

## تأثير فعالية إغلاق انتقاب مخاطية الجيب الفكي باستخدام مادتي تغطية: دراسة راجعة متعددة المراكز

سامر قصبة\*

### الملخص

خلفية البحث وهدفه: يعدّ تدبير انتقاب مخاطية الجيب الفكي تحدياً يواجه الجراح خلال عملية رفع الجيب الفكي. الهدف من الدراسة هو تقييم سريري وشعاعي لنتائج تغطية انتقاب مخاطية الجيب الفكي بمادتي تغطية (Biocollagen® و Surgicel®).

مواد البحث وطرائقه: دُرِسَتْ وبطريقة راجعة 290 عملية رفع جيب أجريت في عدة عيادات سنوية في مدينة دمشق. قُيِّلَتْ 266 عملية في هذه الدراسة لتوافر الوصف الكافي لطريقة تدبير الانتقاب والمعلومات السريرية والشعاعية بعد العمل الجراحي بأسبوع.

النتائج: حدث خلال العمليات السابقة 113 انتقاب مخاطية جيب فكي (21%) غُطِّيتْ بأحد الغشائين Biocollagen® (79%) (سواء أكان موضوعاً كلياً أم جزئياً داخل الجيب) أو Surgicel® (75 حالة) (بطبقة واحدة أو بطبقتين). عُدَّت ثلاث حالات تدبير انتقاب مخاطية متوسط الحجم باستخدام غشاء Biocollagen® عند ثلاثة مرضى مخففة (3%)، وقد أجريت تلك الحالات جميعها من قبل طبيب وُضِعَ بالكامل داخل الجيب. لا يوجد فرق ذو دلالة إحصائية بين نجاح تدبير الانتقاب وكون الغشاء موضوعاً بالكامل أو بشكل جزئي داخل الجيب ( $P = 0.73$ ). إحصائياً توزع النجاح بالتساوي بين التقنيات الأربع المستخدمة لمادتي التغطية ( $P = 0.008$ ).

الاستنتاج: تدعم نتائج هذه الدراسة الاستخدام السريري لكلتا المادتين في إغلاق انتقاب مخاطية الجيب الصغيرة والمتوسطة، وتبقى عوامل أخرى غير النجاح السريري هي المؤثرة في الاختيار بينهما. كلمات مفتاحية: مخاطية الجيب، انتقاب، الجيب الفكي.

\* أستاذ مساعد - قسم جراحة الفم والفكين - كلية طب الأسنان - جامعة دمشق.

## Effect of Sealing the Sinus Mucosa Perforation with two Patching Materials: A Retrospective Multicenter Study

Samer Kasabah\*

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### Abstract

**Background & Objective:** Maxillary sinus mucosa perforation (SMP) management is considered to be a challenge for the surgeon during maxillary sinus floor elevation procedures (SFE). The purpose of this study was to evaluate clinically and radiographically the results of SMP sealing with two patching materials (Biocollagen®, Surgicel®).

**Methods & Materials:** We retrospectively reviewed a total of 290 sinus floor elevation procedures were performed in four dental clinics in Damascus. Only 266 of those procedures were included in this study because of sufficient data related to the SMP management and available 1-week postoperative radiographic and clinical information. Statistical evaluation was performed using Chi-Square tests ( $P < 0.05$ ).

**Results:** SMPs being reported in 113 (42%) of the procedures at the time of surgery, of those only 95 perforations were repaired using either Biocollagen® (21%) (completely or partially placed inside the sinus) or Surgicel® (79%) (one- or two-layer). A total of three moderate SMP managing cases (3%), which were patched with a Biocollagen® membrane was placed totally inside the sinus, were considered failed. However, there was no statistically significant difference between sealing success and whether the collagen membrane was placed totally or partially inside the sinus ( $P = 0.73$ ). Statistically, the success was distributed equally between the four used techniques ( $P = 0.008$ ).

**Conclusions:** The results support the clinical use of Biocollagen® and Surgicel® for repairing small and moderate SMPs. Other factors, other than the clinical success, may be considered in selecting between them.

**Keywords:** sinus mucosa, perforation, maxillary sinus

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\* Assistant Prof. Department of Oral & Maxillofacial Surgery, Faculty of Dentistry, Damascus University.

## Introduction

Due to its versatility and the good results achieved with its use, oral implantology has become a commonly used therapeutic tool. The posterior area of the maxilla is often compromised, as the presence of the maxillary sinus limits the height of the remaining amount of available bone.<sup>1</sup> Lateral techniques of maxillary sinus floor elevation (SFE) have been developed to solve this problem.

