Is Ultrasonic Bone Scalpel Useful in Le Fort I Osteotomy?

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Purpose: Safety and precision are 2 main goals in research to improve bone cutting in maxillofacial surgery. The aim of this prospective clinical study was to analyze the outcomes using an ultrasonic bone scalpel versus a piezoelectric surgical device and the conventional technique in a Le Fort I osteotomy.

Materials and Methods: We designed a prospective, randomized, single-blind cohort study. The predictor variables were the devices used to perform the Le Fort I osteotomy, divided into 3 groups: *1)* ultrasonic bone scalpel (BoneScalpel; Misonix, Farmingdale, NY), *2)* piezoelectric surgical device, and *3)* conventional technique (Lindeman burr and reciprocal saw). The primary outcome of the study was cutting time, whereas secondary outcomes were length of the procedure, total blood loss, intraoperative complications, and postoperative edema. Other variables of interest were age and gender. Data were analyzed using 1-way analysis of variance and the Kruskal-Wallis test.

Results: The study sample was composed of 34 patients with a mean age of 21.5 years, and 63.3% of patients were women. The mean cutting time ($P < .001$) and length of the procedure ($P = .012$) were significantly shorter with the bone scalpel than with the other types of surgery. The ultrasonic bone scalpel showed a significant reduction in intraoperative blood loss of up to 45% compared with the piezoelectric surgical device and the conventional technique ($P = .038$).

Conclusions: The results of this study suggest that the ultrasonic bone scalpel is an effective ultrasonic bone-cutting instrument in a Le Fort I osteotomy as evidenced by the significant decrease in the cutting time, intraoperative blood loss, and postoperative edema compared with the other techniques.

J Oral Maxillofac Surg 78:141.e1-141.e10, 2020

Midface deformities often occur during growth and development owing to hereditary or acquired disorders. These deformities cause dysfunctional, esthetic, and phonation problems. Le Fort I osteotomy is one of the most commonly used orthognathic procedures to correct midface deformities. Since the early 20th century, the techniques for Le Fort I osteotomy were under constant modification and revision. Today, updates are being made in surgical devices, technologies, and pharmacologic methods to minimize complications associated with Le Fort I osteotomy.

Safety and precision are 2 main goals in research to improve bone cutting in maxillofacial surgery. Ultrasonic devices have been used since 1940 for endodontic and periodontal surgery.[1] Recently, piezoelectric surgery, which was introduced by Vercellotti,[2] has gained popularity because of the selective cutting feature and vibration amplitude adjustment between hard and soft tissue in maxillofacial surgery.[3,4] The

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Conflict of Interest Disclosures: None of the authors have any relevant financial relationship(s) with a commercial interest.

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Received March 7 2019

Accepted September 16 2019

0278-2391/19/31147-4

https://doi.org/10.1016/j.joms.2019.09.021

main advantages of ultrasonic instruments are minimizing damage to the soft tissue and increasing the surgical view by reducing bleeding during surgery.[4-6] In addition, piezoelectric surgical devices used for osteotomy decrease postoperative hemorrhage, edema, and nerve damage compared with traditional instruments in orthognathic surgery.[6] However, the main shortcoming of piezoelectric surgery is an increase in bone-cutting time owing to insufficient cutting power and the requirement for a conventional saw and burr osteotomy.[7,8]

An ultrasonic bone scalpel, originally developed for neurosurgical nerve decompression and spinal osteotomy, promises to combine the benefits of previous piezoelectric surgical devices with improved ergonomics and cutting efficiency.[9] It is designed for sensitive separation of bones and does not damage soft tissues. After the success of the ultrasonic bone scalpel in spinal osteotomy, a few studies have been published showing its use in maxillofacial surgery.[10-12]

The purpose of this study was to evaluate the effectiveness of the ultrasonic bone scalpel in a Le Fort I osteotomy. We hypothesized that the ultrasonic bone scalpel may be an ideal instrument for maxillofacial applications. The specific aims of the study were to measure and compare cutting time, length of the procedure, intraoperative blood loss, and postoperative edema between the ultrasonic bone scalpel and a piezoelectric surgical device, as well as conventional cutting instruments.

