

# Intraoperative Complications During Sinus Floor Elevation with Lateral Approach: A Systematic Review

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**Purpose:** To analyze the occurrence of intraoperative complications during sinus floor elevation with a lateral approach and their correlations with the technique adopted by surgeons. Materials and Methods: Electronic and manual searches resulted in 4,417 records on sinus floor elevation. Twenty-one randomized clinical trials (RCTs) and 11 prospective controlled clinical trials (CCTs) reporting occurrence of intraoperative complications were included. Risk of bias was assessed according to the Cochrane tool and a modified Downs and Black quality analysis for RCTs and CCTs, respectively. Results: Sinus membrane perforation and hemorrhagic events following vascular lesions were the only intraoperative complications reported by the selected studies with overall occurrences of 15.7% and 0.4%, respectively. Three different surgical devices (rotary instruments, piezoelectric osteotomes, and manual bone scrapers) were used to perform the lateral antrostomy. Ultrasonic devices and bone scrapers showed a lower incidence (10.9% and 6.0%, respectively) of membrane perforation compared with that of rotary instruments (20.1%). Among the different ultrasonic procedures, erosion of the lateral antral wall showed the lowest membrane perforations (4.7% incidence). Hemorrhagic complications seemed to be extremely infrequent with any surgical technique. Conclusion: Sinus membrane perforation was the most frequently described intraoperative complication during sinus floor elevation with a lateral approach. Thinning the lateral wall of the sinus before performing the antrostomy (either with ultrasonic devices or manual bone scrapers) seemed to be an important factor in preventing membrane perforation during sinus surgery. Further high-quality RCTs specifically investigating intraoperative complication occurrence are needed.

Keywords: hemorrhagic complications, intraoperative complications, membrane perforation, sinus floor elevation

nsufficient bone height to place dental implants is a frequent occurrence after tooth extraction in the posterior maxilla, mainly resulting from postextractive bone remodeling and maxillary sinus pneumatization. Maxillary sinus floor elevation is the most common procedure for obtaining a vertical augmentation of atrophic posterior maxillary crests, which allows for proper implant-supported rehabilitations.

This surgical technique was initially developed by Boyne and James<sup>1</sup> and Tatum<sup>2</sup> in the 1980s, and consisted of a modified Caldwell-Luc approach, where the access to the sinus was obtained with a bony window created on the lateral sinus wall by using a diamond bur on a surgical motor. Perforation of the sinus membrane and bleeding caused by vascular lesions are the main intraoperative complications described during sinus floor elevation with a lateral approach.<sup>3</sup> To minimize these adverse events during the surgical procedure, several surgical variants have been proposed,<sup>4,5</sup> including the use of ultrasonic devices,<sup>6</sup> bone scrapers,<sup>7</sup> and specially designed burs.<sup>8</sup> Previous studies on the effects of accidental membrane perforation on new bone formation and on the implant survival rate reported contrasting outcomes. Proussaefs et al<sup>9</sup> and Nolan et al<sup>10</sup> reported that nonperforated sites demonstrated significantly more bone formation than perforated sites, while Froum et al<sup>11</sup> found that membrane laceration was not a significant factor in terms of vital bone production. Jensen et al<sup>12</sup> and Khoury<sup>13</sup> reported higher rates of implant failures in cases with

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perforations, although Schwartz-Arad et al,<sup>14</sup> Ardekian et al,<sup>15</sup> and Karabuda et al<sup>16</sup> showed no differences in the implant survival rate with respect to membrane integrity. However, an intact sinus membrane after elevation or an adequate repair of eventual perforations is a necessary condition to stabilize a particulate grafting material into the sinus cavity in a reliable way.<sup>17</sup> Hemorrhagic events following lesions of the alveolar-antral artery (an anastomosis between the dental branch of the posterior superior alveolar artery and the infraorbital artery) have also been described as a possible intraoperative complication of maxillary sinus floor elevation with a lateral approach. In the atrophic maxilla (class V-VI Cawood-Howell),<sup>18</sup> the mean distance between this artery and the alveolar crest is approximately 11 mm,<sup>19</sup> and its course can be intercepted by the bony window design.

At present, there are not conclusive data in the literature about the incidence of intraoperative adverse events, which is highly variable among studies, and about possible correlation between the incidence of complications and the surgical technique. Therefore, the aim of this systematic review was to assess the incidence of intraoperative complications during sinus floor elevation with a lateral approach and to evaluate the influence of different surgical techniques on their occurrence. Only clinical trials or prospective controlled studies on patients requiring sinus augmentation, irrespective of the different surgical procedure or comparator, were evaluated for the incidence of intraoperative complications.

