Role of computer assisted designed and manufactured surgical guide in minimizing inferior alveolar nerve injury during sagittal split ramus osteotomy

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ABSTRACT

Background: The surgical guide enabled the surgeon to accurately perform osteotomy, minimize iatrogenic injury to vital structure in vicinity to osteotomy and moving the bony segments to desired position exactly as planned during computer simulation. The purpose of this study is assess the role of computer assisted designed and manufactured surgical guide in minimizing inferior alveolar nerve injury during sagittal split ramus osteotomy (SSRO).

Materials and Methods: A prospective double blind, randomized controlled, clinical trial is designed to assess role of computer assisted designed and manufactured surgical guide in minimizing inferior alveolar nerve injury during sagittal split ramus osteotomy (SSRO). We had two study group, the side of mandibular ramus that were treated by conventional SSRO (can be right or left) and the side that was treated using the computer designed and manufactured surgical guide of same patient (can be right or left side). For every patient the side of mandibular and osteotomy technique was selected by simple random sampling technique (double coin tossing). The statistical analyses were performed using SPSS version 25 (statistics package for social sciences, Chicago. IL). Statistical significance threshold was set to 0.05 (p-value<0.05).

Result: The study population consisted of 10 subjects undergoing SSRO (Sagittal split ramus osteotomy). Seven (70%) were female and three were male. Their mean (±SD) age was 22.4±3024 yrs., range 16 to 27. The mean (±SD) duration of osteotomy on surgical guide assisted SSRO side was 37.2±4.83 and for conventional SSRO side it was 28.2±4.10 and the difference is statistically significant.

Conclusion: Using CAD/CAM surgical guide for SSRO has no significant difference with conventional osteotomy technique regarding minimizing the incidence of inferior alveolar nerve injuries that occurs intraoperatively.

Keywords: Sagittal split ramus osteotomy; Surgical guide; Neurosensory disturbance; Computer.

Introduction

Bilateral Sagittal Split Osteotomy (BSSO) is among a routinely performed surgical procedure for the correction of deformities in maxillofacial region such as prognathism or retrognathism of lower jaw. It was developed by Hugo Obwegeser, in the middle of twentieth century, at Department of surgery, Medical University of

of surgery, Medical University of Graz, Austria [1],[2]. BSSO has many benefits like optimizing the masticatory function, tackling tempromandibular joint Problem and improving facial appearance. Recently it become a major armamentarium in the treatment of obstructive sleep apnea [1]. Since its introduction, BSSO has remained a cornerstone technique for correction of mandibular growth deformities. Regardless of the frequent nature of the BSSO for most oral and maxillofacial surgeons, a wide range of complication has been reported. Death is very rare after BSSO, while inferior alveolar nerve injury being the most common complication [22-24]. During BSSO, the osteotomy is performed along the way of the inferior alveolar nerve (IAN) thus, the chance of IAN injury remains high. The incidence of IAN injury after this procedure ranges from 0% to 100%. The deficit can manifest as numbness or unusual sensations in chin, lower lip, teeth and gingival. The IAN neurosensory deficit accounts for the majority of postoperative complication of BSSO [3]. The common reason elaborated in literatures as the major causes of IAN injury during BSSO are: the way 79 we are handling the IAN during operation [4] and retraction tension we put on extra osseous portion of the IAN during the medial ramus osteotomy [5-8]. A neurosensory disturbance of the lower lip and chin has been described as something that is not important and that does not bother the patients or only rarely does so [15-17]. Regardless of the fact that IAN deficit is purely sensory that affects small area of lower lip and chin skin, it interferes with quality of life of the patient and reported as the most distressing complication after BSSO. IAN injury not only gives rise to unpleasant sensations but may also affect the ability to talk and masticate effectively without traumatizing the affected area [5]. Rapid developments made in computer-aided surgical simulation (CASS) technology and computer aided design/computer aided manufacturing (CAD/CAM) enabled surgeon performing an accurate osteotomy and decreasing IAN injury during SSRO. There are few reports in the literature on the use of computer aided designed and fabricated surgical guides for BSSO and they have indicated good surgical outcomes [20, 21]. The computer fabricated surgical guides described in literature were bulky, which made them challenging and time consuming to place in congested surgical environment of oral cavity. The aim of this study is computer assisted designing and fabricating a surgical guide for SSRO that is cheaper, that can be easily placed at osteotomy site and minimizing inferior alveolar nerve injure during BSSO.