Materials and Methods

STUDY DESIGN AND SAMPLE DESCRIPTION

To address the research purpose, we designed and implemented a prospective, randomized, single-blind cohort study, and the study protocol was approved by the Erciyes University Human Research Ethics Committee. The study population was composed of all patients presenting for evaluation and management of Class III dentofacial deformities between June 2017 and December 2018. Written informed consent was obtained from all patients. The study was performed at the Oral and Maxillofacial Surgery Hospital of the Erciyes University Faculty of Dentistry. To be included in the study sample, patients had to be young adults (aged 18 to 30 years) with an American Society of Anesthesiologists status of class I and had to have a dentoskeletal deformity undergoing Le Fort I surgery, a hemoglobin level in the normal range (12 to 14 g/dL for female patients and 14 to 16 g/dL for male patients), and an international normalized ratio lower than 1.5.

Patients were excluded from the study if they had *1)* neuropathic disease, *2)* long-term use of nonsteroidal anti-inflammatory drugs and opioid-derived drugs, *3)* a history of allergic reactions to drugs, *4)* preoperative signs of inflammation such as pain and swelling in the head and neck, *5)* a history of excessive bleeding during surgery, or *6)* an incomplete follow-up duration.

STUDY VARIABLES

Predictor Variables

The primary predictor variables were the osteotomy devices, divided into 3 groups. The groups were randomly determined. In group 1 (n = 12), the lateral wall of the maxilla was cut from the piriform rim to the pterygomaxillary fissure bilaterally using an ultrasonic bone scalpel (BoneScalpel; Misonix, Farmingdale, NY) with a serrated standard blade (Fig 1), which has a straight configuration and is 20 mm long and 1.0 mm thick. The ultrasonic bone scalpel produces micromotion at a frequency of 22.5 kHz and provides mineralized tissue cutting with a vibration amplitude of 35 to 300 μm.[11] Although amplitude settings of 1 to 10 are available, the setting of 7 was well suited to the range of bone qualities encountered. In group 2 (n = 12), Piezosurgery (OT7; Mectron Medical Technology, Loreto, Italy) was used (Fig 2). In group 3 (n = 12), the conventional technique (Lindeman burr and reciprocal saw; Karl Storz, Tuttlingen, Germany) was used (Fig 3). The surgical procedure was performed with the patient under general anesthesia with nasotracheal intubation. A standard Le Fort I osteotomy was performed in all patients by the same surgeon (A.E.D.) (Video 1). After administration of local

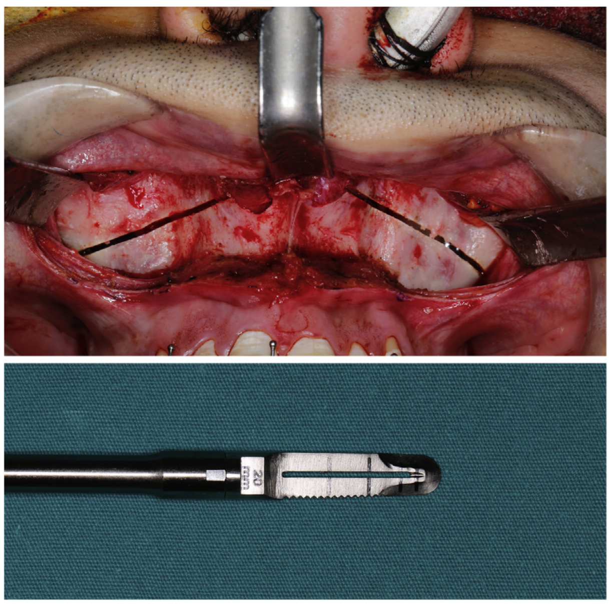

FIGURE 1. Osteotomy lines created using ultrasonic bone scalpel with serrated standard blade (Misonix).

