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Sub-mucosal Peeling of Tongue Base with Radiofrequency for the Treatment of Obstructive Sleep Apnea

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ABSTRACT
Objective: *To investigate efficacy and safety of Sub-mucosal Peeling of Tongue Base with Radiofrequency in obstructive sleep apnea patients.*
Setting: *Zagazig and Suez Canal Universities Hospitals*
methods: *Twenty-one (21) patients underwent Submucosal Peeling for tongue base with Radiofrequency and Anterolateral advancement pharyngoplasty (ALA) Procedures according to the following: Age is ≥18 and ≤60 years old, BMI less than 35kg/m2, patients with moderate to severe OSA (defined as AHI >15) and having multilevel obstruction essentially tongue base collapse. Patients having retropalatal airway obstruction only were excluded. Patients were diagnosed and assessed before and six months after surgery by historyof OSA symptoms, outpatients clinical examination, Epworth sleepiness scale (ESS), Flexible fiberoptic endoscopy with Muller Maneuver, DISE, radiological studies as (Cephalometry) and polysomnography. The idea of this novel operation is to resect the midline tissue of the tongue base via sub mucosal approach with Radiofrequency to improve the retro-lingual collapse in obstructive sleep apnea patients.*
Results: *Post operative results showed decrease in Apnea-Hypopnea Index (AHI) mean from 33 ± 8.4 to 16 ± 6.3 (p value < 0.001). Lowest oxygen saturation (LOS) mean improved from 79.8 ± 5% to 89.4 ± 3.6% (P-value<0.001). According to the international surgical success rate definition the surgical success rate was 81%.*
Epworth Sleepiness Scale score (ESS) decreased from 17 ± 2.9. to 7.6 ± 2.8 (P < .001). Visual analogue scale (VAS) for pain post operative was 4.7 during the 1st week. While no pain was noticed by any patients after one month from operation.
Cephalometric analysis showed a significant difference in Posterior Airway Space (PAS) means that increased from 9.1± 1.5 mm pre-operative to 13.2 ± 1.4 mm post-operative. (p value <0.001, 95% CI).
Conclusion: *SubmucosalPeeling of tongue base with Radiofrequency showed an added measurable value of using Radiofrequency to resect tissues from tongue base safely and effectively in treatment of patients with OSA with minimal minor complications.*
Keywords: *Obstructive apnea; Polysomnography, Cephalometry, , Tongue base Peeling, Radiofrequency.*

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I. Introduction

Obstructive sleep apnea syndrome (OSA) is a critical diseasedefined by repeated events of airway collapse during sleep. The main diagnostic reference for OSAis apnea hypopnea index (AHI) in polysomnography or respiratory disturbance index (RDI). Other diagnostic tools are events of oxygen desaturation in blood during sleep and radiological methods as cephalometry, CT volumetric and MRI scan **(Mintz et al.,1995).**

Air ways obstruction during sleep may occur at different levels as: retropalatal,oropharynx, hypopharynx or multi-level obstruction. Most patients have multi-level obstructions involving both the retropalatal and hypopharyngeal areas**(Arnardottir et al., 2016).** Hypopharyngeal collapse was founded in 50% of OSA patients those have moderate and severe apnea. However, the most frequent cause of antero-posterior narrowing at hypo-pharyngeal area is tongue base collapse**(Shepard &Thawley, 1990).** The diagnosis of hypo-pharyngeal obstruction due to tongue base hypertrophy is made by clinical examination, endoscopic examination, and radiological investigations (**Stuck et al, 2000)**.

The surgical treatment for retro-lingual collapse due to tongue base enlargement is still a challenge because satisfactory long-lasting solution is difficult to obtain. Thus, Base of the tongue surgeries have received significant care over the past years. Many invasive procedures were innovated to treat the tongue base hypertrophy as mandibular osteotomy with genioglossal muscle advancement , tongue base reduction with hyoidepiglottoplasty through anexternal neck approach **,** maxillary mandibular advancement and Trans-oral robotic surgeries (TORS).[1]

