

Sang-Hoon Ahn
Eun-Jin Park
Eun-Suk Kim

Reamer-mediated transalveolar sinus floor elevation without osteotome and simultaneous implant placement in the maxillary molar area: clinical outcomes of 391 implants in 380 patients

Authors' affiliations:

Sang-Hoon Ahn, Private Practice, Daejeon, Korea
Eun-Jin Park, Department of Prosthodontics, School of Medicine, Ewha Womans University, Seoul, Korea
Eun-Suk Kim, Department of Oral and Maxillofacial Surgery, Jukjeon Dental Hospital College of Dentistry, Dankook University, Cheonan, Korea

Corresponding author:

Prof. Eun-Suk Kim
Department of Dentistry
Dankook Jukjeon Dental Hospital
126 Jukjeon-Dong
Suji-Gu, Yongin-Si
Gyeonggi-Do 448-701, Korea
Tel.: +82 31 8005 2370
Fax: +82 31 8021 7270
e-mail: eskimos@dankook.ac.kr

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Abstract

Objectives: Minimally invasive sinus elevation and augmentation using a transalveolar approach can reduce perioperative complications and patient discomfort. A specially designed reamer accomplishes this without the use of an osteotome or a mallet. The objective of this study is to present this technique with relevant clinical cases and patient outcomes.

Material and methods: Series of reamers with one cutting and one reaming edge were used to prepare an osteotomy site for posterior maxillary areas. A total of 391 osteotomies were prepared with the reamer in 380 patients, and 373 implants were placed simultaneously. In addition to the procedure's success parameters, levels of intraoperative patient comfort were monitored using a visual analogue scale.

Results: The mean height of the residual alveolar process was 5.8 (0.9) mm, whereas mean elevation of the sinus floor was 6.2 (0.4) mm. Eighteen (4.6%) Schneiderian membrane perforations occurred, and the 2-year survival rate was 95.4%. The success rate was 92.7% in sites with thin sinus floors (<4 mm) and 96.4% in sites with greater bone height (>4 mm). None of the patients experienced any discomfort during the procedure.

Conclusions: Within the limits of the present study, it can be concluded that reamer-mediated transalveolar sinus floor elevation is a reliable method for implant placement in the posterior maxilla, even at sites with ≤ 4 mm of residual alveolar bone height. This reamer-mediated procedure is less invasive than traditional osteotomy and can minimize patient discomfort during sinus floor elevation.

In the posterior maxilla, diminished bone height provides a challenge for successful osseointegrated implant placement. Sinus floor elevation techniques are used to compensate for the lack of alveolar bone volume. The technique consists of elevating the Schneiderian membrane from the maxillary sinus floor and placing a bone graft or bone substitute into the created space (Jensen 1999). From the clinical viewpoint, two techniques (the lateral and transalveolar approaches) are widely used to elevate the Schneiderian membrane. The lateral window technique, a localized augmentation procedure in the posterior maxilla modifying the Caldwell–Luc operation, that was first reported by Boyne & James (1980), has become an accepted treatment modality in implant dentistry; several techniques and materials have been proposed to enable predictable dental implant placement in the posterior maxilla

(Misch 1987; Small et al. 1993; Smiler 1997; Block & Kent 1997). However, postoperative complications such as pain or swelling resulting from extensive surgical trauma may increase patient discomfort. An alternative approach to elevate the sinus floor was first described by Tatum (1986) and Summers (1994a), who reported the osteotome technique as a less invasive approach than the lateral approach. Fracturing and moving of the sinus floor was performed by gentle tapping of the concave or convex osteotome. This technique has been modified using various spreading and condensing instrumentation, and sinus elevation using various pressure methods has been reported (Bori 1991; Wheeler 1997; Toffler 2001; Fugazzotto & De 2002; Winter et al. 2002; Chen & Cha 2005; Yamada & Park 2007). However, it is reported that it is difficult to control the osteotome tapping force

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while using these techniques in order to produce effective membrane lifting without membrane perforation (Yamada & Park 2007). Further, the amount of sinus floor augmentation and the volume of bone created are limited. The incidence of laceration of the Schneiderian membrane varies from 10% to 33% depending on the height of the elevation (Reiser et al. 2001). Use of the tapping procedure to fracture the sinus floor or adding bone graft material causes patient discomfort during surgery. One of the more severe tapping-induced complications is osteotome sinus floor elevation-related benign paroxysmal positional vertigo (OSFE-BPPV). Although the incidence of OSFE-BPPV is <3%, it takes time to resolve and bothers patients during the healing period (Peñarrocha et al. 2001; Di Girolamo et al. 2005; Sake & Ogle 2005; Su et al. 2008).