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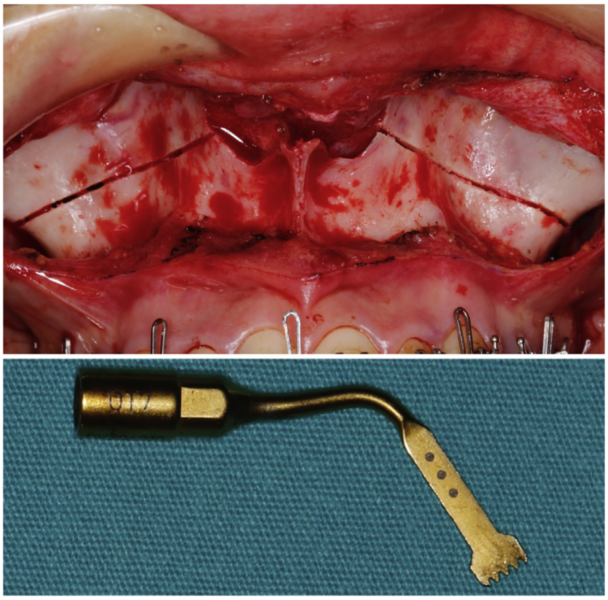

FIGURE 2. Osteotomy lines created using Piezosurgery with insert OT7 (Mectron Medical Technology).

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infiltration anesthesia, a mucosal incision was made using an electric scalpel. A full-thickness mucoperiosteal flap was raised; the lateral walls of the maxilla, zygomatic buttress, and piriformis aperture were exposed; and the pterygomaxillary junction was identified bilaterally. The nasal mucosa was elevated, and the base of the nasal cavity was exposed. The pterygoid plates, nasal septum, and lateral nasal walls were separated with the same type of osteotomes for standardization of the procedure. Down-fracture of the maxilla was performed using a hook and bone spreader after the osteotomies were completed. The maxilla was taken to its new position with the splint, and rigid fixation was performed using a miniplate and monocortical screws (KLS Martin, Tuttlingen, Germany) in all patients.

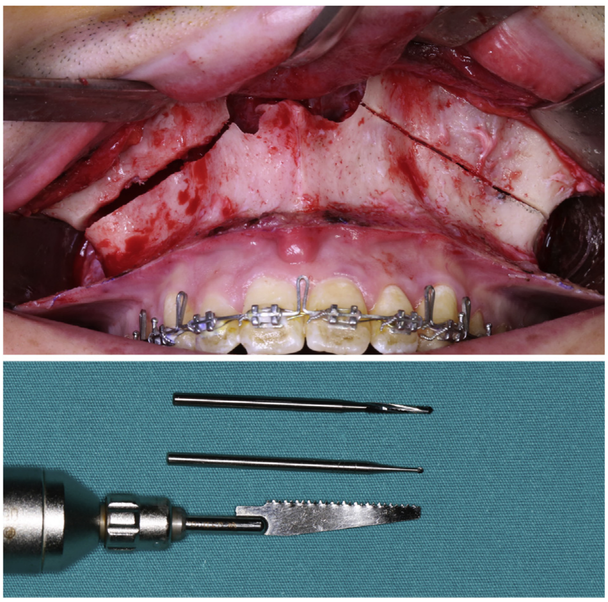

FIGURE 3. Osteotomy lines created using conventional instruments: Lindeman burr *(right)* and reciprocal saw *(left)* (Karl Storz).

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Outcome Variables

The primary outcome variable was cutting time. The time needed for cutting of the lateral wall of the maxilla from the piriform rim to the pterygomaxillary fissure bilaterally was calculated in seconds for each instrument and defined as the cutting time.