All previous approaches and surgeries were considered invasive techniques with high percentage of post-operative morbidities. So, those technique could be refused by patients and surgeons themselves. Consequently, less invasive approaches were innovated to solve the dilemma. DeRowe et al one of the first tried to innovate less invasive approaches by using Repose Kit, which was based on the augmentation of the tongue base anteriorly by a suture positioned via the trans-oral approach (Influ-ENT, San Francisco, CA).[2]

It is worth to be mentioned that in 2003, another recent approach for tongue base collapsewas submucosal minimally invasive lingual excision (SMILE) that characterized by preservation of mucosa and excision of underling tissue only. This technique can be applied by using the harmonic scalpel (SMILE-H) or the plasma-mediated radiofrequency (SMILE-R) by Robinson et al. Unfortunately, the results of less invasive procedures are generally inadequate when compared with invasive procedures and no technique has been found to be ideal treatment for tongue base hypertrophy.[3]

However, Radiofrequency (RF) has frequently been utilized to treat OSA symptoms in a different way. In the electromagnetic (EM) spectrum, a continuous frequency spectrum of vibrating massless energy quanta is referred to as radio frequency (RF). Electric and magnetic fields are arranged at a 90° angle to one another and make up the two types of waves that make up EM radiation. Radio waves are EM radiation with frequencies ranging from 3 Hz to 300 GHz. This radio wave can produce heat energy. The positive effects of radiofrequency surgery are thought to result from scarring of the tissue and a volumetric reduction of the soft tissue caused by thermic lesions. Powel et al was introducing a minimally invasive technique by using the RF, which done under local anesthesia at the outpatient clinicto reducing tongue base volume. Unfortunately, this technique has low complication rate but with low success rates between 20% and 39% could be carried out even with repeated sessions.[4]

In this study we were going to assess the feasibility and efficacy of the tongue base peeling that using RF for removing middle part of the tongue base tissue by (peeling) method instead of reducing it only as a part of multi-level surgery. And through the sub-mucosal approach that offer good accessibility to surgical fields with low complication rate for the treatment of patients having OSAS due to multi-level airways obstruction with hypopharyngeal collapse.

II. Patients and Methods

From 2018 to 2020. Twenty-one (21) OSA patients (14 men, 7 women; age ranged from 31 to 59 years) from the Department of ENT atZagazig and Suez Canal Universities Hospitals, Egypt were included in this study. Pre-operative Comorbidities data showed 77% of our patients have different types of co-morbidities, 12% of themhave DM and 23% have HTN. Inclusion criteriaincluded: Patients having moderate and severe OSA with obstruction at the retro lingual level (Severity of OSA classified according to the American Academy of Sleep Medicine), patients can't bear or refused treatment with (CPAP), Body mass index(BMI) should be less than 35Kg/m2. Exemption criteria included: History notsuggesting of OSA, chronic lung disease, BMI more than 35Kg/m2.

Preoperative assessment included history taking and complete airways examination; Epworth Sleepiness Scale (ESS) assessment, polysomnography (PSG), Flexible Fiberoptic endoscope with muller's maneuver, DISE and cephalometry.All patients were reassessed at 6 months after the surgery with the same preoperative assessment methods. Informed written consent was fulfilled from everypatient.

Surgical Procedure

Sub-mucosal Peeling of Tongue Base using RF with Antro-lateral Advancement Pharyngoplasty (ALA) for retropalatal collapse was done for all patients**.** [5]

Steps of tongue base peeling with RF:

A. Preparation ofsurgicalfields: Dingman mouth gag was used to all cases as it offers good trans-oral surgical approach. Sutures were placed at the anterior 1/3 of the tongue to permit anterior tongue retraction for better visualization and give an easy passage to the posterior tongue and used the endoscopes to give better view for surgical fields (Storz endoscope 45 º, 3mm in diameter). Then the Lingual artery was identified by certain anatomical landmarks according toLauretano et al., study that described the cadaveric position of the tongue base Neurovascular bundle (NVB). They illustratedthe exact locationof NVB is always inferior and lateral within tongue base, that is located "2.7 cm inferior and 1.6 cm lateral to the foramen cecum, 0.9 cm superior to

the hyoid bone, and 2.2 cm medial to the mandible". So, we dissected and removed the tongue base tissue beyond these landmarks to do safe operation and to decrease the risk of NVB damage.[6]

B. Incision: Using the RF in cutting mode to create straight midline incisions were made starting from the circumvallate papillae and extended toward the valleculae about 2-3 cm in length with another 2 small oblique incision (1cm length) starting from foramen cecum towards lateral edge of the tongue with 45º angle on midline (in shape of inverted Y) **(Figure 1**). Sutures were taken at the edges of the incision area to give good exposure to the underlining tissue.