## **MATERIALS AND METHODS**

#### Search Strategy

The present systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement,<sup>20</sup> and it has been registered at the PROSPERO database (http:// www.crd.york.ac.uk/PROSPERO). An electronic search on MEDLINE (PubMed, www.ncbi.nlm.nih. gov/pubmed), Embase (www.embase.com), and SCOPUS (www.scopus.com) was conducted by two independent authors (F.A. and F.B.), selecting articles published from 1980 up to the latest access on February 18, 2014, with no language restrictions, and using the following algorithm: "[sinus elevation] OR [sinus augmentation] OR [sinus lift] OR [sinus grafting]". A manual search of the references of all full-text articles and reviews emerging from the electronic search was also performed. The eligibility assessment was performed independently by two blinded authors (G.P. and R.D.L.). The intraexaminer reliability in the study selection process was assessed through

the Cohen  $\kappa$  test, assuming a threshold value of 0.61.<sup>21</sup> Conflicts were resolved by discussion of each article, until consensus was reached. An attempt to contact the corresponding authors of the included studies was made to retrieve any missing information or clarification of specific items.

#### **Study Selection and Data Collection Process**

This systematic review included human studies on sinus floor augmentation with a lateral approach. considering the occurrence of intraoperative complications between the outcomes of the research. No restrictions were set regarding the surgical technique used to perform the lateral antrostomy. Studies where bone block grafts had been used or in which it was declared that surgery had been performed by inexperienced surgeons were excluded. Only clinical trials, randomized or not, and prospective controlled studies with more than 15 sinus surgeries were screened for inclusion in the review. Studies with the lowest quality within the hierarchy of scientific evidence (such as expert opinions, case reports, case series, retrospective studies) were excluded. Further exclusion criteria were as follows: (1) off topic; (2) ex vivo, in vitro, and animal studies; (3) transcrestal or alternative surgical accesses; (4) expert opinions, case reports, case series, retrospective studies, and prospective studies with less than 15 sinus augmentations; (5) antrostomy technique not clearly described; (6) no clear mention of intraoperative complications; (7) inlay block grafts; and (8) inexperienced surgeons.

#### **Data Items**

The following items were extracted from the selected articles independently by two authors (C.S. and F.A.), by using forms mostly predefined at the protocol stage: (1) year of publication, (2) study design, (3) sample size, (4) sex distribution, (5) mean age or age range, (6) number of treated sinuses, (7) antrostomy technique, (8) surgical devices used for the antrostomy, (9) number of treated sinuses, and (10) observations by the authors about complications. Moreover, primary outcomes included: (1) number of perforations of the sinus membrane and number of patients in whom perforations occurred, (2) perforation rate and confidence interval, (3) number of intraoperative hemorrhagic complications, and (4) surgical phase in which complications occurred. In particular, percentages of the occurrence of intraoperative complications for each included study were collected and presented as a summary measure. The corresponding 95% confidence intervals were also calculated, including continuity correction. Since generally each complication occurred in single patients, with few cases of patients with more than one

episode of the same complications, independence for all the data was assumed.<sup>22</sup> No secondary outcomes were considered herein.

## **Assessment of Risk of Bias**

The Cochrane Collaboration tool for assessing risk of bias was used, in its original form, for the randomized clinical trials (RCTs) reporting intraoperative complications among their primary outcomes.<sup>23</sup> However, regarding all the other study designs (or RCTs where intraoperative complications were not among the primary outcomes), no single approach in assessing methodologic soundness may have been appropriate<sup>24</sup> and, therefore, a slightly modified Downs and Black checklist,<sup>25</sup> consisting of 19 items (Table 1), was used to assess the risk of bias of all the other controlled clinical trials (CCTs). Evaluation was performed without blinding by two authors (C.S. and F.A.), and conflicts were resolved by discussion. A third author (F.B.) was consulted when necessary.

Finally, selective reporting, including information on the occurrence of intraoperative complications according to the different included study groups, was also considered as a risk of bias across studies.

## RESULTS

## **Study Search and Study Designs**

Electronic and manual searches resulted in the retrieval of 4,417 articles. No language restriction was applied in the present systematic review, resulting in the initial inclusion of articles in English, German, Chinese, Russian, Dutch, Italian, and French languages. Among the retrieved publications, a total of 32 studies<sup>26–57</sup> on sinus floor elevation with a lateral approach matching the inclusion criteria were selected for the subsequent analysis. The results of the electronic and manual searches are summarized in Fig 1. Twenty-one studies were classified as RCTs<sup>27,29,31,32,35–37,41–45,47– <sup>54,57</sup> and 11 studies as prospective CCTs.<sup>26,28,30,33,34,38–</sup> <sup>40,46,55,56</sup> The first included study was published in 2003<sup>26</sup> and the last one in 2014.<sup>57</sup> The median year of publication was 2013.</sup>

## **Study Population**

The sample size in the single studies ranged from a minimum of seven<sup>57</sup> to a maximum of 161<sup>56</sup> patients. The total number of treated patients was 948 (472 women, 414 men, and 62 not specified). Four studies<sup>43,47,49,57</sup> did not report the sex distribution. The overall mean age was 53.5 years. The age range varied from 18<sup>35</sup> to 80<sup>37,51</sup> years. Two studies<sup>48,56</sup> did not report the mean age of the patients. The total number of treated sinuses was 1,240.

