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Testing the efficiency of a dedicated drills kit for the maxillary sinus lift: a split-mouth clinical study

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ABSTRACT

Aim The present randomized split-mouth clinical study aims at assessing the clinical efficacy of a drills kit designed for the lateral maxillary sinus lift in comparison with piezoelectric instrumentation.

Materials and Methods Eligible patients, in need of bilateral maxillary sinus floor augmentation before implant placement, were included in the present study. Each patient contributed with two sinuses, randomly allocated to the test or the control group procedures. Sinuses in the test group were treated with the dedicated drills kit, which included different burs and stopper systems for the opening of the lateral antrostomy. Sinuses in the control group were treated with piezoelectric surgery.

Results Seventeen patients, thus 34 maxillary sinuses, were included in the present analysis. The success rate was 100% for both groups. On average, the surgery lasted 38.4±9.01 min with no significant differences between groups. There was a significant difference in the time required for the antrostomy (227±54.6 seconds for the test group and 286±67.5 seconds for the control group). The occurrence of surgical complications was not related to the treatment allocation.

Conclusion The present study documented the efficiency of the dedicated lift drills kit when used for the safe and fast opening of the antrostomy for maxillary sinus augmentation. Further studies with greater sample sizes are recommended to assess the generalizability and external validity of the present results.

KEYWORDS maxillary sinus augmentation, dental implants, bone augmentation

INTRODUCTION

The most common bone augmentation technique for the atrophy of the posterior maxilla is the Sinus Floor Elevation (SFE).
Maxillary SFE was first discussed by Tatum in 1976, then published by Boyne and James in 1980 (1,2), and successively modified by Summers in 1994 (3). In 1987, Misch provided general guidelines and recommended that the lateral wall technique should be used when the height of the residual ridge is 5 mm or less and the implants should be placed either at the time of grafting or 4–6 months later (4).
The lateral approach consists in a modified Caldwell–Luc approach, where access to maxillary sinus is obtained by drilling a bone window in the lateral sinus wall; after its design, the bony window may be either consumed or detached and eventually replaced within the grafted sinus or at its original position (5).
There are numerous studies that have reported high survival rates for implants placed into the augmented sinus. Still, many complications have been described (6). The most common intraoperative complication is Schneiderian membrane perforation, with the consequence of bacterial contamination or loose particles gaining access to the sinus cavity. The reported incidence in the literature varies from 11% to 56%, when rotary window preparation is used (7). The maneuvers that may pose the Schneiderian membrane at risk of perforation/laceration are the flap elevation, the preparation of the lateral window, the elevation of the membrane with hand instruments, and the placement of graft material. Thus, many modifications of the original protocol have been advocated, such as the use of piezoelectric surgery, which has been associated with a lower risk of membrane laceration (4% to 31%) (8). Nevertheless, the piezoelectric tips may require more time to complete the surgery (9).
The present randomized split-mouth clinical study was designed to compare the clinical efficacy of specialized safe cutting-end drills with vertical stoppers (Lateral Approach Sinus Kit®, LAS Kit® – OSSTEM)

against the standard rotary instrumentation for sinus antrostomy.

MATERIALS AND METHODS

Study population
Subjects for this study were selected among those people in need of implant-borne rehabilitation of the upper jaw at the Department of Periodontics and Fixed Prosthodontics at University of Siena, Italy.
After clinical and radiographic examinations, patients presenting with partial edentulism in posterior atrophic maxilla and in need of bilateral sinus floor augmentation before implant placement, were considered eligible for inclusion in this trial. This protocol was approved by the local Ethical Committee of 'Azienda Ospedaliera-Universitaria Senese' Scotte in Siena Hospital, Italy, on 25 June 2018 (Protocol MSL001). The protocol of the study, the outcomes, and possible adverse events were clearly explained to the patients before enrollment and written informed consent was obtained. The trial was registered on clinicaltrials.gov with the following registration number: NCT03272100. All study procedures complied with the principles stated in the Declaration of Helsinki "Ethical Principles for Medical Research Involving 'Human Subjects", adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and as amended most recently by the 64th World Medical Assembly, Fontaleza, Brazil, October 2013.
A randomization protocol was produced with a randomization function (R software, version 4.0.4, R Software Services INC, California, USA) for the distribution of patients in the two treatment groups. Patients were recruited for the study on fulfillment of the following inclusion criteria: 1) age between 20 and 75; 2) systemically healthy; 3) periodontal health or healthy periodontium after periodontal therapy; 4) condition of bilateral edentulism in the posterior maxilla with insufficient bone height and volume for implant placement. The following exclusion criteria were applied: 1) systemic or immunologic diseases; 2) recent acute myocardial pathology; 3) coagulation disorders; 4) metabolic disorders; 5) bisphosphonates therapy; 6) heavy smoking (more than 10 cigarettes/day) or alcoholism; 7) maxillary sinus pathology; 8) former sinus surgery. Patient with active periodontal disease were not included until adequate periodontal health had been reached and maintained. All patients were treated with multiple sessions of oral hygiene instructions until they were able to demonstrate acceptable inflammation control (full mouth plaque and bleeding score under 20%).