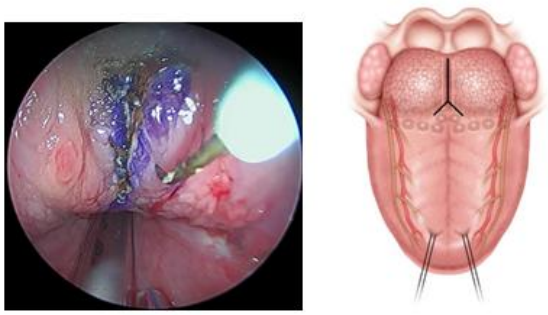

Figure 1: A: Picture shows the midline incision at the tongue base via special RF electrode in cutting mode. **B:** Inverted Y shape incision at the tongue base level that extend from foramen cecum to epiglottis.

C. Removing of tissue: dissection plane started from sub-mucosal to expose the underlining tissue with elevation of the dissected mucosa laterally. Then, removing (Peeling) began in the midline starting from the vallecula posteriorly towards foramen cecum anteriorly. The lateral extent of resection was 1cm on each side and medial to previously identified lingual artery with 1.5cm in depth "oblong in shape" by using radiofrequency system (Ellman S, Germany, loop electrode in coagulation-cutting mode. Steps of tongue base Peeling showed in (**Figure2).**The whole steps of the of the tongue base Peeling procedure and removed tissue illustrated in **(Figure 3).**

Figure (2): Shows loop Electrode used in Peeling technique

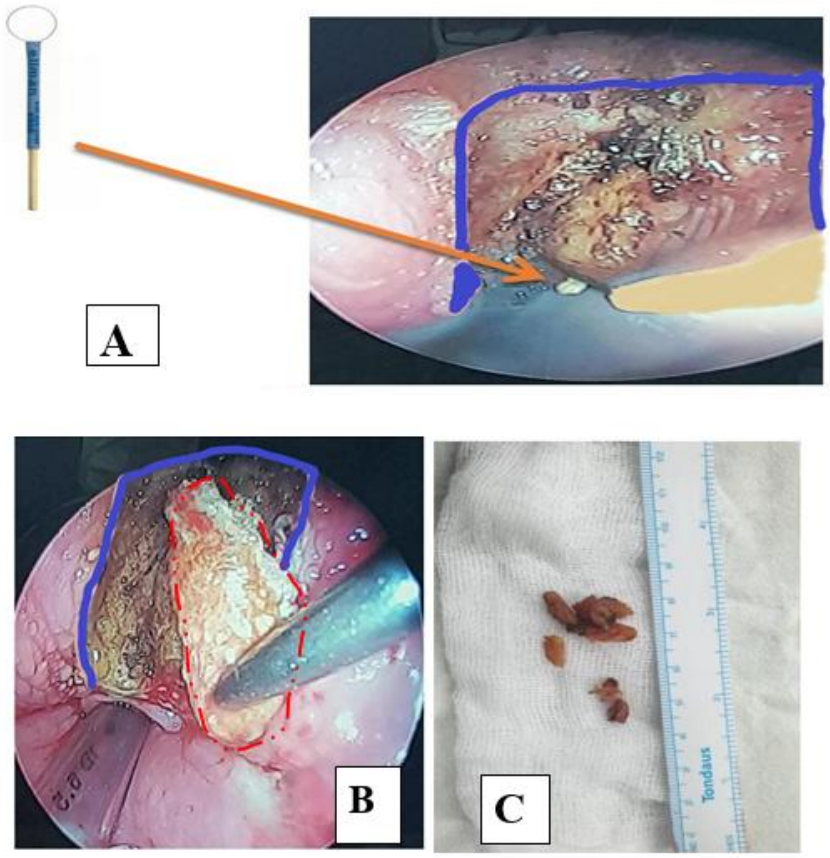

Figure 3 : Steps of peeling technique : **A**: Shows the engagement of the loop electrode into the tongue tissue starting from posterior to anterior . **B**: Piece of tongue tissue peeled by our technique (Notice: The size of peeled tissue was the same width of the endotracheal tube).**C**: The resected tissues were collected to calculate its volume .