In the present study, a specially designed reamer with one cutting edge (CE) with an 85° cutting angle (CA) was used for minimally invasive transalveolar sinus floor elevation. Because this technique does not involve the use of an osteotome and mallet, it may induce less tactile sensitivity and less discomfort in patients than the conventional osteotome technique. For evaluation of its clinical performance, reamer-mediated transalveolar sinus floor elevation and simultaneous dental implant installation were performed in consecutive clinical cases by a limited number of doctors. The success parameter of the implants, level of intraoperative patient discomfort using the visual analogue scale (VAS), and convenience in handling were monitored.

Material and methods

From February 2007 to February 2009, the specially designed reamer (Hatch-Reamer®; Sinus-tech, Seoul, Korea) was used for transalveolar sinus floor elevation with simultaneous implant placement at 391 sites (Table 1) in 380 patients (200 males, 180 females) with a mean age of 50.8 years (range, 24–65) by five doctors. Unlike a conventional reamer (no end-cutting blade) or a drill having a sharp end-cutting point, this reamer had one cutting blade with obtuse angle and it could remove bone in the vertical direction from

Table 1. Localization of the implants in the posterior maxilla (n = 391)

| Implant site | No. of implants |
|--------------|-----------------|
| 1st premolar | 19 |
| 2nd premolar | 59 |
| 1st molar | 181 |
| 2nd molar | 132 |
| Total | 391 |

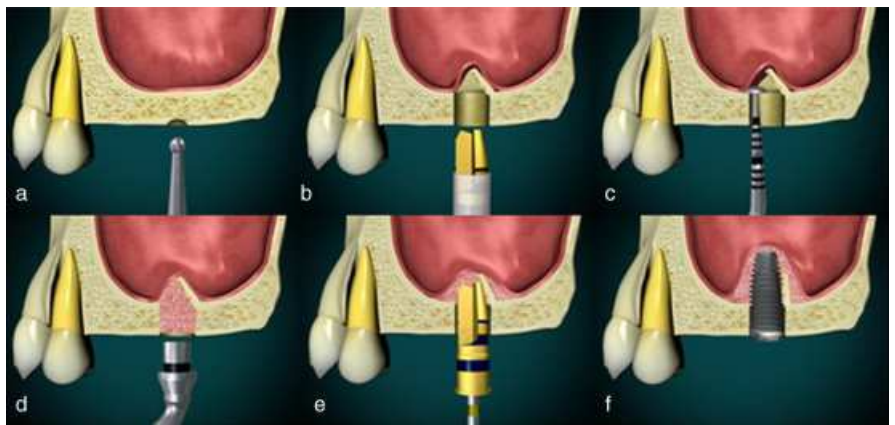


Fig. 1. Illustrations of the reamer-mediated transalveolar sinus floor elevation procedure. (a) Two mm round bur marking. (b) Cutting and lifting of the sinus floor by the reamer acts like a trapdoor. (c) Confirming sinus floor elevation and intact Schneiderian membrane using a round-tip probe. (d) Packing the osteotomy with graft material. (e) Elevating the Schneiderian membrane via augmentation of the graft with the reamer (at 30 r.p.m.). (f) Implant placement.

periphery to center (Fig. 1). All doctors were skilled at implant surgery but did not have any experience with the reamer before this study. All patients signed informed consent forms. Patients had single or multiple teeth missing from the maxilla. Patients with systemic disease exhibiting risk factors for surgery as well as untreated periodontitis or sinusitis were excluded from the study. Reamer-mediated transalveolar sinus floor elevation was indicated at maxillary premolar and molar implant sites with a residual bone height of ≤ 8 mm. The residual bone height was determined for each site by the authors from panoramic X-ray view and computer tomography (CT) scan after calibration. For sinus floor augmentation, only the bovine bone mineral (Bio-Oss; Osteohealth, Shirley, NY, USA or OCSB; Nivec, Seoul, Korea) or a mixture with autogenous bone collected during the reaming was used. The implants used the following: TiO-blasted screw type 4.5–5 mm in diameter and 8–13 mm in length (Astra ST; Astra Tech, Mölndal, Sweden); HA-coated fin type, 4–5 mm in diameter and 8–12 mm in length (Bicon®; Boston, MA, USA), and SLA (sandblasted with large grit and acid etched) screw type, 4.3–5.3 mm in diameter and 8–13 mm in length (RF fixture, Snucone®; Daegu, Korea). After implant placement, the sinus floor elevation height was estimated from the length of the implant and postoperative panoramic X-ray view.