Materials and Methods

A clinical trial study was designed in which we compared computer designed and fabricated surgical guide assisted SSRO and conventional SSRO by examining IAN after surgery. Before patient enrollment, the ethics committee of Tehran University of Medical has approved the project in accordance with tents of the Helsinki Declaration and the national ethical guideline for medical research Ethics (Approval Code: IR.TUMS.VCR.REC.1396.3722). Then trial protocol was registered on Iranian Register of clinical trial and has been approved (Registration reference is IRCT20150107020601N2). The study was conducted on patients that were visited at Oral and Maxillofacial Surgery Department of Sina Hospital, Tehran University of Medical sciences, Tehran, Iran from March 2017 until March 2018.

Inclusion criteria: Age 18-35yr and those Patients that had treatment plan of BSSO (either Monomax BSSO or Bimax).

Exclusion criteria

The following subjects were excluded from our study

- Patients with a history of trigeminal nerve neurosensory disturbance (pre-operative screening was done for all candidates).
- If genioplasty is included in treatment plan.
- Patient with TMJ ankylose, facial asymmetry (unilateral mandibular hyperplasia, hypertrophy).
- Unwilling to sign informed consent.

Method of assignment to study groups.

We had two study group, the side of mandibular ramus that were treated by conventional SSRO (can be right or left) and the side that was treated using the computer designed and manufactured surgical guide of same patient (can be right or left side). For every patient the side of mandibular and osteotomy technique was selected by simple random sampling technique (double coin tossing). The trial participant, surgeon assessing inferior alveolar nerve neurosensory disturbance during post-surgery follow up and statistician analyzed the data were not informed what technique used for which side.

Design and manufacturing of surgical guide

Obtain the 3D models

Using facial CT- scan data imported into DICOM (Digital Imaging and Communications in Medicine), we reconstructed three dimensional surface using mimics software (version 14.0 Materialise Leuven, Bel-

gium). Designing and Manufacturing a surgical guide For the side chosen for a CAD/CAM guide assisted SSRO, based on the surgical simulation result, we designed a surgical guide using mimics software. First, we drew the initial SSRO line by taking the inferior alveolar nerve into consideration as such, the distance from inferior border and buccal cortex evaluated by setting 3D models of the mandible and facial tissue as 70% and 10% transparent respectively.

The designed surgical guide indicate the relative position of inferior alveolar nerve as follows: the vertical thickness (height) of the guide indicates the distance of canal from mandibular oblique ridge, while the proximal edge of a guide indicate the position of medial ramus osteotomy. The lingual border enables the surgeon performing the oblique osteotomy buccal to the inferior alveolar canal. The CAD guide has two holes that enables its fixation to buccal cortex during osteotomy (Figure 1 and 2). Then surgical guide is 3D printed using three Matics software (version 19; Materialise; Leuven Belgium). The material used to make the surgical guide was Acrylonitrile Butadiene styrene (chemical formula $(C8H8) x \cdot (C4H6) y \cdot (C3H3N) z$).

Surgical procedures

SSRO using the CAD surgical guide

During actual surgery, in operation room, the SSRO procedure was performed under general anesthesia. Through an intra-oral approach, after injection of local anesthesia, the body and ramus of mandible was exposed by routine SSRO incision, after dissection of surrounding tissue and exposure of lingual, the manufactured device was positioned and fixed to the exposed mandible. As mentioned above the proximal edge of the guide should be at level of lingual that help as landmark for placement of the guide. Then using the prefabricated holes on guide, two mini screws, approximately 2-3mm longer than the thickness of the device was used to fix the guide into position. Following confirmation of correct fitting, the osteotomy line was drawn in such order, the medial ramus osteotomy was done following the proximal edge of the surgical guide using surgical bur while retracting the surrounding tissue with elevator. The oblique osteotomy line was drawn following the lingual border of the guide starting at the junction with medial ramus osteotomy site until the distal edge of the surgical guide. During the oblique osteotomy the height of the CAD guide show the cutting depth of the saw. The vertical osteotomy line was drawn following the distal margin of surgical guide. The indictor on guide indicates the position of