Randomization and allocation concealment
The randomization of sites was performed immediately before the surgery; an independent evaluator distributed the test and control sites for each patient according to a computer-generated randomization list. Each patient received a bilateral maxillary sinus floor elevation procedure based on two different surgical approaches for the sinus cavity access. On the control side, the osteotomy was performed using piezoelectric surgery, while on the test side, the Lateral Approach Sinus Kit (LAS-Kit, Osstem and Hiossen Implant, UK) was used to create the bone window. The LAS-Kit includes specialized safe cutting-end drills with vertical stoppers for safer and faster access to the sinus membrane.
The patients recruitment started in January 2019; all subjects were checked up to 6 months after the surgery . All surgeries were carried out by the same expert operator (NB) at the oral surgery sub-unit facilities,

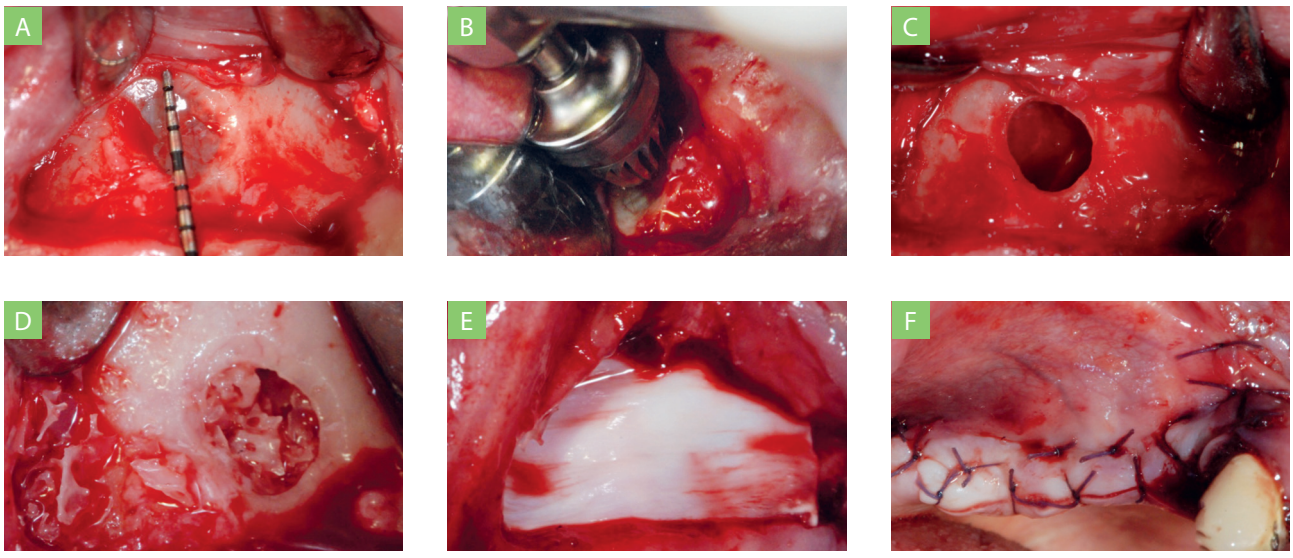

FIG 1 Treatment sequence for the test sinuses. a) 6x6mm antrostomy outline; b) the antrostomy is performed with the LAS kit drills; c) the antrostomy is completed and membrane appears integer; d) the sinus is grafted with bone particles; e) the augmented area is covered with a membrane; f) the surgical flap is sutured.