The secondary outcome variables were length of the procedure, total blood loss, intraoperative complications, and postoperative edema. The length of the procedure was recorded as the time elapsed from the mucogingival incision to the down-fracture in minutes. The reason for determining this period is that the amount of movement with or without maxillary impaction and the degree of fixation difficulty vary for each patient. These variables adversely affect standardization and may prolong the operation time independently of the instrument type. Therefore, the time between the incision and the down-fracture performed as standard in each patient was determined as the length of the procedure. When calculating total blood loss, we measured the amount of fluid collected by using the same type of suction and sponge during the operation, in milliliters, at the end of the Le Fort I osteotomy. Actual blood loss was determined by subtracting the amount of irrigation solution from the total fluid volume. During the operation, nasal mucosa lacerations, undesirable fractures, and neurovascular damage were recorded as intraoperative complications. We used the 3dMD imaging system (3dMD, Atlanta, GA) and 3dMD Vultus software to evaluate the amount of postoperative edema. Three-dimensional images were taken at 3 days and at 6 months after surgery. The images of the patients were taken at maximum intercuspation when the lips were free and the eyes were open. To obtain standardization on 3-dimensional images, the anatomic landmarks of the bilateral medial and lateral canthus, nasion, tragus, commissure, and upper-lip white roll were determined, and the area between these points was calculated (Fig 4). Cutting time, length of the procedure, blood loss, and postoperative edema were measured by an unbiased researcher.

The other outcome variables were age (in years) and gender (male or female). These variables were used primarily for descriptive purposes and randomization, but data analyses also were performed.

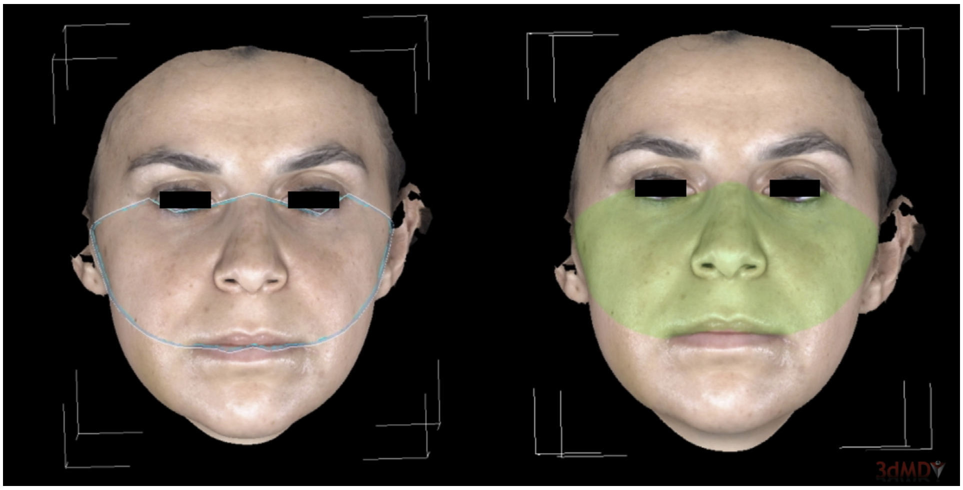

FIGURE 4. The amount of postoperative edema was measured using the 3dMD imaging system and 3dMD Vultus software.

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STATISTICAL ANALYSIS

A sample size of 10 patients per group was calculated to be necessary to detect a strong effect using the Cohen approach[13] with an error of 0.05 and power of 80% when defining the sample size calculation. Data normality was assessed using histograms, quantile-quantile plots, and the Shapiro-Wilk test. Variance homogeneity was examined using the Levene test. To compare the differences among groups, either 1-way analysis of variance or the Kruskal-Wallis test was applied for quantitative data. The Fisher exact test was applied for qualitative data. Tukey, Siegel-Castellan, and Bonferroni-adjusted z tests were used for multiple comparisons. Covariance analysis (adjusted mean: secondary outcome variables) was used to compare the primary outcome variable (cutting time) between all groups. Pearson correlation analysis was performed for the direction and strength of the relationship between cutting time and secondary outcome variables, and simple linear regression analysis was performed to determine the cause-and-effect relationship between primary and secondary outcome variables. Data were expressed as mean ± standard deviation, median (first quartile to third quartile), or frequency (percentage). Analyses were conducted using TURCOSA (Turcosa Analytics, Melikgazi, Turkey; www.turcosa.com.tr). $P < .05$ was considered statistically significant.