Sinus mucosa perforations (SMPs) are considered to be the most common surgical complications in SFE procedures<sup>2</sup> and the frequency of occurrence can reach 58%.<sup>3</sup> This complication, as described in the literature, is associated with postoperative complications include increased risk of acute or chronic sinus infection, bacterial invasion, swelling, bleeding, wound dehiscence, graft material losing, decreased bone formation and early dental implant failure, and disruption of normal physiologic sinus function.<sup>4;2;5</sup>

Anatomical as well as technical factors have been implicated in SMP, as they can complicate SFE procedure and increase the risk of SMP during the procedure. The anatomic factors were reported to be sinus septum and sinus floor convolutions,<sup>6;3;7</sup> narrow and wide sinus,<sup>6;8</sup> angulation between the medial and lateral sinus walls,<sup>9;10</sup> thickness of the lateral maxillary sinus wall,<sup>11</sup> thickness of SM,<sup>12;7;13</sup> convex lateral sinus wall,<sup>8</sup> absence or a small height of residual alveolar bone,<sup>6;14;8</sup> connection between SM and oral mucosa,<sup>8</sup> previous sinus infection or surgery,<sup>12</sup> and thickening/radiographic cyst-like lesions.<sup>15;12;16</sup> The technical factors include the surgeon's experience,<sup>17</sup> visibility and access and osteotomy design,<sup>18;19</sup> and overfilling of the maxillary sinus with graft material.<sup>20;21</sup>

The preferred SMP management is not clearly defined in the literature and a wide range of surgical techniques were used.<sup>22</sup> The most common technique was the placement of patching membrane/material overlaid on the SMP.<sup>23</sup> Sealing the SMP using autologous fibrin glue or fibrin tissue sealant,<sup>24;25;26;27;24</sup> or suturing the SMP<sup>29;23;30;12;31</sup> were less common techniques.

Several patching membranes/materials were used to cover the SMPs such as collagen membrane,<sup>32;33;34;35;12;31;36;17</sup> collagen tape,<sup>23</sup> collagen sheet,<sup>37</sup> Surgicel<sup>®</sup>,<sup>38;39;3;40;17</sup> lamellar bone sheet,<sup>41;23;42;31;8</sup> a perforated  $\beta$ -TCP thin strip,<sup>43</sup> platelet-rich fibrin (PRF) membranes,<sup>44;45;46;47</sup> de-epithelialized fibromucosal graft harvested from the palate,<sup>48</sup> and pedicled buccal fat pad graft.<sup>49;50</sup>

Surgicel<sup>®</sup> (Ethicon, Johnson & Johnson) is a sterile, fully resorbable knitted haemostatic agent prepared by the controlled oxidation of regenerated cellulose.<sup>51</sup> Biocollagen<sup>®</sup> (Biotek, Isomed) is a collagen membrane has been utilized in guided bone regeneration.

According to our knowledge, there is no study compared between Biocollagen<sup>®</sup> and Surgicel<sup>®</sup> for managing SMPs.

## Aim of the study

The purpose of this study was to evaluate retrospectively the results of sealing SMPs by Biocollagen<sup>®</sup> or Surgicel<sup>®</sup> clinically and radiographically in four dental clinics in Damascus.

## Materials & Methods

### Study Sample

The data of 290 SFE surgeries, performed at an academic dental implant center and 3 private clinics in Damascus during the period from 2007 until 2011, were studied retrospectively. Only 266 SFE surgeries fulfilled the requirements of the study, where sufficient data were available related to SMP occurrence and management, and postoperative radiographic and clinical information. Those surgeries were performed under local anesthesia by 5 surgeons on 215 patients (120 females and 95 males, age range between 19-72 years).

### Surgical procedure

The same SFE protocol was used in these clinics, which was described by Boyne and James.<sup>52</sup> In this technique a bony window is created in the lateral wall of the maxilla. Through this window the sinus mucosa is dissected from the bone of the alveolar process of the maxilla and is dislocated upward. The newly-formed space is filled with grafting material which creates favorable conditions for insertion of an implant. The dental implants were inserted either by one-stage or two-stage procedures.

### Radiographic study and follow-up

The patients were called for clinical check-ups after a week. Panoramic or CBCT radiographs were performed postoperatively, according to the surgeons' preference. The recorded data was obtained retrospectively and pooled for analysis. Only those procedures with sufficient data related to the SMP occurrence and management, and with enough available postoperative radiographic and clinical information, were included in this study.

### Clinical and radiographic success criteria

The criteria prescribed by Proussaefs et al.<sup>35</sup> was used to evaluate the success of SMP management. SMP sealing was considered "successful" radiographically

when there was a sharp definition between the grafted and nongrafted sinus area and no graft particles exists beyond the borders of SM, and clinically when there was no reported postoperative complications (infection, persistent pain, swelling) occurred in any of the SFE procedures. In this study, SMPs were classified according to the extent as small (up to 2 x 2 mm), large (above 10 x 10 mm), or moderate size between them.

#### Statistical study

The effects of the patching material on the management was statistically evaluated applying Chi-Square test ( $P < 0.05$ ).

#### Results

SMPs were determined by direct visualization and Valsalva maneuver, and have occurred in 113 cases (42%). Of the occurred SMPs, 16 (14%) were small with no need for management, since the elevation was extended in all directions until it was possible to lift the SM without tearing so as to let the perforation close by itself, was sufficient management. Two surgeries had to be terminated due to impossibility of achieving a high-quality closure.