inferior alveolar canal relative to buccal cortex and inferior border (Figure-3). After performing all the cut with saw the surgical guide was removed and osteotomy was finalized with chisel. On the opposite side after injection of local anesthesia, mandibular body and ramus approached with SSRO incision, the necessary dissection was done, the inferior alveolar nerve at lingual exposed and guarded will big periosteal elevator. Osteotomy was done using routine anatomic land marks without guide, with a surgical saw and final separation of segment was done with chisel. During the procedure the duration of osteotomy for both conventional and CAD surgical guide assisted, the position of inferior alveolar nerve after segment separation, (exposed, not exposed, exposed but not manipulated, need of manipulation of inferior alveolar nerve) laceration of inferior alveolar nerve was registered on questionnaire.
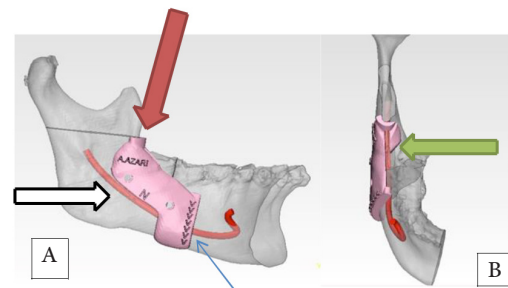

Figure 1. Three dimensional view of CAD/CAM surgical guide for SSRO, (A) indicating site of medical ramus osteotomy (red arrow), position of IAN and canal (white arrow) vertical and inferior border osteotomy site thin arrow, (B) the oblique osteotomy (green arrow).
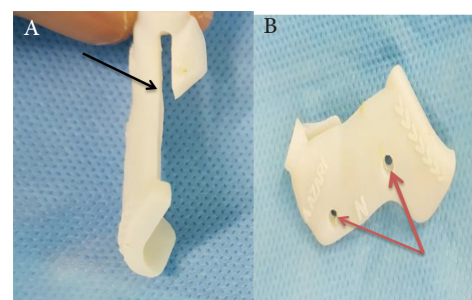

Figure 2. CAD/CAM surgical guide for SSRO A) Top view of surgical guide indicate site of oblique osteotomy (black thin arrow) B). Lateral view of SSRO surgical guide, two screw holes used for fixation. inferior margin indicates canal position (thin arrow).
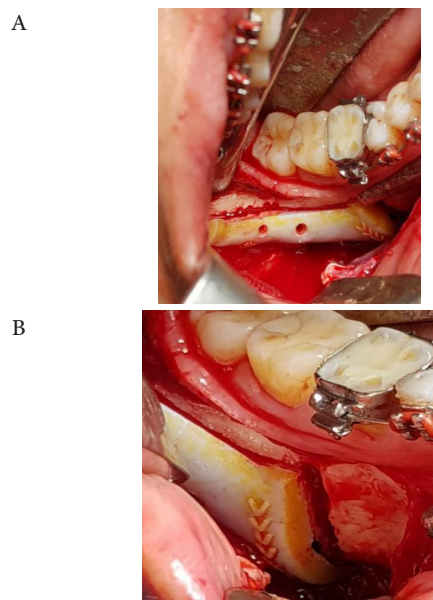
A

B

Figure 3. During the operation, the cutting guide was positioned on the mandible as planned and fixed with two min screws. A) Oblique osteotomy line guided by superior margin of surgical guide. B) Vertical and inferior border osteotomy guided by anterior margin.