Statistical methods

Using SPSS version 25, data management and statistical analysis were conducted (IBM, Armonk, New York, United States). Means and standard deviations were used to summarize numerical data, whereas percentages and numbers were used to summarize categorical data. Using a paired t-test, quantitative data from pre- and post-operative periods were compared. P values of 0.05 or less were regarded as significant.

III. Results

The age of our patients ranged from 31 to 59 years with mean and standard deviation of 50.19±9.52 **(Table 1)**. There were 14 male patients representing (66.7%) and 7 female patients representing (33.3%). Body mass index of patients ranged from 28 to 35 with mean and standard deviation of 32.14±2.87

AHI decreased from 33 ± 8.4 to 16 ± 6.3 (P<.001). Epworth Sleepiness Scale score decreased from 17 ± 2.9. to 7.6 ± 2.8 (P < .001), and lowest oxygen saturation (LOS) level improved from 79.8± 5% to 89.4 ± 3.6 % (P < .001).

Table 1. Preoperative and Postoperative Polysomnography, Cephalometry and ESS Findings:

Variables	Mean ± SD (n = 18),		P Value
	preoperative	postoperative	
ESS	17 ± 2.9.	7.6 ± 2.8.	<0.001
AHI	33 ± 8.4.	16 ± 6.3.	<0.001
LOS, %	79.8± 5.	89.4 ± 3.6	<0.001
Snoring index by PSG	409.4	120.6	<0.001
PAS by cephalometry	9.1± 1.5 mm.	13.2 ± 1.4 mm	<0.001

Abbreviations: AHI: apnea hypopnea index; ESS: Epworth Sleepiness Scale; LOS: lowest oxygen saturation level; PAS: posterior airway space; AP: antro-posterior

Cephalometric parameters showed PAS was increased from 9.1± 1.5 mm. to 13.2 ± 1.4 mm. **(Figure4).**

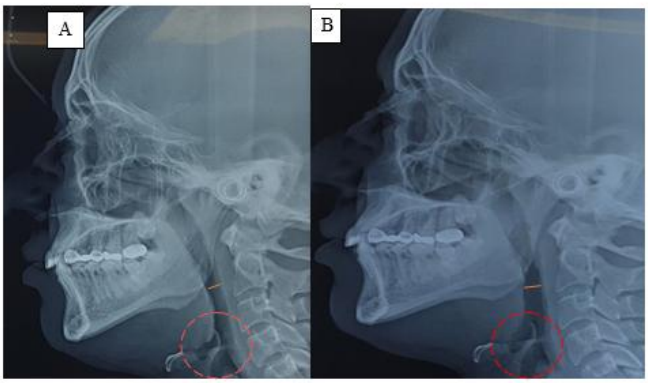

Figure 4: Cephalometric measures A) Preoperative PAS at the level of tongue base dimension (8 mm) , B) Postoperative PAS AP dimension (13 mm) .The red circle illustrate the marked improvement of the space between the tongue base and epiglottis postoperatively .

Theamountofthetonguebasetissue removed was ranged from **9 cc to 15 cc** for all patients. Next table shows the percentage of tissue removed (CC) in our patients. **(Table2)(Figure 5 showed how to calculate removed tissue).**

Tissue removed by CC	Percent
9cc	9.6%
10cc	9.6%
11cc	19%
12cc	19%
13cc	19%
14cc	9.5%
15cc	14.3%

Table (2): The percentage of tissue removed (CC) in patients.

