular bone and the fibula, which rendered the guide unstable after resection and thus only the emergence of the implant could be assessed. This is one of the limitations of conventional guides like EasyGuide or NobelGuide (Nobel Biocare): intraoperative variables cannot be considered. Nonetheless, their reasonable cost and ease of use render them accessible to most clinicians.

The errors observed resulted from a combination of factors including drilling deviations, surgeon error, inaccuracy of the system itself, and error of the drilling machine (1.1-degree angular deviation and 0.2-mm translation).[1] The systems were tested in edentulous patients without bone anchorage, with a poor mouth opening, and, for three of seven patients, on flaps and remodeled anatomy of the jaw, which are extreme conditions for testing such systems. Nonetheless, there does not seem to be a statistically significant difference between native mandibular bone and reconstructed jaws, even though higher values were found for the patient treated with a fibula flap.

The extraoral system showed good accuracy when tested on a human cadaver, with 1.19-degree angular deviation and 0.2-mm translation resulting from drilling errors and the inaccuracy of the system.

Most studies concerning computer-assisted implant surgery[2,3] describe the protocol but do not give pre- and postoperative matching or quantitative evaluation of accuracy. One study[4] reports satisfactory accuracy with 2.04-degree mesiodistal and 2.71-degree buccolingual angular deviation and 0.42-mm mesiodistal and 0.5-mm buccolingual translation. However, in this study, the guide was tested on partially edentulous patients with some dental anchorage, which has proven to allow better accuracy than mucosal guides with underlying osseous support.[5] According to Ruppin et al,[6] there is no statistical difference in accuracy between navigation using optical tracking and stereolithographic guides.

The results obtained with the devices in this study remain clinically satisfactory in terms of accuracy but have to be improved. The lack of accuracy is related to the lack of bone anchorage of the systems. Therefore, the intraoral system achieves better accuracy and reproducibility than the extraoral system; it provides a more stable bearing surface and is placed closer to the operative field, which reduces the elasticity of the system. The pressure of the guide on the mucosa is higher than with the extraoral system, thus avoiding movement of the guide due to the mobility of the soft tissues.

The time for placement and removal was 7.8 and 7.6 minutes for the extraoral and the intraoral systems, respectively. This is a short amount of time, especially since only the first patients treated with these systems are presented and some decrease in time can be expected through practice. According to Metson,[7] the increase in operating time when using optical systems is

20 to 30 minutes when first using them. Moreover, the systems require no modifications to the operating room. The nasotracheal probe is placed and the mask is fit before connection to the respirator. The cost of the procedure is quite moderate, especially compared to navigational or optic systems; it compares favorably with other conventional guides.

The bulk of both systems reduced the access to the operative field, which is a problem when the degree of mouth opening is poor, such as with irradiated patients. The extraoral system decreases the elasticity of the cheeks and lips, whereas the vertical wedges of the intraoral system reduce the area for implant placement in the premolar (or intraforaminal) region.

Both systems are easy to install, even if some steps may prove critical. For the extraoral system, the accuracy of the link between the fiducial marker (the cube) and the mask usually requires two operators. The insertion of the intraoral system was found to be difficult for one patient due to insufficient mouth opening, and one operator had to force the mandible open while the second put the system in place. This problem requires the presence of an operator (or a radiologist) during CT scanning or teaching the patient how to put in and remove the system, as was the case for one of the three patients treated with the intraoral system.

The stabilization of the guide during surgery on completely edentulous patients is difficult to obtain.[8] In this study, stabilization was achieved via the repositioning systems, which placed the guide under pressure on the mucosa. Even if the result was clinically satisfactory for most patients, stabilization was impossible in one patient, even during CT scan acquisition, because of uncontrolled mandibular movements as a result of Parkinson disease. This patient could not undergo surgery since he died before implant placement.

Good patient comfort is important because the repositioning systems are placed and removed three times while the patient is awake (during the manufacturing of the device, CT scan acquisition, and postoperative CT scanning). The score obtained for comfort was good, which is especially important for oral cancer patients in whom miniscrews placed on thick flaps can cause local inflammation and pain.

Conclusion

In spite of nonoptimal accuracy and overload, both systems are original and interesting since they are noninvasive (no miniscrews required) and can be used in edentulous patients. Accuracy and bulk remain to be improved, however. The population tested combined completely edentulous patients and patients who had undergone multiple jaw surgeries, two of the most difficult situations for testing a positioning system. More satisfactory results should be obtained in partially edentulous patients. After an adequate learning curve, the system should allow minimally invasive or flapless surgery. Minimally invasive surgery could be very interesting in irradiated jaws since it seems to decrease peri-implant bone resorption[9] and peri-implant inflammation of the soft tissues.[10] Furthermore, pain and discomfort are also decreased. Noninvasive repositioning systems can be clinically successful; nonetheless, their use should be reserved for treating arches in which miniscrews cannot be placed, especially when the flap is thick. The use of these systems for extraoral implants is currently being tested.

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