Clinical inferior alveolar nerve sensory testing

The inferior alveolar nerve was assessed for paresthesia/anesthesia by trained resident after surgery as such using different tests listed below. Quantitative neurosensory testing The testing procedure were explained and demonstrated to the patient before each test. The testes were done while the patient was sitting with his/her eyes closed in a quiet, calm and comfortable room in semi-reclined position. The tests were performed bilaterally at the vermillion border of lower lip. The clinical sensory tests were performed in all patients post operatively at second week, first and 3rd months as follows, mechanoreceptor tests (brush direction and two-point discrimination) followed by nociceptive fiber testes (pinprick and temperature). The tests were done in the same order and by the same investigator. The results of the tests were registered on prepared questionnaire.

Brush-stroke direction discriminations (BSD)

Tactile direction discrimination was tested with a 5mm wide soft brush (we used cotton), swept manually on test area {Essick, 1992 #80} {Fridrich, 1995 #5} {Fruhstorfer, 1976 #36}. Ten pairs of stroke were used, with randomly varying direction to the left or to the right. The patient had to identify the interval containing a stimulus movement from right to left {Van Boven, 1994 #37}. When the correct response percentage was above or equal to 90%, the result was considered normal.

Two-point discrimination (TPD)

This is a test, which assesses the quantity and density of functional sensory receptors and afferent fibers. If sharp points are used, the small myelinated A-delta and unmyelinated C-afferent fibers are assessed. If blunt points are used, the larger myelinated A-alpha afferent fibers are assessed. 2-P is measured with any instrument with which the distance between two points can be altered. With the patient's eyes closed, the test is initiated with the points essentially touching so that the patient is able to discriminate only one point. The normal values vary a lot, the average value being around 5mm [28].

Temperature-Warm/ cold discrimination (W/C)

Warm cold discrimination was determined with two small test tubes containing waters. The temperature of cold water was 15-20^{0}c and that of warm waters was 40-45^{0}c. The test area was randomly touched with the test tube 10times and the patient had to decide whether the stimulus was warm or cold. The results of the test were deemed normal when equal or above 90% of the answer were correct.

Pin prink test

This test is done by touching the skin of lip or chin with sharp needle. The patient should feel a sharp pain to be reported as normal.

Subjective neurosensory testing

Visual analog scale (VAS)

VAS is an uninterrupted unmarked horizontal line, 100m in length, anchored by word descriptors at each end. The patient mark on the line that points what they feel represents perception of their current state. The VAS is an accepted tool for standardizing or quantifying symptoms and compliant [29].

Statistical Analysis

The statistical analyses were performed using SPSS version 25 (statistics package for social sciences, Chicago. IL). The mean with SD values for continuous variables and frequencies and percentages for categorical variables of baseline and follow-up characteristic were presented. Comparison between a surgical guide assisted SSRO and conventional SSRO was performed using paired t-test for continuous variables. Comparison between surgical guide assisted SSRO and convectional SSRO was performed using Wilcoxon test for categorical variables. Statistical significance threshold was set to 0.05 (p-value<0.05).

Result

The study population consisted of 10 subjects, Seven (70%) were female and three were male. Their mean (±SD) age was 22.4±3.24 yrs., range 16 to 27. The mean (±SD) duration of osteotomy on surgical guide assisted SSRO side was 37.2±4.83 and for conventional SSRO side it was 28.2±4.10. There was statistically significant difference between the two techniques, surgical guide assisted SSRO took longer time (mean difference 8.80, 95%CI 3.36- 14.23 and p-value<0.01). During surgery intra-operative parameters related to IAN (nerve position and laceration) were assessed by surgeon. The IAN were attached to distal segment in all cases and no laceration was noted on surgical guide assisted SSRO, on opposite side three (30%) IAN was attached to proximal segment which needed active free dissection and nerve manipulation to release the adherence. The difference in nerve position between the two techniques was not statistically significant p-value=0.16. One unfavorable fracture occurred in both techniques and the difference was not statistically significant p-Value=1.00.

Brush direction stroke test

At two weeks after surgery, 73% of conventional SSRO had abnormal brush direction stroke discrimination at lower lip, compared to 71% of abnormal thresholds in the surgical guide assisted SSRO. The difference between the two techniques was not statistically significant at one month and three month after surgery P-value>0.05, mean difference 0.3 and 95% CI ranges -0.289 to 4.82. At three month after surgery, on surgical guide assisted SSRO the mean (SD) correct response to brush direction stroke test was 69%±1.19. Mean (±SD) correct response to brush direction stroke test on conventional side was 66%±0.99.