Surgical procedure

The overall procedure was illustrated in Fig. 1. Treatment of the posterior maxilla was carried out under local anesthesia. A crestal incision was made with full-thickness flap reflection. The proposed implant site was first clearly marked at 1 mm depth using a 2 mm round drill. A 2 mm reamer was taken to a depth of 1 mm below the

sinus floor as measured from preoperative radiographs. A guide pin was then placed to verify the implant positioning. A series of reamers was applied to enlarge the osteotomy site. The diameter of the final selected reamer was 0.5–1.5 mm less than the implant diameter depending on alveolar bone density. The hand piece was gently pushed to keep the contact between the reamer and the bone of the sinus floor. The entire reaming procedure was performed at 50 r.p.m. without saline irrigation. Autogenous bone chips were collected during the procedure. Loss of the sensation of resistance occurred when the sinus floor was cut off. At this point, a round-end probe was used to release the Schneiderian membrane around the edge of the hole of the sinus floor, to check membrane integrity, and to verify the depth of the osteotomy. Perforation of the Schneiderian membrane was determined using the Valsalva maneuver. Graft material was then added to the osteotomy, gently packed with a blunt-end condenser, and apically displaced 2 mm deeper than the residual bone height with the final reamer at 30 r.p.m. After each graft, the reamer was advanced 2 mm until the planned height was attained (2–3 mm longer than the implant length). Finally, the osteotomy was half-filled with the graft material and the implant was placed. The final insertion torque of the implant was tried to be maintained between 8 and 25 Ncm, which is displayed on the surgical drilling unit (INTRAsurg 300 or 300 plus, KaVo Dental GmbH, Biberach, Germany), except for the fin type implant. Selection of the implants was performed on the basis of the primary stability, depending on the quantity, and the quality of the residual alveolar bone. Panoramic radiographs or CT scans were taken immediately after the procedure to confirm graft containment and the implant placement. Submersion or non-submersion of the implant was selected depending on the