## **Intraoperative Complications**

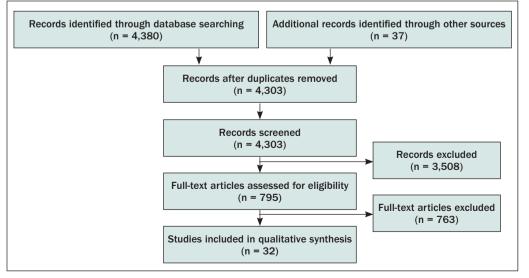
The main results obtained from the included studies are summarized in Table 2. Sinus membrane perforations and hemorrhagic events were the only intraoperative complications mentioned in the studies selected in this systematic review. Membrane perforation occurred in 195 sinus augmentation procedures in a total of 1,240 treatments (15.7% [13.7 to 17.9]), while two hemorrhagic events were reported during the treatment of 542 sinuses (0.4% [0.06 to 1.4]).

# Sinus Membrane Perforation in Relation with Surgical Technique

Rotary Instrument Antrostomy. Nineteen studies<sup>26-30,35,36,38-40,43,44,47,49,51,52,54,56,57</sup> describing rotary instrument antrostomy were included, treating a total of 558 patients and 736 sinuses. The total number of sinus membrane perforations using this technique was 148 (20.1% [17.3 to 23.2]). In 15 of these studies,<sup>26–30,35,36,38–40,43,47,49,54,57</sup> surgeons followed Tatum's technique (window outlining and its reflection into the sinus), treating 338 patients (for a total of 460 sinuses) with the occurrence of 103 perforations (22.4% [18.7 to 26.5]). In three studies,<sup>44,51,56</sup> surgeons removed the bony window after outlining the antrostomic area with a round bur. There were 195 patients treated with this technique, for a total of 251 sinuses, and 37 perforations occurred (14.7% [10.7 to 19.9]). In one study,<sup>52</sup> the antrostomic approach was performed by removing the buccal bone with a specially designed trephine bur in 25 sinuses (Group 1), and by consuming a bony window with a round bur in 25 sinuses (Group 2). Two perforations occurred by using the trephine bur (8.0% [1.4 to 2.7]) and eight perforations when performing the window erosion with conventional rotary instruments (32.0% [15.7 to 53.5]).

Ultrasonic Antrostomy. Twelve studies<sup>29,31,32,37,41,45,46,48,50,53–55</sup> describing ultrasonic antrostomy were included, with a total of 306 patients and 329 treated sinuses. The total number of sinus membrane perforations using ultrasonic devices was 36 (10.9% [7.9 to 14.9]). In seven of these studies, 29,31,32,37,41,54,55 surgeons adopted the window outlining and reflection technique. This approach was used in 109 patients, for a total of 119 sinuses, and 21 perforations occurred (17.6% [11.5 to 25.9]). In three studies, 46,48,50 surgeons removed the bony window after outlining the antrostomic area by ultrasonic devices. Ninety-one patients were treated with this technique, for a total of 104 sinuses, and the occurrence of 10 perforations was reported (9.6% [5.0 to 17.3]). In the last three studies,<sup>45,50,53</sup> the bone was removed by consuming it with ultrasonic devices. There were 106 patients treated with this technique, for a total of 106 sinuses. Perforation occurred in five cases (4.7% [1.7 to 11.1]).

<ul> <li>No./Item</li> <li>Reporting <ol> <li>Is the hypothesis/aim/objective of the study clearly described?</li> </ol> </li> <li>Are the main outcomes to be measured clearly described in the Introduction or Methods section?</li> <li>Are the characteristics of the patients included in the study clearly described?</li> <li>Are the intraoperative complications clearly described?</li> <li>Are the main findings of the study clearly described?</li> <li>Does the study provide estimates of the random variability in the data for the main outcomes?</li> <li>Have all important adverse events that may be a consequence of the intervention been reported?</li> <li>Is the reporting of intraoperative complications one of the outcomes of the study?</li> <li>Is the antrostomy technique clearly and specifically described?</li> <li>Is the exact surgical phase in which complication occurred clearly described?</li> <li>Is the number of patients in which perforation occurred clearly reported?</li> <li>Is the number of surgeons clearly mentioned?</li> </ul>	Yes No Yes No Yes No Yes	1 0 1 0 1 0
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11. Is the number of patients in which perforation occurred clearly reported?	Yes No	1 0
	Yes No	1 0
12. Is the number of surgeons clearly mentioned?	Yes No	1 0
	Yes No	1 0
<ol> <li>Are the confounders involved in the occurrence of complications listed? (previous surgeries, smoking, adhesions, allergies, etc)</li> </ol>	Yes No	1 0
External validity		
14. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	Yes No Unable to determine	1 0 0
15. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	Yes No Unable to determine	1 0 0
16. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	Yes No Unable to determine	1 0 0
nternal validity: bias		
17. Were the main outcome measures used accurate (valid and reliable)?	Yes No Unable to determine	1 0 0
nternal validity: confounding		0
18. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	Yes No Unable to determine	1 0 0
19. Were patients recruited over the same period of time?	Yes	1



**Fig 1** Flow diagram of the search strategy.

If the main outcomes are first mentioned in the Results section, the question should be answered no.

