Comparison Postoperative Complications of a Novel Combined Reciprocal/Osteotome Approach (Ghasemzadeh approach) Versus Conventional Rhinoplasty: A Prospective Clinical Trial Study

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Abstract

Objective: This article for the first time described a novel, hybrid approach to internal rhinoplasty by combining a reciprocating saw/osteotome. We compared it with conventional "pure" instrument (osteotomies performed by chisel only) in terms of cutting time and postoperative complications such as ecchymosis, edema, pain and overall patient's satisfaction with surgery.

Materials and methods: We conducted a prospective, randomized, double-blind clinical trial study. To assess variables of the study 60 patients were divided into two groups: 1) 30 patients underwent new approach and 2) 30 patients underwent conventional osteotomies. The outcomes of the study were cutting time in minutes and postoperative edema, ecchymosis and pain and overall patient's satisfaction which were measured at two time points: days 2 and 7 after surgery. Data were analyzed using repeated measure ANOVA test.

Results: The mean cutting time was significantly lower in Ghasemzadeh approach group when compared with usual osteotome group (P value=0.001). On both 2 and 7 days following surgery, ecchymosis (P value=0.001 and =0.033, respectively) and pain (P value= 0.001 and 0.001, respectively) was significantly lower in Ghasemzadeh approach group than in the usual osteotome group. The mean level of edema on postoperative 2 days was lower but not significant in Ghasemzadeh approach group than in the usual osteotome group (P = .09), while it was significant on 7 days (P value=0.001). The patient's satisfaction reported by the Ghasemzadeh approach group was significantly better than usual osteotome group on 2 and 7 days following surgery.

Conclusion: It is concluded that the use of combined reciprocating saw/osteotome in rhinoplasty showed that swelling, pain, ecchymosis and short-term patient satisfaction was improved with this technique.

Keywords: *Rhinoplasty, Reciprocal, Osteotome, Edema, Pain, Ecchymosis, Satisfaction*

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Introduction

Rhinoplasty is considered a popular, efficient and still challenging cosmetic and plastic surgery.[1] Common intraoperative and postoperative complications associated with this procedure are challenges to the surgeons. The cutting time and postoperative complications in the few

days following surgery such as ecchymosis which limits visual fields, and eyelid edema which interferes with social activity are very uncomfortable for the patients.[2] Moreover, it is well confirmed that the soft tissue damage is the main cause of edema and ecchymosis.[3,4]

Although, several approaches namely internal lateral osteotomy and external osteotomy (1) and also various devices including conventional osteotomes (e.g. burrs or chisel), new piezoelectric devices and ultrasound scalpel with its own pros and cons have been used or introduced to decrease soft tissue injury and decrease rhinoplasty related complications.[5] However, there is still a challenge to choose a method and a device which can minimize these complications in rhinoplasty. Soft tissue injury is still frequently observed due to the use of traditional devices during rhinoplasty.[6] Peizoelectrive devices, recently the most studied devices, are a relatively new and efficient for bony craniofacial surgeries in terms of low bone injury, lower risk of soft tissue damage compared with traditional osteotomes.[7] However, several studies reported main disadvantages of piezoelectric devices such as longer cutting time,[8] inadequate cutting power[9] and the lack of visibility[10] which might still be the key obstacles preventing the popularity of the method in rhinoplasty cases. In addition, ultrasound scalpel is rarely evaluated in rhinoplasty.

The current study is the first to introduce a novel, combined approach to internal rhinoplasty by combining a reciprocating saw and conventional osteotome (chisel) to evaluate the most important outcomes in rhinoplasty. The aim of the present prospective and randomized clinical trial study was to compare cutting time and postoperative complications on the use of a novel and combined reciprocating saw /osteotome (namely Ghasemzadeh approach) and traditional pure osteotome during internal rhinoplasty.