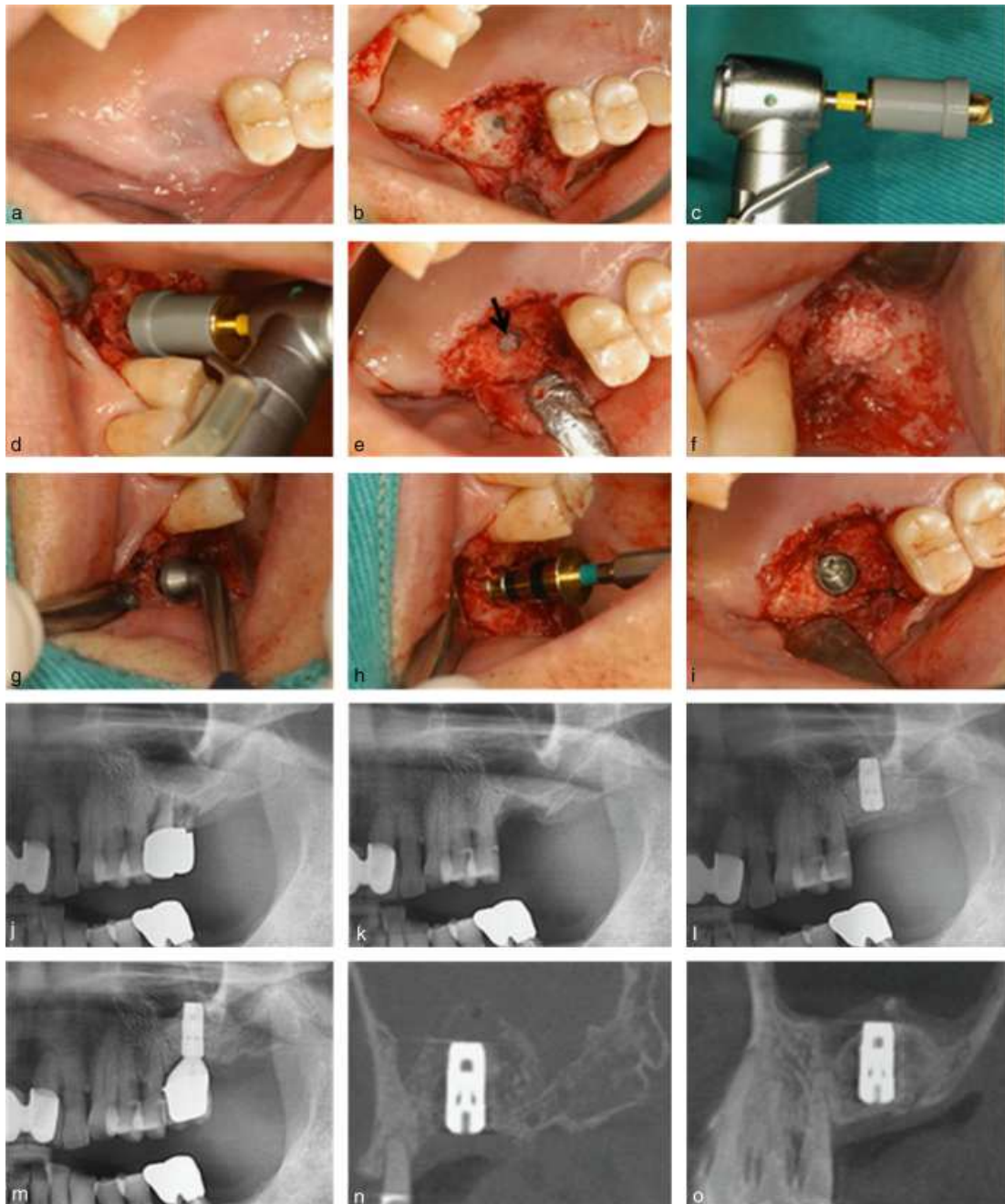


Fig. 2. Clinical case of a 56-year-old female patient. (a) Surgical site. (b) Flap reflection and marking with a 2 mm round bur. (c) Reamer with a stopper. (d) Reamer-mediated sinus floor cutting. (e) Trapdoor-like bone fragment (black arrow) attached to the Schneiderian membrane. (f) Grafting the osteotomy. (g) Packing with a condenser. (h) Reamer-mediated sinus floor elevation. (i) Implant installation. (j) Preoperative radiographic view (left upper first molar). (k) Nine weeks after extraction (2 mm sinus floor thickness). (l) Sinus floor elevation and simultaneous implant installation (5 mm in diameter and 10 mm in length). (m) Ten months after implant placement. (n) Sagittal section of a computed tomography (CT) scan taken immediately after implant placement. (o) Sagittal section of a CT scan taken 9 months after implant placement.

primary implant stability. Submerged implants before uncovering and non-submerged implants before prosthetic treatment were allowed to heal for 4–9 months. A 2-week healing period was allowed for the uncovering procedure (Fig. 2). When perforations occurred during the procedure, they were treated with short implant placement, lateral-approach sinus floor elevation, or delayed for 3 months for healing depending on the perforation severity. Perforation cases were excluded from the implant success evaluation.

Clinical examination

Prostheses included single-tooth restorations and multiple-unit implant-supported restorations and consisted of 172 single crowns, 112 two-unit fixed partial dentures (FPDs), 83 three-unit FPDs, and 24 four-unit FPDs. After the prosthetic treatment, all patients were seen every 3–6 months for maintenance and evaluation. The criteria for implant survival were based not only on implant function but also on the modification of the Albrektsson et al. (1986) success criteria

proposed by Rosen et al. (1999) in their retrospective analysis of implants placed using the osteotome technique. Osseointegrated implants were restored and functional for an average loading period of 28.4 months (range, 18–36 months).

Patient acceptance

After the surgical procedure, patients were asked to give their impression of the surgical procedure concerning pain and discomfort using a VAS in

which 0 indicated "total acceptance or no inconvenience" and 10 indicated "total refusal or unpleasant or painful feelings."

Statistical methods

Statistical analysis was carried out with SPSS statistics for Windows (Ver. 18.0, IBM corporation, Somers, NY, USA). The χ^2 -test was used to identify the statistical correlation among the height of the residual alveolar bone, implant length (amount of elevation), and the implant failure. The statistical significance was determined with the significance level of 0.05.