Results

In this study, 36 Class III patients with maxillary retrognathia underwent Le Fort I osteotomies. Two patients were excluded from the study because of lack of postoperative follow-up records. The flowchart of patient participation in this study is shown in Figure 5. A total of 34 patients were included in the study, and 21 (63.3%) were women. The mean age of the patients was 21.5 years (range, 18 to 30 years) at the time of surgery. No statistically significant differences were found between the groups in terms of age ($P = .579$) and gender ($P = .227$) (Table 1). The ultrasonic bone scalpel (group 1) was used as the cutting instrument in 10 patients, the Piezosurgery device (group 2) was used in 12, and the conventional instruments (group 3) were used in 12.

CUTTING TIME (PRIMARY OUTCOME)

The mean difference in cutting time between the groups is shown in Table 1. The mean cutting time was 137.9 ± 41.5 seconds in the bone scalpel group, whereas it was 225.83 ± 9.17 seconds in the Piezosurgery device group and 219.5 ± 49.9 seconds in the conventional group. The mean cutting time was significantly shorter in the bone scalpel group than in the Piezosurgery device and conventional groups ($P < .001$) (Fig 6).

LENGTH OF PROCEDURE

The mean difference in the length of the procedure between the groups is shown in Table 1. The mean length of the procedure was shorter in the bone scalpel group than in the Piezosurgery device and conventional groups (Fig 7). The length of the procedure in the bone scalpel group was significantly shorter than that in the conventional group ($P = .012$).

TOTAL BLOOD LOSS

The mean difference in blood loss between the groups is shown in Table 1. Mean blood loss was lower in the bone scalpel group than in the other 2 groups (Fig 8). Total blood loss in the bone scalpel group