In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

Treatments and placebo (where relevant) that are to be compared should be clearly described.

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests, which are considered below.)

In non-normally distributed data, the inter-quartile range of results should be reported. In normally distributed data, the standard error, standard deviation, or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided.)

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

For the question to be answered yes, the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case control studies where there is no information concerning the source of patients included in the study.

For a study that does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

#### **Bone Scrapers**

Three studies<sup>33,34,42</sup> including 97 patients and 150 sinuses described antrostomies obtained by consuming the lateral bone wall of the sinus using a manual bone scraper, recording nine membrane perforations (6.0% [1.6 to 8.8]). One of these studies<sup>33</sup> reported a technique involving the exclusive use of bone scrapers to consume the antrostomy area. There were 45 patients treated with this technique, for a total of 90 sinuses, and only one perforation of the sinus membrane occurred (1.1% [0.1 to 6.9]). Another study<sup>34</sup> reported an association between bone scrapers, used to thin the lateral wall of the maxillary sinus, and burs, used to consume and remove the residual thinned bone. There were 34 patients treated with this approach, for a total of 42 sinuses, and five perforations occurred (11.9% [4.5 to 26.4]). The last study<sup>42</sup> reported an association between the bone scraper and piezoelectric osteotome. The bone scraper was used to consume the lateral wall of the maxillary sinus and the piezoelectric osteotome to outline and remove the residual bony window. Eighteen patients were treated, for a total of 18 sinuses, and three perforations were recorded (16.7% [4.4 to 42.3]).

#### **Surgical Phase of Perforation Occurrence**

Only four studies<sup>34,46,50,54</sup> out of 32 included in this systematic review described the exact moment in which membrane perforation occurred. The 14 perforations reported in these studies occurred in the following phases: during manual elevation with blunt elevators (11 perforations), during antrostomy (two perforations), and during flap opening (one perforation).

# Table 2 Protocols and Main Outcomes of the Included Studies

Study	Study design (level of evidence)	Sex of patients (No.)	Mean age (± SD and/or range)	Antrostomy technique	Surgical device	No. of treated sinuses	No. of perforations/ No. of patients with perforations
Stricker et al <sup>26</sup> (2003)	CCT	29 F; 12 M	55 (38–73)	Window outlining and reflection	Diamond round	66	25/19
Barone et al <sup>27</sup> (2005)	RCT	12 F; 6 M	46.7 (37–60)	Window outlining and reflection	Round steel bur	36	4/3
Thor et al <sup>28</sup> (2005)	CCT	17 F; 2 M	58 (35–75)	Window outlining and reflection	Round bur	38	12/11
Barone et al <sup>29</sup> (2008)	RCT	10 F; 3 M	56.6 (45–67)	Window outlining and reflection	Piezoelectric osteotome Round bur	13 13	4/4 test 3/3 control
Bornstein et al <sup>30</sup> (2008)	ССТ	34 F; 22 M	53.9 (19–74)	Window outlining and reflection	Round bur	59	18/NR
Felice et al <sup>31</sup> (2009a)	RCT	6 F; 9 M	56 (45–70)	Window outlining and reflection	Piezoelectric osteotome	15	1/1
Felice et al <sup>32</sup> (2009b)	RCT	8 F; 2 M	50 (35–60)	Window outlining and reflection	Piezoelectric osteotome	20	2/2
Galindo-Moreno et al <sup>33</sup> (2010)	CCT	17 F; 28 M	50.4 (35–72)	Consuming	Bone scraper	90	1/1
de Vicente et al <sup>34</sup> (2010)	CCT	21 F; 13 M	51.5 (34–69)	Consuming	Bone scraper and round bur	42	5/NR
Koch et al <sup>35</sup> (2010)	RCT	15 F; 16 M	46.5 (18–75)	Window outlining and reflection	Round bur	31	9/9
Borges et al <sup>36</sup> (2011)	RCT	11 F; 6 M	57.9 (NR)	Window outlining and reflection	Round bur	34	3/3
Esposito et al <sup>37</sup> (2012)	RCT	9 F; 11 M	57.6 (45–80)	Window outlining and reflection	Piezoelectric osteotome	20	4/0
Pieri et al <sup>38</sup> (2012)	CCT	11 F; 9 M	54.6 (± 5.3) (47–69)	Window outlining and reflection	Round bur	40	6/5
Canullo et al <sup>39</sup> (2012)	CCT	16 F; 14 M	58.3 (± 11.1)	Window outlining and reflection	Round bur	30	4/4
Avila-Ortiz et al <sup>40</sup> (2012)	CCT	12 F; 9 M	57.6 (23–69)	Window outlining and reflection	Round bur	24	5/NR
Felice et al <sup>41</sup> (2012)	RCT	10 F; 10 M	58.5 (45–75)	Window outlining and reflection	Piezoelectric osteotome	20	5/5
Barone et al <sup>42</sup> (2013)	RCT	12 F; 6 M	59.4 (49–64)	Window outlining and removal	Bone scraper and piezoelectric osteotome	18	3/3
Khairy et al <sup>43</sup> (2013)	RCT	15 NR F; NR M	38 (22–54)	Window outlining and reflection	Round bur	15	5/5
Cannizzaro et al <sup>44</sup> (2013)	RCT	14 F; 6 M	53.3 (30-72)	Window outlining and removal	Round bur	20	2/2
Merli et al <sup>45</sup> (2013)	RCT	21 F; 19 M	50.7 (38–66)	Consuming	Piezoelectric osteotome	40	2/2
Cortes et al <sup>46</sup> (2013)	CCT	19 F; 23 M	58.8 (± 5.6) F 62.3 (± 8.2) M	Window outlining and removal	Piezoelectric osteotome	42	3/NR
Yilmaz et al <sup>47</sup> (2013)	RCT	10 NR F; NR M	56.9 (± 5.95) (46–65)	Window outlining and reflection	Round bur	20	5/NR
Testori et al <sup>48</sup> (2013)	RCT	8F; 5M	NR	Window outlining and removal	Piezoelectric osteotome	26	3/3
Tosta et al <sup>49</sup> (2013)	RCT	30 NR F; NR M	44 (18–70)	Window outlining and reflection	Round bur	30	0/0
Stacchi et al <sup>50</sup> (2013)	RCT	44 F; 28 M	55.4 (± 10.1) (42–73)	Window outlining and removal	Piezoelectric osteotome	36	4/4
				Consuming		36	0/0
Altintas et al <sup>51</sup> (2013)	RCT	7 F; 7 M	49.5 (23–80)	Window outlining and removal	Round bur	14	0/0