Two-point discrimination

Regarding the two point discrimination, there was no significant difference between surgical guides assisted SSRO and conventional SSRO sides on assessment of lower lip and chin sensory function during postoperative time. P value>0.05 with lower mean values observed at both surgical guides assisted SSRO and conventional SSRO sides throughout the post-operative period of 3 months as shown in Table-4.

Response to temperature

As displayed in table 5 below, mean (SD) response to temperature test in surgical guide assisted SSRO at 2nd week 1st month and 3rd month post-surgery times were: 2.7±1.16, 5.8±1.22 and 8.1±1.37 respectively which showed significant improvement during the

three months postoperative follow up time, when compared with conventional SSRO side there was no significant difference between the two method throughout the follow up time P value>0.05 (mean difference 0.1, 0.5 and 0.5, range -0.53 to 0.73, 0.27 to 1.27 and -0.34 to 1.34 at 95% CI at 2nd week, 1st month and 3rd months respectively).

Subjective evaluation

Patients subjective evaluation of their neurosensory disturbance had highly significant difference between the surgical guides assisted SSRO and conventional SSRO sides at 1st month and 3rd after surgery P=0.000, with significantly better value reported on computer designed surgical guide assisted SSRO sides. The patients reported improvement of their lower lip sensation in the post operation period of 3 month, with higher mean value on the surgical guide assisted SSRO sides compared to the conventional side at 2nd week, first month and third month after surgery as shown on Table 6 and Figure 8.

Pin prick test

At 2nd week after surgery 80% of surgical guide assisted SSRO side had abnormal response to pinprick needle test of lower lip, compared to 90% of abnormal response to needle test on conventional SSRO side. The difference was significant between two techniques at 1st month after surgery, p Value=0.05 and was not significant at 3rd month post operatively even though the abnormal response was reduced to 10% in surgical guide assisted group and decreased to 50% in conventional group p>0.05.
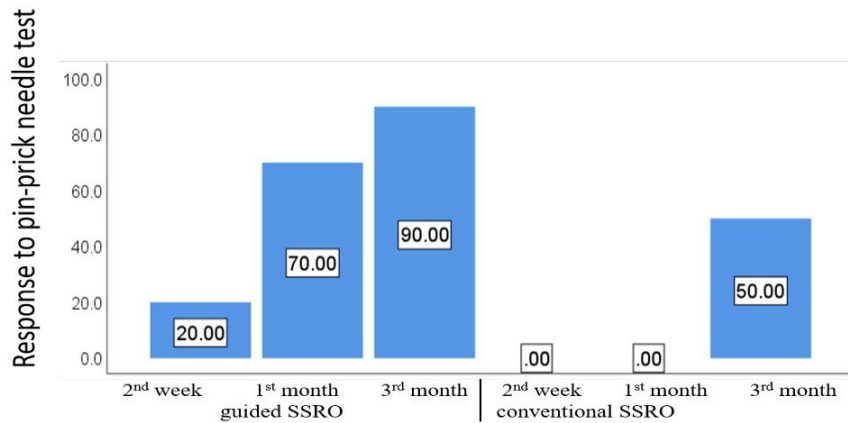
Figure 2. Incidence of IAN sensory disturbance based on pin prink test (with 95% CI) of surgical guide assisted SSRO (n=10) conventional SSRO (n=10).

Duration (min) of SSRO	Guided SSRO (n=10)	Conventional SSRO (n=10)	Mean difference	95%CI	p-Value
	Mean-SD	Mean-SD			
	37.2±4.83	28.2±4.10	8.80	3.36 –14.23	0.005

Table 1. Duration of osteotomy assessed by the surgeon during sagittal split ramus osteotomy in surgical guide assisted SSRO group (n=10) and conventional SSRO (n=10).
SSRO: Sagittal split ramus osteotomy.