Materials and Methods

Study design and sample description

We designed and conducted a multicenter, prospective, randomized, and double-blind clinical trial to achieve the purposes of the research. The study protocol was approved by the Ethics Committee of Arak University of Medical Sciences (Ethical code: IR.ARAKMU.REC.1399.085). In addition, the study received trial registration code from Iranian Registry of Clinical Trials (registration ID: IRCT20170316033094N2 registered in https://irct.ir/). The study followed Helsinki Declaration. The participants composed of patients undergoing for rhinoplasty and met inclusion and exclusion criteria between April 2020 and July 2020. Written informed consent was assigned by all patients. The predictor variables were the devices used to perform the rhinoplasty osteotomy, divided into two groups each one 30 participants: *1)* a combination of reciprocating saw and osteotome (chisel) which we named it Ghasemzadeh approach in which vertical osteotomies were performed using chisel and transverse osteotomies were cut by reciprocal, in patients without nasal hump the medial cutting also performed using reciprocal, and 2) conventional "pure" osteotome (chisel) in which all vertical, transverse and medial osteotomies performed by chisel. The study was conducted at two centers including Apadana Hospital (included 15 patients in novel group and 15 patients in conventional group) at Ahvaz and Day Limited Surgery Center (included 15 patients in novel group and 15 patients in conventional group) affiliated to Arak University of Medical Sciences at Arak. The inclusion criteria were the age between 18 to 50 years, no anesthesia contraindication (American Society of Anesthesiologists status I and II), and no serious pulmonary airway malformation such as septal deviation or breathing dysfunction. Patients were excluded if they had neuropathic disease, prolonged use of nonsteroidal anti-inflammatory drugs (NSADs) and opioid-derived medications, a history of medication-induced allergic reactions or declined to participate in the study. The diagram of patient's participations is shown in Figure 1.

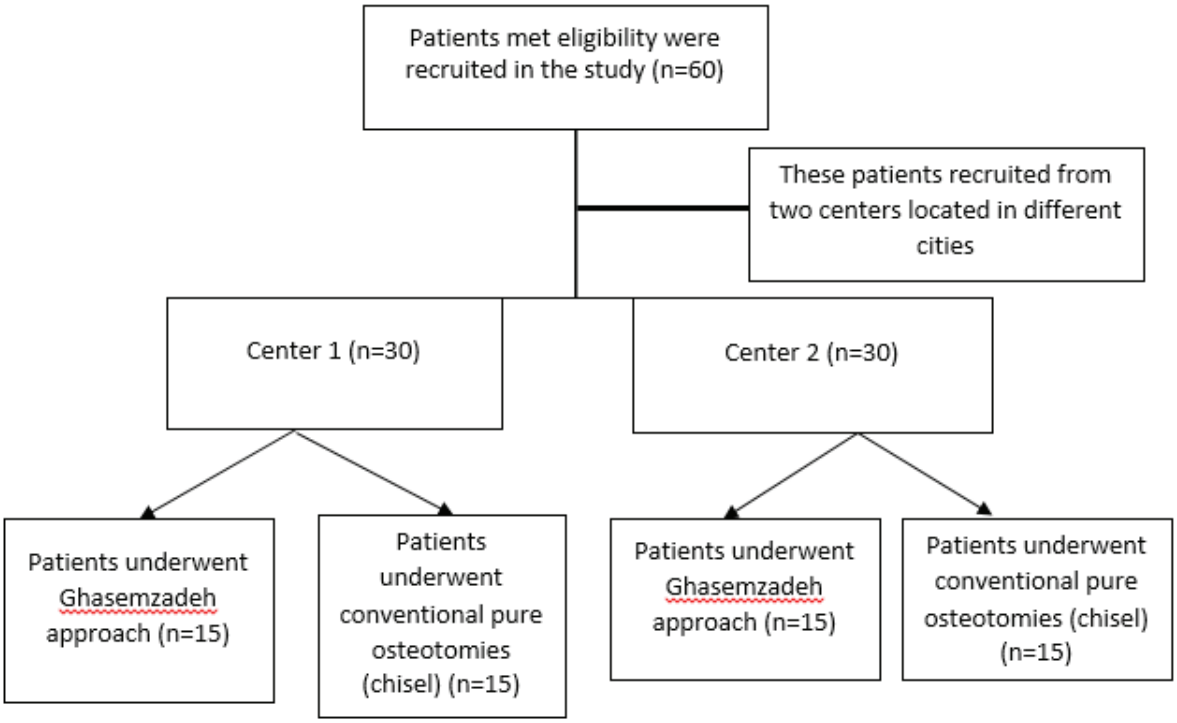

Figure 1. Diagram of patients' participation.