RCT = randomized clinical trial; CCT = controlled clinical trial; NR = not reported; M = male; F = female.

Perforation rate (95% CI)	Surgical phase of perforation occurrence	No. of hemorrhagic complications	Reported considerations about complications
37.9%	NR	NR	In 19 patients, 25 perforations of the sinus membrane were noted during sinus floor surgery
(26.5–50.7)			(37.87%); 69% of those cases have been repaired with fibrin glue.
11.1% (3.6–27)	NR	NR	The perforations were carefully closed with a collagen membrane. The study protocol was not modified.
31.6% (18-48.8)	NR	NR	NR
30.8% (10.4–61.1) 23.1% (6.2–54)	NR	NR	NR
30.5% (19.5–44)	NR	2	The perforations of the sinus membrane were repaired intraoperatively with a fibrin sealant in
30.3% (13.3-44)		Z	11 cases, and seven perforations were sealed with a resorbable collagen membrane that was trimmed and placed at the site of the perforation before insertion of the graft material. In two SFE procedures, arterial bleeding from the bony window occurred and was handled with cautery.
6.7% (0.4–34)	NR	None	The laceration of the sinus membrane was closed with resorbable synthetic barrier.
10.0% (1.8–33.1)	NR	None	Three perforations occurred during the sinus augmentation procedure but one rupture of the lining was induced by incorrect handling of the rigid resorbable barrier.
1.1% (0.1-6.9)	NR	None	NR
11.9% (4.5–26.4)	During membrane elevation	None	Only in one of these five cases did the perforation in the sinus membrane have to be treated; thus, it was patched with a portion of membrane.
29% (14.9-48.2)	NR	NR	In the case of an accidental perforation of the sinus membrane, the perforation was covered with a collagen membrane.
8.8% (2.3–24.8)	NR	NR	These perforations were left without sutures or membranes.
20% (6.6–44.3)	NR	None	A resorbable barrier was placed internally to contain the granules of grafted bone.
15% (7.1–29.1)	NR	NR	The perforations of the sinus membrane were treated intraoperatively with the aid of a resorbable collagen membrane.
13.3% (5.3–29.7)	NR	NR	They were repaired using a collagen membrane.
20.8% (9.2–40.5)	NR	NR	All perforations were sealed intraoperatively.
25% (9.6–49.4)	NR	None	A resorbable barrier was placed internally to contain the granules of grafted bone.
16.7% (4.4–42.3)	NR	None	The perforations were treated with resorbable collagen barriers.
33.3% (13–61.3)	NR	NR	Perforation was managed by folding the sinus membrane on itself and by placement of an absorbable collagen membrane over the perforation.
10% (1.8–33.1)	NR	None	A barrier was used to contain the graft, using the pouch technique. A collagen membrane was placed against the perforated site as well as along the internal surface of the maxillary sinus.
5.0% (0.9–18.2)	NR	None	A collagen membrane was placed against the perforated site as well as along the internal surface of the maxillary sinus. The collagen membrane was then folded along the lateral access window to form a pouch.
7.1% (1.9–20.6)	One tear during flap opening, two during elevation	None	In sinuses with a small sinus membrane perforation (less than 5 mm), resorbable collagen membrane was placed to close the membrane perforation at this stage.
25% (9.6-49.4)	NR	None	All of the perforations were sealed with a collagen membrane.
11.5% (3-31.3)	NR	NR	Any perforations were covered with resorbable collagen barrier membranes.
0% (0-14.1)	NR	NR	NR
11.1% (4.4–25.3) 0% (0–9.6)	During membrane elevation with manual instrument (2) and during antrostomy (2)	None	Two perforations occurred during membrane elevation with manual instruments, all 4 in group outlining. Three out of four perforations were associated with the presence of Underwood's septa ( $P < .05$ ).
0%	NR	None	NR