Results

A total of 391 reamer-mediated sinus floor elevations with simultaneous implant placement were performed in 380 patients, 200 men, and 180 women (average age, 50.8 years). These procedures were accomplished at 132 second molar, 181 first molar, 59 second premolar, and 19 first premolar sites. Eighteen (4.6%) perforations of the Schneiderian membrane occurred. Seven (1.8%) perforations occurred during the first 100 cases and the other 11 (2.8%) perforations occurred in the final 291 procedures. Interestingly, the perforation rate in alveolar bone height < 5 mm was only 2.8%. (Table 2) In 373 non-perforated osteotomies, the mean height of the residual alveolar process was 5.8 ± 0.9 mm (range, 2–8 mm), and the mean elevation of the sinus floor was 6.2 ± 0.4 mm (range, 4–10 mm). All of the implants were placed simultaneously. Seventeen (4.6%) implants failed, six of which were detected as early failures (during the healing period) and 11 of which failed during the early loading period (< 12 months). During the follow-up period, the overall success rate of the 373 implants was 95.4%. In sites with thin sinus floors (< 4 mm), the success rate was 92.7%, while in sites with bone heights > 4 mm, the success rate was 96.4%. The success rate was lowest in cases in which 10–12 mm implants were placed at alveolar bone heights < 4 mm. (Table 3) A significant correlation was found between the implant length (amount of elevation) and implant survival at the residual bone height of < 4 mm ($\chi^2 = 15.320$; $P = 0.002$, Table 3).

With regard to patient acceptance, almost 100% of the patients experienced either no discomfort or were subjected to minimal inconvenience during the procedure (Fig. 3). Nine (2.4%) of 380 patients complained of jaw muscle myalgia or pain around the temporomandibular joint from the prolonged mouth opening, but they did not feel bad during the surgical procedure or experience any vertigo or disorientation after the surgery.

Table 2. Perforation of the Schneiderian membrane during the reamer-mediated sinus floor elevation ($n = 391$)

| Residual bone height | Number of sites | Perforation (n) | Frequencies (%) |
|----------------------|-----------------|-----------------|-----------------|
| ≤ 4 mm | 98 | 2 | 2 |
| 4–5 mm | 79 | 3 | 3.8 |
| 5–6 mm | 90 | 6 | 6.7 |
| 6–7 mm | 64 | 0 | 0 |
| > 7 mm | 60 | 7 | 11.7 |
| Total | 391 | 18 | 4.6 |

Table 3. Residual bone heights, implant lengths, survival rates, and statistical correlations between implant length (amount of graft) and implant survival with regard to the residual bone height ($n = 373$)

| Residual bone height (mm) | Implant length (mm) | Implants (n) | Implants lost (n) | Survival (%) | Chi-square test | |
|---------------------------|---------------------|--------------|-------------------|--------------|-----------------|-------|
| | | | | | χ^2 | P |
| ≤ 4 | ≤ 8 | 26 | 0 | 100 | 15.32 | 0.002 |
| | 8–10 | 53 | 2 | 96.2 | | |
| | 10–12 | 17 | 5 | 70.6 | | |
| | > 12 | 0 | 0 | – | | |
| Subtotal | | 96 | 7 | 92.7 | | |
| 4–5 | ≤ 8 | 14 | 1 | 92.9 | 0.513 | 0.916 |
| | 8–10 | 34 | 1 | 97.1 | | |
| | 10–12 | 27 | 1 | 96.3 | | |
| | > 12 | 1 | 0 | 100 | | |
| Subtotal | | 76 | 3 | 96.1 | | |
| 5–6 | ≤ 8 | 9 | 0 | 100 | 0.246 | 0.97 |
| | 8–10 | 37 | 1 | 97.3 | | |
| | 10–12 | 38 | 1 | 97.4 | | |
| | > 12 | 0 | 0 | – | | |
| Subtotal | | 84 | 2 | 97.6 | | |
| 6–7 | ≤ 8 | 8 | 1 | 87.5 | 3.244 | 0.355 |
| | 8–10 | 27 | 0 | 100 | | |
| | 10–12 | 28 | 1 | 96.4 | | |
| | > 12 | 1 | 0 | 100 | | |
| Subtotal | | 64 | 2 | 96.9 | | |
| 7–8 | ≤ 8 | 3 | 0 | 100 | 0.494 | 0.92 |
| | 8–10 | 11 | 1 | 90.9 | | |
| | 10–12 | 38 | 2 | 94.7 | | |
| | > 12 | 1 | 0 | 100 | | |
| Subtotal | | 53 | 3 | 94.3 | | |
| Total | | 373 | 17 | 95.4 | | |