Surgery description

All operations were performed by two surgeons (in two centers) under general anesthesia. Procedures began as a standard open rhinoplasty by a transcolumellar incision with the bilateral regular marginal incision. This was performed in a same manner for both groups of Ghasemzadeh approach and conventional osteotome. Whereas, in Ghasemzadeh approach a reciprocating saw with a blade 0.35 mm thick and 10 mm long (Model SGR-1, Japan) (Figure 2) was used to perform transversal osteotomy and a chisel (black and black surgical, Inc., Atlanta) was used to perform vertical osteotomy. A sample of application of reciprocal during transverse cutting is represented in Figure 3. Transverse osteotomy performed by reciprocal saw is shown in Figure 4. Sharp and symmetric transversal cutting osteotomy in CT scan view (Figure 5(.

Figure 2. A reciprocal saw has been used in current study.

Figure 3. Using Reciprocal saw during transverse cutting.

Figure 4. Transverse osteotomy performed by reciprocal saw.

Figure 5. Sharp and symmetric transversal cutting osteotomy in CT scan view.

Some medications were prescribed for all patients after surgery for 7 days (Cephalexin 500 mg per 6 hours and Acetaminophen 325 mg and codeine 10 mg per 6 hours).

Statistical Analysis

Data were analyzed using SPSS software. The mean cutting time was compared between two groups and two surgeons using ANCOVA test. The mean ecchymosis, edema, pain and overall patient's satisfaction were compared between two groups using repeated measure ANOVA test.

Results

In this study, 60 patients were included and underwent internal rhinoplasty and all participants were women. The mean age of the patients was 27.7 ± 7.6 years (range, 18 to 46 years) at the time of surgery.

Cutting time

The comparing mean cutting time between the two groups and two centers is shown in Table 1. In center 1 with experienced surgeon, the mean cutting time was significantly lower in the Ghasemzadeh approach group when compared with usual osteotome group (P value=0.001), in addition it was also significantly lower in center 2 another surgeon in the Ghasemzadeh approach compared with osteotome device group (P value= 0.04).Whereas the mean cutting time did not differ significantly between two centers (surgeons) in terms of Ghasemzadeh approach (P value=0.3) (Table 1). The mean cutting time was significantly higher for experienced surgeon when compared with less experienced surgeon in terms of conventinal osteotome group (P value=0.006) (Table 1).

Table 1. Comparing mean cutting time of rhinoplasty between surgeons and two groups (Ghasemzadeh approach and conventional rhinoplasty).

	Osteotome	Ghasemzadeh approach	P value
Center 1, minutes	5.5 ± 0.8	4.3 ± 0.9	0.001
Center 2, minutes	4.8 ± 0.5	4.5 ± 0.1	0.04
P value	0.006	0.3	
The results were presented based on ANCOVA test.			

Postoperative Outcomes

The post-operative outcomes on days 2 and 7 after surgery was shown in Table 2.

Table 2. Repeated measures ANOVA test investigating comparisons between variables on 2 and 7 days following rhinoplasty.

	Conventional	Ghasemzadeh approach	P value
Ecchymosis			
At 2 days	2.45 ± 0.6	1.4 ± 0.7	0.001
At 7 days	1.3 ± 0.6	0.5 ± 0.6	0.033
Edema			
At 2 days	2.43 ± 0.5	2.07 ± 0.6	0.09
At 7 days	1.5 ± 0.5	1.07 ± 0.2	0.001
Pain			
At 2 days	3.5 ± 1.6	1.6 ± 1.7	0.001
At 7 days	1.43 ± 1.7	0.3 ± 0.6	0.001
Overall patient satisfaction			
At 2 days	2.8 ± 0.7	1.9 ± 0.7	<0.001
At 7 days	1.9 ± 0.4	1.1 ± 0.3	<0.001

Discussion

This prospective multicenter clinical trial revealed that Ghasemzadeh approach (combined reciprocating saw/osteotome) has superiority over pure osteotome instrument on cutting time and also postoperative parameters such as eyelid edema on 7 days after surgery, ecchymosis, pain and overall patient's satisfaction in rhinoplasty during first week following surgery.