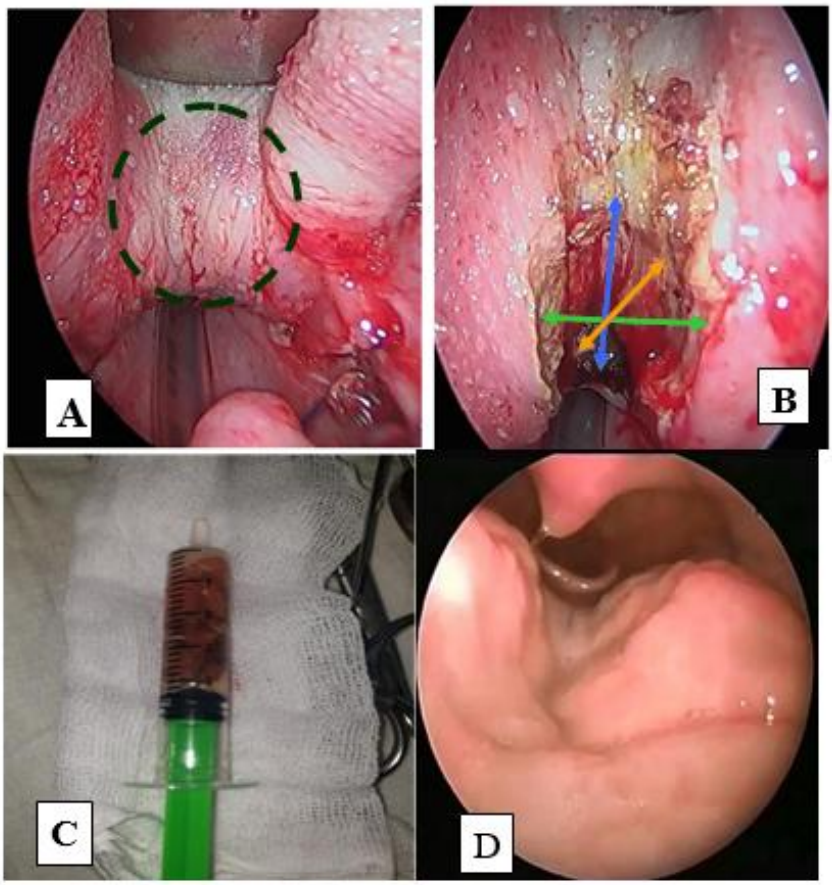

Figure 5 : Shows dimensions of removed tissue by Peeling method during the surgery in A & B picture. A:The picture demonstrate the endoscopic view of the tongue base pre-operative with demarcation of targeted tissue to be removed . **B**: shows dimensions of resected tissue. Notify the blue line indicate Ant-post diameter (2.5 cm) , green line indicate total side to side dimension (2 cm) and orange line shows the depth of the cavity (1.5 cm).**C**: Removed tissue s were collected in syringe **D**:Post operative view of the tongue base during Muller Maneuver.

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The mean of pain measurement according to visual analogue scale were at the 1st week (4.7) , 2nd .week (3.14) and 1month (0.19) post operative . No pain was noticed by any patients after that period. In addition to that, The percentage of patients suffered from taste disturbance in post operative period were (28.6%) at the 1st and 2nd week, While at 3rd week was (9.5%) and (0%) from the 4th week.

"Success was defined by AHI decrease by 50% and / or AHI below 20", according to this definition; there were 17 successful patients **(81%)** meet this criterion of success while 4 patients (19%) didn't meet the success criteria despite clinicalimprovement.

IV. Discussion

The base of the tongue has a complex structure, and it is a complicated area to get access to it during surgery because of its position and its intrinsic structure, which is composed of multiple neurovascular structures. Moreover, the critical issue in dealing with the tongue base from overhead is the hardnessto manage any neuro-vascular structures injuries. [7]

The central region of the tongue base has no major neurovascular structures. But by moving laterally the main blood supply to the tongue base (lingual artery) is covered by the hyoglossus muscle. So, we can assume that resection of midline tissue of the tongue is safe because the major NVB structures of the tongue baselocated far from midline under thehyoglossus muscle**.** [8]

All surgical procedures that targeted the retro-lingual collapse specially the base of the tongue are divided into two main categories: -. Highly invasive procedure: it has high success rate but with little safety margin, high complication and not accepted by most of the patients as Modified Genioglossus advancement,

Maxillary mandibular advancement, and TORS. While less invasive or minimally invasive procedure: Has higher safety profile but with less success rate in comparison with the firsttype.