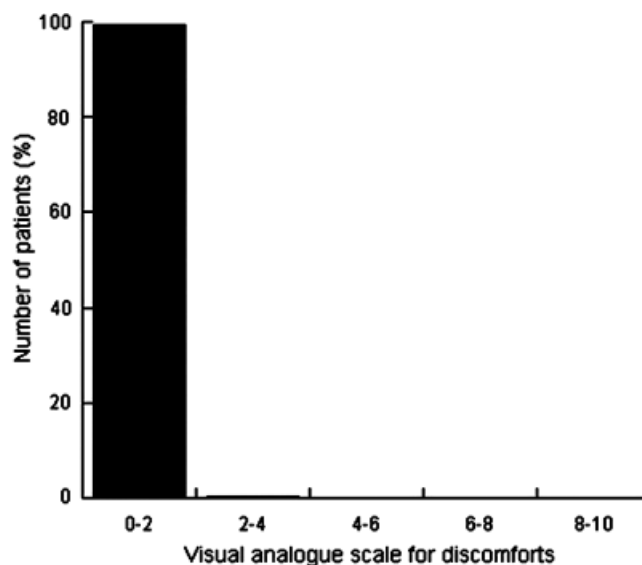


Fig. 3. Visual analogue scale for determining subjective perioperative patient discomfort during reamer-mediated transalveolar sinus floor elevation (0–2, none or minimal; 2–4, mild; 4–6, moderate; 6–8, severe; 8–10, profound discomfort, $n = 380$).

Discussion

Although the osteotome procedure and reported modifications have proven efficacious in managing moderate vertical deficiencies in the posterior maxilla, such circumstances are still challenging for less experienced clinicians and sometimes result in patient discomfort. The hydraulic pressure infrafracture technique designed by Summers (1994b) and Davarpanah et al. (2001) could be impractical in cases in which the bone is extremely soft and no definite sinus floor exists. Moreover, the drilling and direct osteotome infrafracture approach suggested by Cavicchia et al. (2001) and Toffler (2004) would increase the risk of membrane perforation. Furthermore, the percussive forces of tapping or malleting provoke noise, bad feelings, and vibration in patients or can even give rise to vertigo in severe cases (Peñarrocha et al. 2001).

Considering a less surgically invasive and more “patient-friendly” method, a specially designed reamer may be a good alternative to the conventional osteotome technique. The basic action mechanism of the reamer comes from its one-edged blade situated at a specific angle (85°). The reamer consists of a CE with a CA, a reaming edge (RE), and a vertical groove (Fig. 4). The CE performs the primary bone cutting and makes the bony hole circular. The CA creates the angle between the CE and the tip of the reamer and provides the CE cutting function. If the CA is 90° , the CE cannot cut the bone, so the chance of Schneiderian membrane perforation may increase with an acute angle (like a drill), although cutting efficiency of the reamer is improved. The RE removes the remaining bone in the osteotomy laterally 180° behind the CE. In addition, the flat end of the RE performs a light vertical pushing action on the sinus floor during the reaming and the groove removes the bone chips. These actions make a round-form bone shell on the cortical bone of the sinus floor. The reamer thins, fractures, and finally displaces this bone shell vertically in the sinus cavity when balanced between the hardness of the cortical bone shell of the sinus floor and the compressive force of the operator’s hand without tearing the Schneiderian membrane. This is referred to cutting, lifting, and elevation of the sinus floor. The thin bone shell prevents direct contact between the reamer and the sinus membrane and reduces the chance of membrane perforation. Considering a previous report that described a 2.2% perforation rate with a residual bone height > 6 mm (Ferrigno et al. 2006), it is important to note that the perforation rate in alveolar bone heights < 5 mm was only 2.8%. In addition, 8–10 mm long implants placed in < 4 mm alveolar bone height showed a 96.2% survival rate that was not significantly