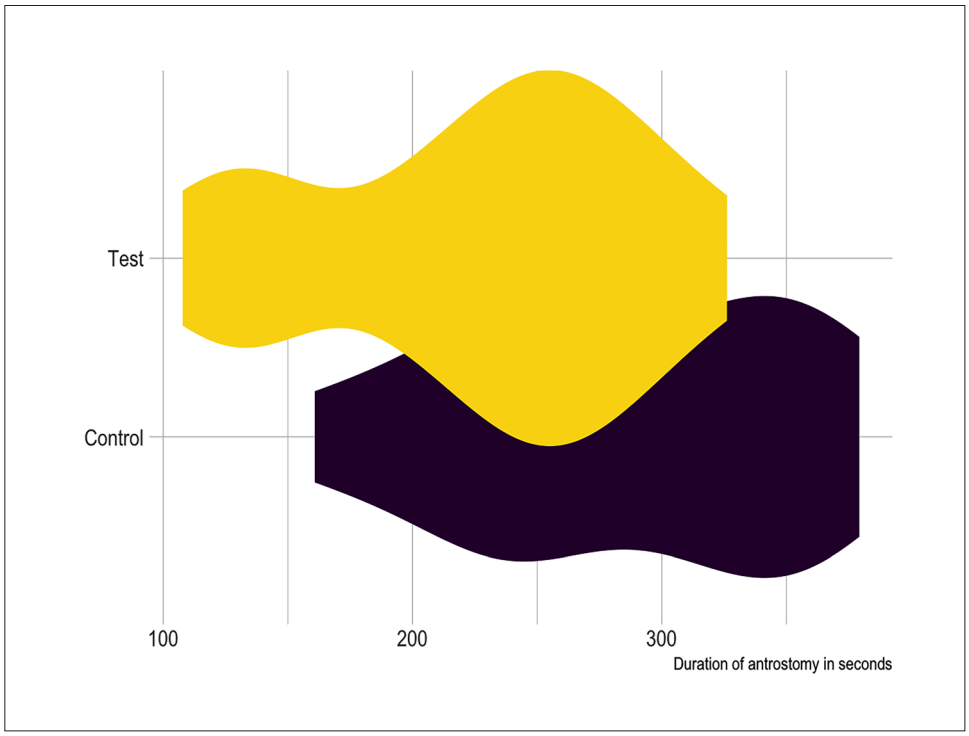

FIG 2 Violin plot with the relative distribution of the average time (in seconds) required for the completion of the sinus lateral wall antrostomy for both groups.

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Surgical Intervention: Control Side
Under local anesthesia, a small (<20mm) full-thickness mucoperiosteal minimally invasive envelope flap was elevated. The flap included a horizontal incision less than 20 mm and one or two vertical incisions (2 mm maximum) as per Baldini et al. (9). Once the flap was raised, a bone window of 6 × 6 mm was opened, using the Piezosurgery System (Mectron s.p.a., Carasco, Italy), to gain access to the maxillary sinus (10). The bone wall was reduced using a bone-shaving device (OP3 tip, Mectron s.p.a., Carasco, Italy) until the sinus membrane became evident. The sinus membrane was lifted starting from the inferior border of the osteotomy site, and completely and carefully dissected from the medial and inferior walls of the sinus. All surgical procedures were performed with great accuracy to avoid damage and perforation of the membrane. The sinus was filled with deproteinized bovine bone (Bio-Gen granules, Bioteck, Arcugnano, Italy), and the bone window was covered with a collagen membrane (OsteoBiol, Tecnoss, Torino, Italy). The membrane was sutured to the exposed connective surface in the peripheral area of the flap and a periosteal-releasing incision flap was sutured with sling sutures using 5/0 absorbable threads.

Surgical Intervention: Test side (Fig 1)
The flap design was identical to the one of the control side. Then, the sinus cavity access was performed using the Lateral Approach Sinus Kit (LAS-Kit, Osstem Implants, UK), specifically designed for a conservative lateral approach for the sinus floor elevation. After the CT scan residual bone width evaluation, a shaped round-shaped bone window was outlined using the dome drills; the drilling depth was controlled by using the appropriate drill stopper system. The wall was consumed until reaching the membrane with the dome drills. The rest of the surgical procedure was pursued as per the control group.
The duration of the procedure was measured from the beginning of the incision to the last suture using a digital chronometer. The patients and the clinician who gathered the data were not aware of the type of surgery.