Number of literatures and papers explained minimally invasive procedures for tongue base collapse in OSA patients, As Tongue base reduction with RF by Powel et al ,[4]SMILE technique by Robension et al [9] and Tongue base suspension by DeRowe et al .[2]Unfortunately, the results of less invasive procedures are generally inadequate when compared with invasive procedures,so there was no method that was found to be effective.[3] From this point of view, we tried to find an operation that offer the balance between the efficacy with invasive technique and safety with minimally invasive procedures.

In our study the body mass index of patients ranged from **28** to **35** with mean and standard deviation were **32.14±2.87. Lin et al**. highlighted3 clinical signs that improvedthe surgical success rate: preoperative BMI less than 30, preoperative AHI less than 60, and the lack of lateralpharyngeal wall collapse. After tongue base procedures, patients with these signs had a success rate of 86.7% vs a success rate of 53.8% in the other investigations if they haven't..[10] Also, all of our failed patients were having BMI **between 34 and 35.** This may explain the impact of BMI on success rate.

The mean preoperative ESS ranged from **13** to **21** with the mean of **17 ± 2.9**. **Postoperative ESS** ranged from **3** to **12** with the mean of **7.6 ± 2.8.**High statistically significant difference between pre& postoperative ESS was noticed**(p value < 0.001).**

Lee et al., held a meta-analysis that compared 2 surgical techniques for tongue base reductionwithTORSVsCoblationshowed: 12studieswith610patientsinthe TORS group and it showed a reduction of ESS mean by–**7.6.**While 150 patients in the Coblation group in different 6 studies revealed a reduction in ESS meanby–**4.14.** Both methods found significantreduction in the mean of ESS score (P .0001), however TORS showed better results than plasma ablation..[11]Our results showed reduction in ESS means by **- 9.4** and this rate higher than Coblation groups and comparable to those groups undergone TORS surgery. It may relate to how much amount of tissue can be removed by eachsurgery.

On Cephalometry, statistical analysis of PAS at the level of tongue base for all ourpatients between preoperative and postoperative data showed a substantial difference. The mean preoperative PAS increased considerably from (**9.1± 1.5)** to (**13.2 ± 1.4)**postoperatively**.** PAS increased by about 5 - 8 mm postoperative. **Riley et al,** demonstrated the PAS was a predictive sign of OSA specially if ≤ 11mm. **Butterfield et al**., also documented the significance of increasing PAS from ≤11 mm preoperatively to ≥11 mm postoperatively associated with improvement of patient's symptoms after MMA..[12]Also, **Holty et al** described in their meta-analysis for assessment MMA the only parameter can expect the surgical success by cephalometry is PAS.[13]

The mean preoperative AHI ranged from **22** to **50** with the mean of **33 ± 8.4. Postoperative AHI** ranged from **10** to **30** with the mean of **16 ± 6.3** with significant difference between pre and postoperative AHI.Our results showed reduction of the AHI mean by **-17.**

Vicinietal., resultsshowed the AHI mean reduced by **- 19.9** by using TORS.[14]While**Babademez et al.,**demonstratedintheirpaperstthereductionofAHIindexmeanswere**-9.5**and**-18.9**inSmile-R and Smile - H groups respectively **.** While in another study compared between Group 1 patients underwent endoscopic lingual lightening by Coblation (CELL)and relocation pharyngoplasty (n = 30), and group 2 patients underwent single soft palate procedure only (n = 60). The mean AHI decreased from 48.4 to 16.5 (P < .001) in group 1 (multilevel procedures) and from 44.2 to 20.1 (P < .001) in group 2 (single level procedure). So, the change in AHI mean changed significantly after tongue base surgery..[15]

Many authors published studies that described the effect of radiofrequency reduction of tongue base (RTBR) using a long electrode and high energy. In addition to that the success rate ranged from 33% to 39 only according to meta-analysis held in 2008 **.**[16] While, in our study we used the RF properties in a better form by resect the tissue instead of reduction only which give more effective results with preservation of the RF safety borders.