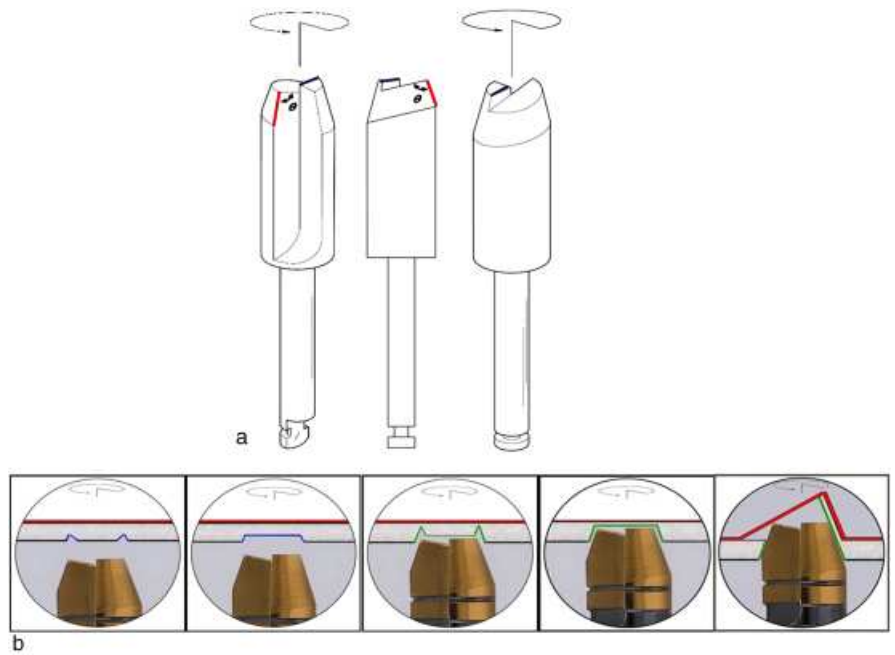


Fig. 4. (a) Illustrations of the structure of the reamer used for sinus floor elevation. The red line is the cutting edge (CE), the blue line is the reaming edge (RE), and θ is a cutting angle (85°). (b) Illustration of the mechanism of reamer-mediated transalveolar sinus floor elevation. The CE forms a ditch on the sinus floor and the RE flattens it. Repetitive action makes the sinus floor thin. Finally, the sinus floor is cut into a circular form by the CE without direct contact between the reamer and the Schneiderian membrane resulting in a trapezoid-like bone fragment.

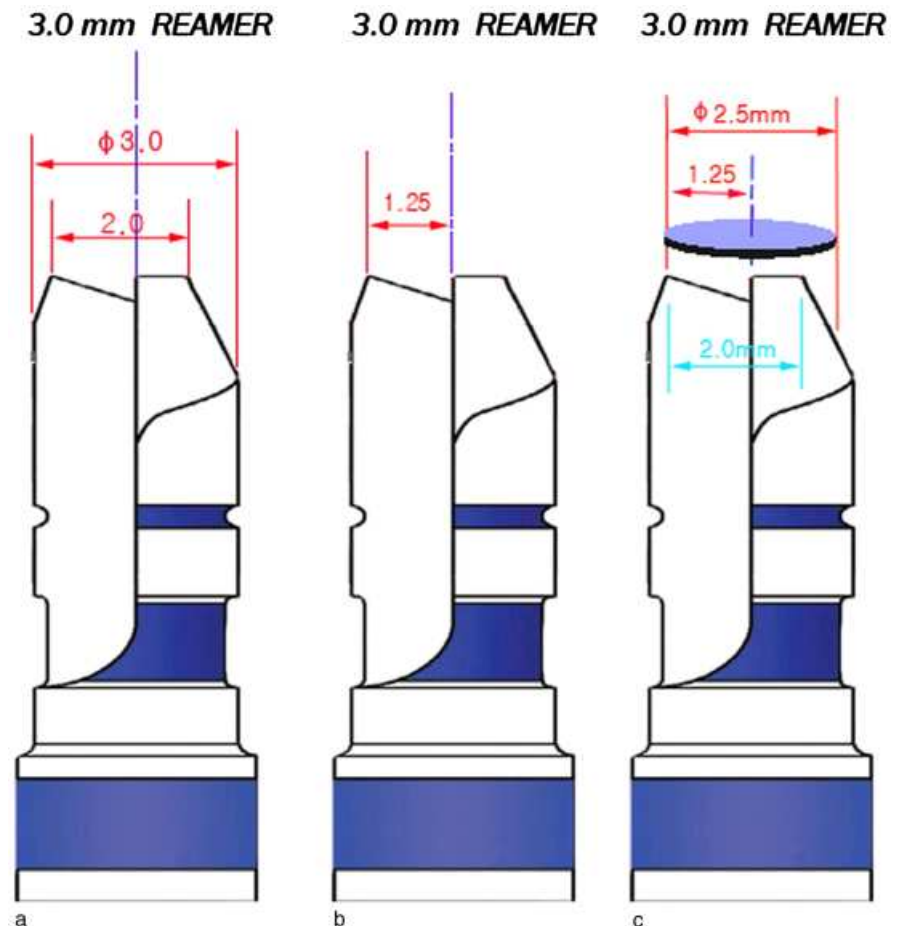


Fig. 5. Schematic drawings of the 3-mm-diameter reamer. The working diameter of the 3.0 mm reamer is 2 mm (a). The radius of the cutting edge tip is 1.25 mm (b). Theoretically, the resulting osteotomy in the sinus floor is 2.5 mm in diameter (c).