Post surgical protocol
All patients received 2 gr of amoxicillin before starting the surgical procedure and then continued for 5 days (2 gr amoxicillin per day). Painkillers (Ibuprofen 600 mgr) were prescribed to be assumed in case of necessity. Chlorhexidine mouthwash was prescribed twice a day for the following 21 days. Sutures were removed after 14 days.
The use of dentures was not permitted until they had been adjusted and refitted; and not before 2 weeks after surgery.

Outcome measures
This clinical trial tested the null hypothesis that there were no differences between the control and the test groups to access the maxillary sinus cavity.

Intra-surgical measurements
Once the flap was designed, bone window dimensions were recorded using a periodontal probe: bone window length and height were measured, bone window area

was then calculated.

Radiographic assessment
The buccal bone wall thickness was recorded for each sinus in order to assess the initial within-patient correlation coefficient regarding the relative difficulty of the surgery according to Testori et al. Maxillary Sinus Elevation Difficulty Index (MSED) (11).

Time for surgical procedure
The primary outcome of the study was to determine if there were differences in surgical intervention duration between the two tested procedures. A clinician, not involved in the surgical procedure, recorded all time-related outcomes. After administering local anesthesia, time was measured for each surgical procedure as follows:

- Total time of intervention from incision to the last suture (minutes)
- Partial time for wall opening (seconds)
- Partial time for sinus elevation (seconds)

Complications
The occurrence of any surgical complication was documented for both groups.

Data analysis
Because of the lack of preliminary data on the study primary outcome, and success rate, the sample size estimate relied on previous literature (12).
Descriptive and longitudinal statistics was performed on the R free software- "Vigorous Calisthenics" (version 4.0.4, R Software Services INC, California, USA). The nonparametric analysis on average surgery duration was implemented on the ld.f1 function within the package nparLD. This non-parametric method exhibits a competitive performance for small sample sizes and outliers. A p value < 0.05 statistic (ATS) was calculated for the global alternatives. A further mixed effect model (function lmer within package lme4) was used to control for crossed random effects posed by patients contributing with more than one sinus. This formula expects that there are going to be multiple responses per patient, and these responses will depend on each subject's baseline level. This effectively resolved the non-independence that stemmed from having multiple responses by the same subject.

RESULTS

Eighteen patients were enrolled and accepted to participate. One patient was not included in the analysis as he did not attend the follow-up visit. Seventeen patients were included in the final analysis, each contributing with two sinuses, one allocated to the control group and one to the test group. Patients were followed from the moment of recruitment (enrollment started in 2019) up to a month after surgery. The mean age of the cohort was 58.5±7.90 years. The initial within-patient correlation coefficient was substantial, thus the efficacy of the split-mouth design was ensured. In particular, the within-patient correlation coefficient was estimated using the Testori et.al Maxillary Sinus Elevation Difficulty Index (MSED)(11). Baseline exploratory variables of the sample population are described in Supplemental Table 1, as well as the inferential statistics for the outcome variables.
The average Buccal Wall Thickness of the Maxillary Sinus was 1.62±0.52 mm with no significant difference among

Patient Demographics	Total (n = 17 patients, 34 sinuses) Mean ± SD	Test (n =17) Mean ± SD	Control (n =17) Mean ± SD
Age (years)	58.5±7.90	58.5±7.90	58.5±7.90
Female	9/8		
Maxillary Sinus Elevation Difficulty Index (MSED)	Moderate	Moderate	Moderate
Buccal bone wall thickness (mm)	1.62±0.52	1.59±0.51	1.65±0.55
Bone window dimension (mm^2)	30.60± 5.00	30.17± 4.53	31.05± 5.53
Surgery Duration (min)	38.4±9.01	38.7±8.85	38.2±9.43
Treatment group effect	Pvalue>0.05		
Wall opening duration (sec)	256±51.7	227±54.6	286±67.5
Treatment group effect	Pvalue<0.05*		
Sinus lifting duration (sec)	434±119	405±115	463±120
Treatment group effect	Pvalue>0.05		
	Total (%)	Test (%)	Control (%)
1-month Success	34 (100%)	17 (100%)	17 (100%)