#### Table 2 Protocols and Main Outcomes of the Included Studies (cont)

Study	Study design (level of evidence)	Sex of patients (No.)	Mean age (± SD and/or range)	Antrostomy technique	Surgical device	No. of treated sinuses	No. of perforations/ No. of patients with perforations
Kazancioglu et al <sup>52</sup> (2013)	RCT	11 F; 14 M	45.6 (± 6.9) (35–63)	Window outlining and removal Window outlining and consuming	Trephine rotary instrument Round bur	25 25	2/2 8/8
Del Fabbro et al <sup>53</sup> (2013)	RCT	18 F; 12 M	52.3 (± 11.6) (37–66)	Consuming	Piezoelectric osteotome	30	3/3
Delilbasi et al <sup>54</sup> (2013)	RCT	8 F; 13 M	47.5 (31–66)	Window outlining and reflection	Piezoelectric osteotome Round bur	11 10	1/1 1/1
Mazzocco et al <sup>55</sup> (2014)	ССТ	7 F; 13 M	55 (35–70)	Window outlining and reflection	Piezoelectric osteotome	20	4/4
Cha et al <sup>56</sup> (2014)	ССТ	65 F; 96 M	NR	Window outlining and removal	Round bur	217	35/NR
Wildburger et al <sup>57</sup> (2014)	RCT	7 NR F; NR M	58 (47–72)	Window outlining and reflection	Round bur	14	3/NR

RCT = randomized clinical trial; CCT = controlled clinical trial; NR = not reported; M = male; F = female.

#### Table 3 Risk of Bias for the Randomized Clinical Trials According to the Cochrane Tool

Study	Sequence generation	Allocation concealment	Blinding <sup>a</sup>	Incomplete outcome data	Selective outcome reporting	Other sources of bias	Overall risk of bias
Barone (2008)	Low	Low	Low	Low	High	Unclear	High
Felice (2009a)	Low	Low	Low	Low	Low	Low	Low
Felice (2009b)	Low	Low	Low	Low	Low	Unclear	Unclear
Koch (2010)	Low	Unclear	Low	Low	High	Low	High
Esposito (2012)	Low	Low	Low	Low	Low	Low	Low
Felice (2012)	Low	Low	Low	Low	Low	Unclear	Unclear
Barone (2013)	Low	Low	Low	Low	Low	Low	Low
Cannizzaro (2013)	Low	Low	Low	Low	Low	Low	Low
Merli (2013)	Low	Low	Low	Low	Low	Low	Low
Tosta (2013)	Unclear	Unclear	Low	Low	High	Unclear	High
Stacchi (2013)	Low	Low	Low	Low	Low	Low	Low
Kazancioglu (2013)	Unclear	Low	Low	Low	High	Low	High
Delilbasi (2013)	Low	Unclear	Low	Low	High	Unclear	High

<sup>a</sup>The risk of bias for nonblinded operators performing the treatment was not judged as a significant risk of bias.

#### **Hemorrhagic Complications**

Sixteen studies<sup>26–29,35,36,38–40,43,48,49,52,54,56,57</sup> did not consider the occurrence of hemorrhagic complications between the reported outcomes. The other 16 selected studies<sup>30–34,37,41,42,44–47,50,51,53,55</sup> recorded the presence of intraoperative hemorrhagic complications: in one study,<sup>30</sup> two alveolar antral artery hemorrhages occurred while performing Tatum's technique with round burs. Fifteen studies<sup>31–34,37,41,42,44–47,50,51,53,55</sup> reported the absence of significant bleeding during antrostomy. Hence, two hemorrhagic events were reported during 542 sinus floor elevations with a lateral approach performed with rotary or ultrasonic instruments (0.4% [0.6 to 1.5]).

#### **Risk of Bias in Individual Studies**

Detailed information on the risk of bias in individual studies is reported in Tables 3 and 4. From the assessment performed with Cochrane Collaboration's tool, five RCTs<sup>29,35,49,52,54</sup> were shown to be at a high risk of bias, with two RCTs<sup>32,41</sup> showing an unclear risk of bias, while six RCTs<sup>31,37,42,44,45,50</sup> did not show a significant risk of bias. Regarding the RCTs evaluated with the modified Downs and Black tool and the CCTs, the overall scores ranged from 6<sup>26</sup> to 14<sup>36,55,58–60</sup> on a 19-point scale. Three studies<sup>26,47,57</sup> had an overall score below the threshold and were thus judged as affected by a significant risk of bias, four studies<sup>27,39,40,43</sup> reached 10 points, five studies<sup>34,38,46,48,56</sup> reached 11 points, two studies<sup>28,51</sup> reached