Our results also show statistically significance improvement in LOS as **Preoperative** LOS ranged from **70 % to 88** % with a mean of **79.8± 5.** While **Postoperative** LOS increased and ranged from **82 % to 95**% with a mean of **89.4 ± 3.6.** Our mean was improved by **9.6.**

In our study, the volume of the tongue base tissue removed was ranged from **9 cc to 15 cc** for all patients. The volume of tissue resection may be associatedwiththe surgicalresults. Furthermore, our findings revealed no correlation between the amount of tissue removed and the success rate. However, this may be explained by post resection fibrosis and scar formation that play an important role in post operative parameters in addition to the volume of resectedtissue.

In the literature studies showed the amount of tissue removed and correlated it with the surgical success. **Friedman et al.** noticed the resection of 2.28 g of tongue base did not show any significant correlation with the improvement in AHI, LOS, or ESS. **(Friedman et al., 2012).** While **Lin et al** revealed that average volume of tissue removed was 27 ml by using Robotic technique for tongue base reduction.Also, they reported a strong correlation between the surgical success and the volume of tissue resected from tongue base**..**[17]

Other investigations used the water displacement technique to estimate the resected amount in milliliters and reported a tissue resection of roughly 7–11 mL**..**[18] For improved outcomes, **Eesa et al.** recommended to resect 10–20 cc, and at least 7 mL to remove tongue base obstruction during robotic surgery **.**[19] It is crucial to keep in mind that a larger patient can have more tissue and hence need more tissue to be removed, and vice versa. As a result, it's crucial to avoid following these reported resection volume numbers at random.

The percentage of patients suffered from taste disturbance in post operative period were (28.6%) at the 1st and 2nd week, While at 3rd week was (9.5%) and (0%) from 4th week .

Any tongue base surgery has associated with high risk of lingual artery injury because of its proximity course to the tongue base. For those reasons we depended on strict landmarks and dimensions to avoid any major neurovascular injury. For that reason no severe postoperative complications were documentedas:heavy bleeding which needed 2nd surgical intervention, severe airways edema or injury of hypoglossal nerve. Only some minor complications were documented as mild to moderatepain intensity during swallowing, mild airways edema for some patients of which controlled by medication.

Regarding to operative time and learning curve for our new technique were decreased over the course of the study and a steady decrease in operative time to reach as short as 20 min at the end of this study.

"Success rate was defined by AHI reduction by 50% and/or AHI below 20 post operative". According to this definition, there were 17 successful patients represents 81% of our patients meet these criteria of success. Therefore, **Mehmat et al** compared the success rate after tongue base resection with TORS and Coblation.Surgical success was seen in 75.6% of TORS patients and 78.7% of Coblation patients.

Friedman et al. compared the results of TORS for tongue base reduction in patients who underwent SMILE and with individuals who had radiofrequency of the tongue base (RFBOT). These three groups had Z-palatopharyngoplasty for palatal collapse. When compared the surgical success of RFBOT (20.8%) to the TORS (66.7%) that was statistically significant (p = 0.001) and SMILE's success rate was 45.5%,.[20] A meta-analysis of 1978 patients found that multilayer sleep apnea surgery with at least two implicated anatomical sites the nose, oropharynx, and hypopharynx had an overall success rate of 66.4%. **.**[21]

In our study only 4 patients (19%) did not meet the necessary requirement for success definition, and they have been considered as failed patients. In spite of that all those failed patients showed subjective improvement in their symptom's and their sleep pattern as well.

Limitation of the study

There are some study limitations. First, the study was based on a small sample size, which made it difficult to use statistical tests while analysing the correlations. Second, the Cephalometric measurement was done by manual tracing which may led to some statistical bias, but we tried to avoid this by fixing the radiologists who take the measurements, and take these measurements twice ,then the means were used in the statistical analysis. Finally, this study only demonstrated the short-term results, after 6 months.

V. Conclusion:

Sub-mucosal Tongue Base Peeling and ALA were proved to be effective surgeries used to improve the multilevel airway collapse in those patients have OSA. All assessment tools were used as PSG, ESS and radiological studies showed that Sub-mucosal Peeling of Tongue Base with RF has ability to resect a sensible amount of tongue base tissue efficiently instead of reduction the volume of tongue base tissue only. Also, it showed high level of safety profile without any major complication if the dissection done within certain anatomical landmarks.

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