SUPPLEMENTAL TABLE 1 Patients' demographics, clinical outcomes, and treatment group effect. The asterisk* denotes statistical significance

Complications	Total (n = 17 patients, 34 sinuses)	Test (n =17)	Control (n =17)	Management
Severe bleeding from the subantral artery	3	1	2	Prolonged pressure on the bone
Membrane Perforation	6	3	3	Collagen membrane
Emphysema	1	1	0	4 days of additional betamethasone and instructions for the patient

SUPPLEMENTAL TABLE 2 Complication occurrence stratified by group.

groups.
On average, the surgery lasted 38.4±9.01 min with no significant differences between treatment groups. However, the multiway analysis displayed a significant difference in terms of duration when the time for antrostomy was assessed alone (Fig.2). On average, the time required to complete the antrostomy was 227±54.6 seconds for the test group and 286±67.5 seconds for the control group (p value <0.05). This measure seemed moderately related to the wall thickness, according to Pearson's correlation test (cor 0.60). No differences could be observed for the membrane lifting part of the surgery, which lasted, on average, 434±119 seconds.
Ten patients displayed surgical complications including hemorrhage, emphysema, and membrane perforation, with the latter being the most common occurrence. Neither the complication rate nor the complication type was related to the treatment group (Table 2). The success rate was 100% for both groups.

DISCUSSION

The lateral sinus augmentation is a surgical procedure usually performed with either rotatory surgical instrumentation or with a piezoelectric device. These approaches are well documented in the scientific literature, however, they have been often related to potential damage for the sinus membrane (13).
In this study, the authors compared the piezoelectric instrumentation with the use of LAS Kit® - OSSTEM for the creation of the sinus antrostomy.
Results showed no significant differences between treatment groups for the overall surgery time (38.4±9.01 min) or for the membrane lifting part of the surgery (434±119 seconds). The difference became significant between piezoelectric instrumentation and LAS Kit® when only the antrostomy time was considered: 286±67.5 seconds and 227±54.6 seconds, respectively.
The time required the perform the antrostomy is influenced by the thickness of the buccal wall of the maxillary sinus. A thin buccal bone (≤1 mm) usually allows surgeons to identify the membrane below the cortical wall more easily, conversely, an excessive thickness in the buccal bone (> 2 mm) usually requires more time for completing the antrostomy and might increase the risk of membrane perforation when using rotating instruments (14).
The problem of buccal wall thickness variability can be partially overcome with the LAS Kit®. Its LAS-drills allowing it to adapt to several different bone density and several different anatomy of the maxillary sinus (inclined or with septum).

There is a general agreement in the literature regarding the longer time period required for operations with the Piezosurgery device (15). Cutting procedures during antrostomy are substantially longer due to the low cutting efficacy compared with conventional osteotomy devices (12).
In the present study, the perforation of the membrane was the most frequent complication, although no differences were observed between groups. Rachana Singh et al (16), however, demonstrated the efficacy of a safer lateral window approach sinus augmentation procedure using the LAS Kit®. The authors showed that when sinus lift of Type I and Type II membrane was done using LAS Kit®, the chances of perforations compared to the conventional technique were much lesser. However, it must be highlighted that the drills of the LAS kit might be hard to use in the case of irregularity of the buccal bone thickness.
One major limitation of the present study is the difficulty in establishing the appropriate sample size due to the lack of relevant literature related to LAS kit. It must also be highlighted that the same expert surgeon performed all procedures, thus probably dulling the real differences between the two techniques, especially in terms of complications incidence. Furthermore, the results were not stratified according to sinus morphology and dimensions.
It would be important to implement the design of this study while observing differences in clinical outcomes and timing between experts and beginners of the sinus augmentation procedure.

Conclusion

The present study addressed a designated drills kit for the antrostomy during maxillary sinus augmentation procedures. The results supported the efficiency of this technique, in particular, the bony window opening was sensibly faster with the LAS kit when compared with piezoelectric surgery. Further studies with larger

samples size and data stratification according to the expertise of the surgeon and the sinus difficulty score are recommended.

Conflict of interest

The authors declare the absence of any conflict of interest related to this study.