Perforation rate (95% CI)	Surgical phase of perforation occurrence	No. of hemorrhagic complications	Reported considerations about complications
4.0% (0.7–14.9)	NR	NR	Resorbable collagen membrane was placed to close the membrane perforations.
16.0% (7.6–29.7)			
10.0% (2.6–27.7)	NR	None	P-PRP membrane, or detaching and folding the sinus membrane
9.1% (0.5-42.9) 10% (0.5-45.9)	During membrane elevation	NR	Perforations closed with a collagen membrane barrier
20.0% (6.6–44.3)	NR	None	Perforations closed with a collagen resorbable membrane barrier
16.1% (11.6–21.9)	NR	NR	In case of membrane perforation, collagen membranes and fibrin glue were used.
21.4% (5.7–51.2)	NR	NR	Perforations occurred because of the presence of septa or cicatrisation of the membrane due to previous sinus operation: in these cases, a collagen membrane was inserted and caused uneventful healing.

										Item										
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Tota
Stricker (2003)	0	0	1	0	0	0	0	0	1	0	1	0	0	1	0	1	0	1	0	6
Barone (2005)	1	1	1	0	1	0	1	0	1	0	1	0	0	1	0	1	0	1	0	10
Thor (2005)	1	1	1	0	1	0	1	0	1	0	1	1	0	0	0	1	1	1	1	12
Bornstein (2008)	1	1	0	1	1	1	1	0	1	0	0	1	0	1	0	1	1	1	1	13
Galindo-Moreno (2010)	1	1	1	1	1	1	0	0	1	1	1	0	0	1	0	1	1	1	0	13
De Vicente (2010)	1	1	1	1	1	0	1	1	1	0	0	1	0	1	0	1	0	0	0	11
Borges (2011)	1	1	1	0	1	1	1	0	1	0	1	1	0	1	0	1	1	1	1	14
Pieri (2012)	1	1	1	0	1	1	1	0	0	0	0	1	0	1	0	1	1	0	1	11
Canullo (2012)	1	1	1	0	1	1	0	0	0	0	1	0	0	1	0	1	1	1	0	10
Avila-Ortiz (2012)	1	1	1	0	1	1	0	0	1	0	0	0	0	1	0	1	1	1	0	10
Khairy (2013)	1	0	0	0	1	1	1	0	1	0	1	0	0	1	0	1	1	1	0	10
Cortes (2013)	1	1	0	1	1	1	0	0	1	0	0	1	0	1	0	1	1	0	1	11
Yilmaz (2013)	1	1	0	1	0	0	1	0	0	0	0	1	0	1	0	1	0	1	1	9
Testori (2013)	1	1	0	0	1	1	0	0	1	0	1	1	0	1	0	1	1	1	0	11
Altintas (2013)	1	1	1	1	1	1	0	0	1	0	1	0	0	1	0	1	1	1	0	12
Del Fabbro (2013)	1	1	1	1	1	1	1	0	1	0	1	0	0	1	0	1	1	1	0	13
Mazzocco (2014)	1	1	1	1	1	1	1	0	0	0	1	1	0	1	0	1	1	1	1	14
Cha (2014)	1	1	1	0	1	1	0	0	1	0	0	1	0	1	0	1	1	1	0	11
Wildburger (2014)	1	1	0	0	1	1	0	0	0	0	0	0	1	1	0	1	1	1	0	9

12 points, three studies<sup>30,33,53</sup> reached 13 points, and the last two studies<sup>36,55</sup> reached 14 points.

## DISCUSSION

Sinus membrane perforation and bleeding deriving from injuries to the alveolar-antral artery are the main intraoperative complications occurring during the sinus floor elevation procedure. They have an immediate impact in complicating the surgical procedure and could have a negative influence on the clinical outcomes (postoperative complications, new bone formation, and implant survival rate). Sinus membrane perforation, if not properly treated, can result in the impossibility of an adequate stabilization of particulate grafting material or in its delayed dissemination into the sinus cavity in the immediate postoperative period.<sup>17</sup> A recent study showed that 10% of membrane perforations could not be repaired and resulted in termination of the sinus

elevation procedure.<sup>58</sup> Another study<sup>10</sup> demonstrated that antibiotics use for postoperative sinusitis and graft failure are likely more frequent in sinuses with perforated membranes at augmentation. However, contrasting outcomes have been reported regarding the influence of membrane integrity on new bone formation and implant survival rate, even if the only systematic review<sup>59</sup> published so far demonstrated that survival of the implants diminishes when they are placed in elevated sinuses with perforated membranes.

Alveolar-antral artery lesion during sinus surgery can cause profuse bleeding, especially if the diameter of the bony canal is larger than 1 mm, as in 29% of the cases in one study.<sup>19</sup> Bleeding can hinder a clear vision of the surgical field and should be adequately treated with electrocautery or bone wax to complete the procedure and to avoid the possibility that postoperative secondary vasodilatation could cause a hemosinus, which can occur even several hours after the end of the surgery.<sup>3,60</sup> Moreover, maintenance of the integrity of the anastomosis could contribute to bone graft neoangiogenesis, improving formation of regenerated tissue.<sup>61</sup> The purpose of this systematic review was to assess the type and incidence of intraoperative complications during sinus floor elevation with a lateral approach to ultimately evaluate whether there is evidence supporting the association between different surgical techniques and occurrence of complications.