Fig. 6. Clinical case of a 40-year-old female patient. (a) Preoperative radiographic view. (b) Sagittal section of the computed tomography (CT) image. The sinus septum is not clearly shown. The sinus floor was 5 mm thick. (c) Coronal section of the CT image in which the sinus septum could be confirmed. (d) Eight months after implant placement (5 mm in diameter and 10 mm in length). (e) Sagittal section of the CT scan (8 months postoperative). (f) Coronal section of the CT scan (8 months postoperative) in which the sinus floor was displaced superiorly and laterally without membrane perforation.

different from that of bone height >6 mm. Osteotome-mediated transalveolar sinus floor elevation was recommended in residual alveolar bone heights ≥ 5 mm with implants ≥ 8 mm (Pjetursson et al. 2009). This reamer technique could be a safe modality, even in cases of short residual alveolar bone height and frequencies of the membrane perforation might be independent of the original height of the residual alveolar bone. However, the success rate was low in the bone of <4 mm placed with 10–12 mm length implants and the statistical analysis showed the clinical correlation between the implant length (amount of elevation) and the implant survival at the residual bone of <4 mm. It is supposed that elevation of the membrane over 10 mm with crestal approach may be beyond the resistance capacity of the Schneiderian membrane. It could be correlated with the study by Reiser and colleagues. In their cadaveric study, the incidence of the perforation was increased when the level of the maxillary sinus membrane elevation was over 6 mm. Even though the membrane was not torn at the osteotomy of the floor, the perforation could have occurred during too much elevation and could have been masked by the graft material. This might not be detected by

the Valsalva maneuver and resulted in compromised bone healing. Reamer-mediated sinus floor elevation over 10 mm at residual bone of <4 mm is still technique sensitive and at the site of <4 mm with favorable crestal bone, 8–9 mm elevation and immediate placement of 8–10 mm implant were recommended. Moreover, due to the nature of the prospective study, the first 100 consecutive cases were attempted mostly in residual alveolar bone heights of 7 mm because perforations at this height could be managed more easily with short implants. This explains why the perforation rate (11.7%) at this height was so high. However, most clinicians could reduce the perforation rate after four or five trials with the reamer.

The reamer technique is also beneficial for initial implant stability. For instance, a 3-mm-diameter reamer theoretically produces a 2.5 mm round hole, and this smaller apical diameter may contribute to bicortical installation and better implant anchorage (Fig. 5). This feature might be associated with the high implant survival rate in residual bone heights ≤ 5 mm. In a previous study using human cadavers (Reiser et al. 2001), a main cause of perforation occurrence was the presence of antral septae or sharp collateral bony

walls. Use of the reamer can overcome these anatomic limitations. In our preclinical study, the reamer made a bony coagulum instead of a trapdoor or hatch-like bone shell in a beveled sinus floor (data not shown). It was observed that the bony coagulum laterally displaced the Schneiderian membrane, prevented direct contact between the reamer and the membrane, and reduced the perforation rate (Fig. 6).

BPPV is a rare complication related to the osteotome technique in which patients suffer from dizziness or nausea during the healing period. Although the exact causes of osteotome-related BPPV remain unclear, avoidance of excessive percussive forces and hyperextension of the head should be recommended. Use of the mallet-free reamer does not provoke such percussive forces or hyperextension of the head. Pjetursson et al. (2009) reported that over 23% of patients experienced the unpleasant feeling, vertigo, head hyperextension, nausea, and disorientation during the osteotome procedure. In the current study, patient acceptance of the reamer procedure was very high and only 2.4% of the 380 patients complained of light to moderate myalgia from the prolonged mouth opening. They also preferred the reamer procedure without saline irrigation to the initial drilling with irrigation.

In conclusion, the specially designed reamer enables easy, predictable internal sinus elevation and augmentation without the use of an osteotome and mallet. It can also safely elevate the sinus floor, regardless of its shape (e.g., irregularities in thickness or septum). Its lack of an irrigation system results in availability of autogenous bone chips for sinus augmentation. The reamer is also minimally invasive and minimizes patient discomfort during the perioperative period. This study showed that reamer-mediated transalveolar sinus floor elevation compares favorably with the osteotome or the modified Caldwell–Luc technique with regard to Schneiderian membrane perforations and the degree of achievable membrane elevation. The long-term usefulness of this system should be evaluated in more extensive prospective clinical cases.

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