#### The managing surgical procedure

The managing of SMPs was performed using "patching technique" using either Biocollagen<sup>®</sup> by three surgeons, or Surgicel<sup>®</sup> by two surgeons. When Biocollagen<sup>®</sup> was used to manage SMPs, it was used either as a patch limited inside the sinus cavity or it was cut so that part of it remained outside the window and the other part fitted in the sinus and unfolds. When Surgicel<sup>®</sup> was the material of choice, one strip was used to cover the SMP, and in the case of insufficient functioning of the first strip, another strip was used as a second layer. Accordingly, the 95 managed SMPs were divided into six experimental groups according to the size of perforation and the used material for SMP closure: group 1a (N=47): small size/Surgicel<sup>®</sup>, group 1b (N=5): small size/Biocollagen<sup>®</sup>, group 2a (N=19): moderate size/one-strip Surgicel<sup>®</sup>, group 2b (N=9): moderate size/two-strip Surgicel<sup>®</sup>, group 2c (N=10): moderate size/ totally inside the sinus cavity Biocollagen<sup>®</sup>, group 2d (N=5): moderate size/ partially inside the sinus cavity Biocollagen<sup>®</sup> (Table 1).

**Table 1. SMPs number with respect to the size, used material, and the management success.**

Sinus Mucosa Perforation (N=113)						
Size	N. (%)	Management			Unsuccessful Management	
Small < 2 mm	16 (14%)		No need			
Small < 2 mm	52 (46%)	47	Surgicel <sup>®</sup>			0
		5	Biocollagen <sup>®</sup>			0
2 mm ≤ moderate < 10 mm	43 (38%)	28	Surgicel <sup>®</sup>	19	one-strip	0
				9	two-strip	0
		15	Biocollagen <sup>®</sup>	10	totally inside the sinus cavity	3
				5	partially inside the sinus cavity	0
Large > 10 mm	2 (2%)	Abandoned				

Only 3 SMP sealing cases of group 2c were considered an unsuccessful because of reported subacute maxillary sinusitis in combination with lacking definition between the grafted and nongrafted sinus area radiographically. These 3 cases were managed by the same operator.

#### Statistical study

There was no statistically significant difference between sealing success and whether the collagen membrane was placed totally (group 2c) or partially inside the sinus (group 2d) ( $P = 0.73$ ). There was no statistically significant relation between the sealing success and whether Surgicel<sup>®</sup> was used as one- or

two-strip, since no unsuccessful management in these two groups was reported (Table 1).

Statistically, the success was distributed equally between the four used techniques (groups 2a, 2b, 2d, and 2c) ( $P = 0.008$ ).

#### Discussion

Similarly to the study published by Aimetti et al.<sup>53</sup>, the results of current study confirmed that small SMPs do not need treatment when the surgery might be continued by releasing all the attachments of the surrounding sinus mucosa to the bone and folds itself during the elevation.

The three unsuccessful SMP repair cases in this study were from 2c group, where the disadvantage of the technique might be the dislodging, or at least obscure, the position of the membrane as the graft material is being added leaving the SMP unrepaired. Even though, the difference in sealing success was not statistically significant comparatively with the technique in group 2d, the second technique might be better recommended. Moreover, some authors recommended, in extreme cases, drilling small holes into the lateral wall for the placement of sutures or tacks that will help stabilize the reparative membrane.<sup>32;33;4;31;36;17</sup>

The advantages of collagen membrane in managing SMPs were reported to be highly malleable, adaptable easily to the SMP, the semi-rigid structural integrity allow a versatile application to SMP, the mechanic resistance of the closure is very high and can be used for the successful restoration of the defects extending over the majority of the upper side of the augmentation space.<sup>4;35</sup> However, being the material relatively expensive and the problem of membrane shifting as the graft material is being added were the main disadvantages.<sup>4</sup>

Surgicel<sup>®</sup> was used successfully, in current study, to repair small to moderate SMPs. The advantages of Surgicel<sup>®</sup> in managing SMPs were reported to be technically simple, fast, reliable, and economical.<sup>3;51</sup> However, it showed limited bactericidal qualities, and

had no contraindications in the maxillary sinus. The use of either one- or two-strip of Surgicel<sup>®</sup> didn't show statistically significant difference in current study. This might be interpreted by the fact that the use of the second strip is only after unsecure closure by the first strip.<sup>51</sup> Surgicel<sup>®</sup> was not used in current study for the managing large SMPs, this is recommended by other studies that reported it as impractical for large and complete SMPs because of its lack of rigid structural integrity and fast resorbing properties.<sup>38;39;3;51;17</sup>

Two cases of large and unmanageable SMP were the reasons to abandon the procedure similarly to other reports.<sup>54;29;55</sup> As alternative, block graft instead of a cancellous graft was suggested to reduce the risk of material migration into the sinus cavity.<sup>56;57</sup>

### Conclusions

Our data support the theory that SMP can be problematic, but if it is appropriately managed it could hardly be connected with the development of postoperative complications. If small or moderate SMP has developed during SFE procedure, patching materials such as Surgicel<sup>®</sup> or collagen membrane can be used for the repair. Both materials provide a secure method to manage SMP. It is recommended to kept part of the collagen membrane outside the sinus window to minimize it from moving. Further prospective and randomized controlled studies are warranted to qualify these observations.

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