Parameters	Guided SSRO (n=10)	Conventional SSRO (n=10)	p-Value
IAN attached to proximal segment	0	3	0.16
IAN attached to distal segment	10	7	0.16
Free from both segment	0	0	1.00
IAN laceration	0	2	0.85
Bad split	1	1	1.00

Table 2. Intra-operative parameters assessed by the surgeon during sagittal split osteotomy in surgical guide assisted SSRO group (n=10) and the conventional group (n=10).

Test	Schedule	Guided SSRO (10)	Conventional SSRO (10)	Mean deference	95% CI	P-value
		Mean-SD	Mean-SD			
Brush direction	2nd week	2.9±1.10	2.7±.67	0.2	-0.67-1.08	0.619
	1st month	4.6±1.07	4.7±.094	0.1	-0.72-0.52	0.726
	3rd month	6.9±1.19	6.6±0.96	0.3	-0.289-0.88	0.279

Table 3. Incidence of IAN sensory disturbances based on the threshold to brush direction test of surgical guide assisted SSRO (n=10) and conventional SSRO (n=10).

Test	Schedule	Guided SSRO (10)	Conventional SSRO (10)	Mean deference	95% CI	P-value
		Mean-SD	Mean-SD			
Two–point discrimination	2nd week	18.80±7.56	19.7±6.81	0.90	-2.53-0.733	0.244
	1st month	10.6±4.67	11.2±5.02	0.6	-1.77-0.578	0.279
	3rd month	5.1±2.68	5.7±2.7	0.6	-1.37-0.169	0.111

Table 4. Incidence IAN sensory disturbances based on the threshold of two-point discrimination test of surgical guide assisted SSRO (n=10) and conventional SSRO (n=10).

Test	Schedule	Guided SSRO (10)	Conventional SSRO (10)	Mean deference	95% CI	P-value
		Mean-SD	Mean-SD			
Temperature	2nd week	2.7±1.16	2.6±1.26	0.1	-0.53-0.73	0.726
	1st month	5.8±1.22	5.3±1.16	0.50	0.27-1.27	0.177
	3rd month	8.1±1.37	7.60±1.50	0.50	0.34-1.34	0.213

Table 5. Incidence IAN sensory disturbance based on the threshold to temperature test of surgical guide assisted SSRO (n=10) and conventional SSRO (n=10).

Test	Schedule	Guided SSRO (10)	Conventional SSRO (10)	Mean deference	95% CI	P-value
		Mean-SD	Mean-SD			
Visual Analog Scale (VAS)	2nd week	33±6.32	32±6.32	1	-3.06-5.06	0.591
	1st month	56±9.66	55±7.07	1	-5.26-7.26	0.726
	3rd month	83±9.48	81±7.37.30	2	-4.57-8.57	0.509

Table 6. Incidence of IAN sensory disturbance based on subjective sensory disturbance (VAS) of surgical guide assisted SSRO (n=10) and conventional SSRO (n=10).

Discussion

Since its introduction, BSSO has remained a cornerstone technique for correction of mandibular growth deformities. Regardless of the frequent nature of the BSSO for most oral and maxillofacial surgeons, a wide range of complication has been reported. Death is very rare after BSSO, while IAN neurosensory disturbance being the most common complication [22-24]. During BSSO, the osteotomy is performed along the way of the inferior alveolar nerve (IAN) thus, the chance of IAN injury remains high. The incidence of IAN lesion after this procedure ranges from 0% to 100%. The deficit can manifest as numbness or unusual sensations in chin, lower lip, teeth and gingival. The IAN neurosensory deficit accounts for the majority of postoperative complication of BSSO [3]. The common reason elaborated in literatures as the major causes of IAN injury during BSSO are:

1. The way we are handling the IAN during operation [4].

2. The retraction tension we put on extra osseous portion of the IAN during the medial ramus osteotomy [5-8].

The introduction of computer aided surgical simulation (CASS) technologies enables the surgeons to simulate the entire orthognatic surgery and test surgical plans in computer till the best possible outcome is achieved [3,5]. The tremendous advance in this technology opened the way to transfer the computerized surgical plan to the patient at the time of surgery using CAD/CAM guides. The surgical guide enabled the surgeon to accurately perform osteotomy, minimize iatrogenic injury to vital structure in vicinity to osteotomy and moving the bony segments to desired position exactly as planned during computer simulation [27]. There are few reports in the literature on the use of computer aided designed and fabricated surgical guides for BSSO and they have indicated good surgical outcomes [20,21]. Al-Ahmad H.T et al [21] in their pilot study on 8 patients (8 sides guide assisted SSRO and 8 sides Conventional SSRO) in which they evalu-

ated an innovative computer assisted SSRO to reduce neurosensory alterations following orthognathic surgery. They did a post-operative quantitative neurosensory testing using three sensory threshold tests (tactile threshold, two-point discrimination, and direction of brush stroke) and subjective neurosensory 388 testing using VAS of lower lip and chin bilaterally at 1st week, 1st month, 3rd month and 6 months after surgery. At 1st week after surgery, 83% of the conventional SSRO side had abnormal tactile threshold at lower lip and chin, compared to 67% of abnormal threshold in the computer assisted SSRO sides, which slightly agree with our finding. The abnormal threshold on computer assisted SSRO decreased to 50% with no rate change on the conventional side. For two points, discrimination Al-Ahmad H.T et al found a significant difference between the computers assisted SSRO and conventional sides, with lower mean value observed at computer assisted SSRO side. Concerning the brush direction test, the computer assisted SSRO sides showed 100% normal response at 0ne, three and six months after surgery, while 33% of conventional sides' response remained abnormal 6 months after surgery. The patients' subjective evaluation of their neurosensory disturbance was significantly different between the computers assisted SSRO and the conventional sides, with better values reported on the computer assisted SSRO sides. Patients reported improvement of their lower lip and chin sensation in the post-operative period with higher mean value at the computer-assisted SSRO sides compared to Conventional sides at first, third and six months after surgery. Our study finding showed no significant difference between the two techniques regarding minimizing IAN injury. In last decade, several articles published about the cutting guide uses for orthognatic surgery. These guides provide several advantages. First, the osteotomy line form and place can be well adjusted in computer simulation surgery that allows the osteotomy position be preoperatively planned, this in advance minimize the chance of damage to vital structure during osteotomy. Moreover, using cutting guides allows the surgeon to determine the depth when cutting, leading to minimally invasive and stable osteotomy [30]. To achieve the points outlined above, many authors suggested the issues that should be taken into consideration when fabricating cutting guides

- The guide should be designed with suitable thickness, if it is too thin it may break during surgery causing safety issue.

- Too bulky guides may interfere with cutting or obstructs the position of surgical saw blade.

- In addition, the guide could itself be cut during the osteotomy, leaving traces of the device material at surgical site [30-32].

Using cutting guide is not without drawbacks, like extra cost of the designing and manufacturing of a surgical guide. However, these disadvantages diminish given that CASS and CAD/CAM based orthognatic surgery are already in use and overtaking the traditional analysis and planning. Therefore, no specific CT-scan and 3D models is required for designing and manufacturing the surgical guide, as the 3D model for virtual orthognatic surgery simulation can be used without extra cost. In case indicated, intra-operative modification of the surgical plan is unthinkable, unless the surgical guides are discarded as guide controls all procedures. Whatever, the guides are designed to be slim in dimension, still it is a foreign object can be challenging for surgeon during osteotomy in already congested operating field [33]. In our finding we saw that the extratime devoted for positioning the guide and fixing with screw make the duration of procedure relatively longer.

Conclusion

According to the result of our finding using the computer designed and fabricated surgical guide for BSSO relatively increase duration of operation. Has no significant effect on minimizing bad split, nerve position and post-operative IAN injury compared to the conventional osteotomy. We recommended a prospective study with larger samples size are necessary to further validate this system and Design the guide that can protect the IAN at lingual to minimize injury from rotary instrument and tension of retraction. Acknowledgment. The authors are greatful to all staff members of sina hospital, maxillofacial surgery departments for their support during study.

Conflict of Interest

There is no conflict of interest to declare.

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