Role of the funding source

None

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All authors have viewed and agreed to the submission.

REFERENCES

1. Boyne PJ, James RA. Grafting of the maxillary sinus floor with autogenous marrow and bone. J Oral Surg 1980; 38:613-616.
2. Tatum OH Jr. Lectures presented at the Alabama Implant Study Group, 1977; cited in Smiler DG, Johnson PW, Lozada JL, et al. Sinus lift grafts and endosseous
3. Summers RB. A new concept in maxillary implant surgery: The osteotome technique. Compendium 1994; 15:152,154-156,158 passim; quiz 162.
4. Misch CE. Maxillary sinus augmentation for endosteal implants: organized alternative treatment plans. Int J Oral Implantol. 1987;4(2):49-58. PMID: 3269837.
5. Del Fabbro M, Testori T, Francetti L, Weinstein RL. Systematic review of survival rates for implants placed in the grafted maxillary sinus. J Periodontics Restorative Dent. 2004;24:565-577.
6. Pjetursson B.E, Tan W.C, Zwahlen M, et al. A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. J Clin Periodontol 2008;35:216–40.
7. Molina A, Sanz-Sánchez I, Sanz- Martín I, Ortiz-Vigón A, Sanz M. Complications in sinus lifting procedures: classification and management Periodontol 2022; 88:103–15. https://doi.org/10.1111/prd.12414. 2000.
8. Vercellotti T, De Paoli S, Nevins M. The piezoelectric bony window osteotomy and sinus membrane elevation: intro- duction of a new technique for simplification of the sinus augmentation procedure. Int J Periodontics Restorative Dent 2001; 21:561–567.
9. Baldini N, D'Elia C, Mirra R, Ferrari M. Minimally invasive flap compared to a trapezoidal flap in lateral approach maxillary sinus elevation procedures: Four-month post-loading results from a split-mouth randomised controlled trial. Int J Oral Implantol (Berl). 2019;12(2):209-224. PMID: 31090751.
10. Baldini N, D'Elia C, Bianco A, Goracci C, de Sanctis M, Ferrari M. Lateral approach for sinus floor elevation: large versus small bone window - a split-mouth randomized clinical trial. Clin Oral Implants Res. 2017 Aug;28(8):974-981. doi: 10.1111/clr.12908. Epub 2016 Jul 5. PMID: 27378477.
11. Stacchi C, Troiano G, Berton F, Lombardi T, Rapani A, Englaro A, Galli F, Testori T, Nevins M. Piezoelectric bone surgery for lateral sinus floor elevation compared with conventional rotary instruments: A systematic review, meta-analysis and trial sequential analysis. Int J Oral Implantol (Berl). 2020;13(2):109-121. PMID: 32424379.
12. Barone A, Santini S, Marconcini S, Giacomelli L, Gherlone E, Covani U. Osteotomy and membrane elevation during the maxillary sinus augmentation procedure. A comparative study: piezoelectric device vs. conventional rotative instruments. Clin Oral Implants Res. 2008 May;19(5):511-5. doi: 10.1111/j.1600-0501.2007.01498.x. Epub 2008 Mar 26. PMID: 18371101.
13. Raghoebar G.M, Onclin P, Boven G.C, Vissink A, Meijer H.J.A. Long-term effectiveness of maxillary sinus floor augmentation: a systematic review and meta- analysis. J Clin Periodontol 2019;21:307–18. https://doi.org/10.1111/jcpe.13055.Testori, Tiziano; Weinstein, Tommaso; Taschieri, Silvio; Wallace, Stephen S. (2019). Risk factors in lateral window sinus elevation surgery. Periodontology 2000, 81(1), 91–123. doi:10.1111/prd.12286
14. Delilbasi C, Gurler G. Comparison of piezosurgery and conventional rotative instruments in direct sinus lifting. Implant Dent 2013;22:662-5.
15. Rachana Singh, Jitender Kumar Aurora, R. S. Bedi, Himanshu Chauhan, Adrineel Banerjee, Charukirti Srivastava . Osteotomy in lateral sinus augmentation: A comparative study of rotary technique and Lateral Approach Sinus Kit® NatlJMaxillofacSurg. 2022Aug13(Suppl1):S57S64. doi10.4103njms.NJMS_155_20. Epub 2022 Aug20.