The surgical techniques described in the evaluated studies included the use of rotary instru ments,<sup>26-29,35,36,38-40,43,44,47,49,51,52,54,56,57</sup> ultrasonic devices,<sup>29,31,32,37,41,45,46,48,50,53–55</sup> and manual bone scrapers.<sup>33,34,42</sup> To reduce the risk of bias, studies where surgical procedures were performed by inexperienced surgeons were excluded. Studies using blocks as grafting material were also excluded since the outcome could be biased by the concept that this technique allows the clinician to continue the planned treatment even in cases of membrane perforation. Moreover, only prospective CCTs were considered. Sinus membrane perforation and hemorrhagic events were the only intraoperative complications recorded in the studies selected in this systematic review. Other rare complications described in the literature, such as injury of the infraorbital neurovascular bundle, obstruction of the antral-meatal ostium complex, or adjacent teeth sensitivity,<sup>3</sup> were not reported in any of the included studies. The mean overall prevalence of membrane perforation was 15.7% (195 perforations in 1,240 augmentation procedures), as a combination of the outcomes of three main surgical approaches (rotary, ultrasonic, and manual scrapers). The mean prevalence reported when using rotary instruments equal to 20.1% (148 perforations in 736 treated sinuses) is in accordance with a previous systematic review<sup>62</sup>

considering only studies performed using this technique and reporting an overall prevalence of 19.5%. In recent years, the introduction of alternative surgical approaches for the antrostomy, such as ultrasounds and manual bone scrapers, appeared to reduce the occurrence of membrane perforation (overall prevalence of 10.9% and 6.0%, respectively). However, the use of manual bone scrapers was described in only three studies, 33, 34, 42 including one RCT, 42 with different surgical techniques, and needs to be further investigated to confirm these preliminary results. The use of ultrasonic bone surgery in creating lateral access to the sinus resulted in different outcomes depending on the surgical approach. Bone window outlining and reflection into the sinus was applied in seven studies<sup>29,31,32,37,41,54,55</sup> showing an overall prevalence of perforations of 17.6%, comparable to that of rotary instruments. However, the overall prevalence of perforations decreased significantly to 4.7% when ultrasounds were used to consume the lateral wall before performing the window opening.<sup>45,50,53</sup> Hence, within the limitations and heterogeneity of the included studies, it appeared that thinning the lateral wall of the sinus by using ultrasonic instruments or bone scrapers seemed to reduce the incidence of accidental sinus membrane perforations.

The blood supply to the maxillary sinus occurs via the infraorbital, the greater palatine, and the posterior superior alveolar arteries, as well as their intraosseous branches and anastomoses.<sup>61</sup> Anatomically, the alveolar-antral artery (an anastomosis between the posterior superior alveolar artery and infraorbital artery) is always present at the lateral antral wall,<sup>63</sup> and bleeding caused by accidental damage to this artery may occur during the outlining of the lateral window. However, hemorrhagic events represented an extremely infrequent complication in the studies included in this review: they were reported in 16 studies with a mean prevalence of 0.4%.<sup>30–34,37,41,42,44–47,50,51,53,55</sup>

#### **Limitations of the Review**

The current investigation on the intraoperative complications during sinus floor elevation with a lateral approach was hampered by some factors. A general inaccuracy in describing biologic complications and the surgical technique was encountered. For instance, no specific mention was made in any study about the type of manual elevators used, or about the morphology of the granules or the packing of the grafting material. Moreover, only four studies<sup>34,46,50,54</sup> out of 32 reported the precise moment in which membrane perforation occurred. Indeed, even if, after antrostomy, membrane elevation was performed with manual instruments in all the studies, the possibility to disregard important risk factors for membrane perforation still remains. Only four studies<sup>29,50,52,54</sup> had their primary outcome coinciding with the objective of the review, ie, to compare the influence of different surgical techniques on intraoperative complications. However, three<sup>29,52,54</sup> of these four studies were judged to be at a high risk of bias, with only one study<sup>50</sup> judged as being at a low risk of bias.

## CONCLUSIONS

Taking into account the still limited guality and heterogeneity of the reported studies, the following conclusions may be drawn. Sinus membrane perforation and bleeding deriving from injuries to the alveolar-antral artery are the main intraoperative complications occurring during sinus floor elevation with a lateral approach. Consuming the lateral bone wall of the sinus, by using ultrasonic instruments or bone scrapers, appears to reduce the incidence of accidental sinus membrane perforations. Hemorrhagic events following lesions of the alveolar-antral artery represented an infrequent complication irrespective of the surgical technique used. High-quality RCTs focusing on the intraoperative complications are needed to fully elucidate the critical steps of the intervention and to suggest the more predictable surgical approach to the clinicians.

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