To the best of our knowledge this research is the first to introduce a novel, hybrid approach in internal lateral rhinoplasty by combining a reciprocating saw and conventional osteotome device (chisel) with several advantages over pure osteotome (chisel only) in terms of predictable, precise, rapid and easier osteotomies,

decreased postoperative complications including edema, ecchymosis, pain, and increased overall patient's satisfaction.

Several methods have been introduced to reduce the complicatins of rhinoplasty and achieve better esthetic results.[11,12]

The most important observation and the main advantages of reciprocating saw in the present study is that swelling, pain, ecchymosis and short-term patient satisfaction was improved with this technique, there were no spicules on the cut site, therefore fracture lines are very sharp and finally led to perfect bilateral symmetry. The sharp osteotomies of reciprocating saw on medial and transverse cuts in turn minimize the probability of curved deformities. Moreover, reciprocating saw allowed good visualization of anatomy and also had adequate power of cut eliminating pressure applied by surgeon hand and consequent complications such as unpleasant fractured instruments. Whereas, the disadvantages of the lack of anatomical visibility and inadequate power cut are frequently reported for piezosuregy, the most recently suggested novel technique in rhinoplasty.[9,10]

The cutting time in the present study was significantly shorter in combined approach compared with pure osteotome. In a study by Demirbas et al on the rapidity of cutting time with ultrasonic bone scalpel found that the its cutting time is comparable with reciprocating saw due their similar cutting surface area.[9] A systematic review study has showed that articles mostly reported that the duration of cutting time performed by piezoelectric surgery was longer than that of osteotomies made with a reciprocal saw.[13] Lower operation time is associated with reduces probability of complications due to general anesthesia. The safety of airway management and successfully cardiopulmonary regulation are directly related to the shorter operating time. It has been reported that the amount of blood loss increases by 18% when the operating time prolonged over three hours in craniofacial surgery.[14-18] On the other hand soft tissue injury and longer operation time affect postoperative edema.[9]

We also compared the average eyelid edema between two groups on day 2 (P value=0.9) and on day 7 (P value=0.001) following surgery at present study. The mean eyelid edema on day 7 in combined group was significantly lower than pure osteotome. Postoperative edema is the most frequently reported complication after rhinoplasty. It causes social disturbing and frightening, and it is also much discomfort for the patient.[8,19,20] Rena et al in the study showed that the intense of swelling in patients undergoing SARPE (Surgically Assisted Rapid Palatal Expansion) surgery was comparable between two groups of piezosurgery and reciprocal and it was disappeared quickly in both groups.[21]

Our findings showed that patients undergoing Ghasemzadeh approach experienced significantly less pain and better satisfaction compared with conventional method within a week following surgery. Kiyak et al., in orthognathic surgery reported that pain and satisfaction has strong direct association.[22,23,24] In another study in SARPE surgery has been shown that pain and satisfaction were correlated with each other but not with level of edema.[8]

The strength of the present study included prospective, double blind, clinical, a multicenter, and a relatively larger sample size. In addition, according the findings of current study, the reduced complications and cutting time observed Ghasemzadeh approach owing the effectiveness of this approach. Further studies with a similar methodology and also another microscopic researches are necessary to assess the safety and effectiveness of suggested novel approach. The main weakness of our study was the lack of similar data to compare and support our findings.

It is concluded that the use of combined reciprocating saw/osteotome in rhinoplasty showed that swelling, pain, ecchymosis and short-term patient satisfaction was improved with this technique. However, there is lack of similar studies to compare our findings due to our study is the first in introducing this novel combined approach (reciprocal saw and osteotome). Therefore, more researches are necessary to evaluate this approach.

Conflict of Interest: None

Institution to Which the Work should be Attributed
Arak University of Medical Sciences, Arak, Iran.

Financial Disclosure and Products
None of the authors has a financial interest in any of the devices, or drugs mentioned in this research.

Funding: Not applicable

Ethics approval and consent to participate: Ethical code: IR.ARAKMU.REC.1399.085

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