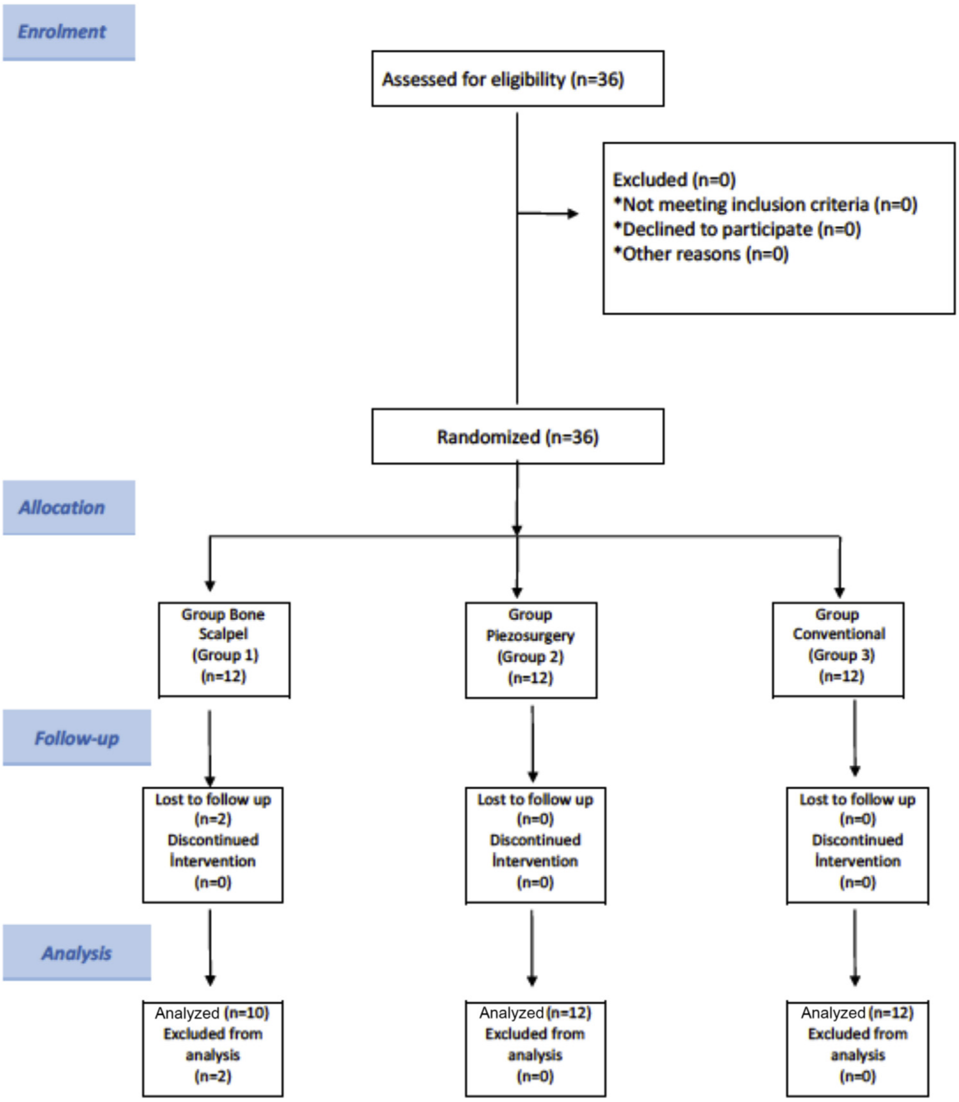

FIGURE 5. CONSORT (Consolidated Standards of Reporting Trials) flowchart of patient participation in study.

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was significantly lower than that in the conventional group (*P* = .030).

INTRAOPERATIVE COMPLICATIONS

Nasal mucosa lacerations were the only complication in this study. The number of lacerations of the nasal mucosa in the bone scalpel group was lower than that in the other 2 groups (*P* = .445) (Table 1).

POSTOPERATIVE EDEMA

The mean difference in postoperative edema between the groups is shown in Table 1. The mean amount of postoperative edema was lower in the bone scalpel group than in the other groups (Fig 9), and the difference between the conventional and bone scalpel groups was statistically significant (*P* = .02).

Discussion

The purpose of this study was to assess the effectiveness of the ultrasonic bone scalpel in a Le Fort I osteotomy. We hypothesized that the ultrasonic bone scalpel may be an ideal instrument for maxillofacial applications. The specific aims of the study were to measure and compare cutting time, length of the procedure, intraoperative blood loss, and postoperative edema between the ultrasonic bone scalpel and the Piezosurgery device, as well as conventional cutting instruments. This study showed that the ultrasonic bone scalpel reduced the cutting time significantly compared with the other osteotomy devices in a Le Fort I osteotomy.

In this study, other findings confirmed our hypothesis. The mean length of the procedure was shorter in the bone scalpel group than in the Piezosurgery device

Table 1. COHORT CHARACTERISTICS GROUPED BY OSTEOTOMY TECHNIQUE

	Group			*P* Value		
Variable	Bone Scalpel (n = 10)	Piezosurgery Device (n = 12)	Conventional Instruments (n = 12)	Bone Scalpel vs Piezosurgery Device	Bone Scalpel vs Conventional Instruments	Piezosurgery Device vs Conventional Instruments
Age, yr	21.4 ± 2.8	22.1 ± 3.3	20.9 ± 2.4	.579*	.596*	.519*
Male gender	3 (30%)	2 (16.67%)	6 (50%)	.227†	.227†	.227†
Cutting time, seconds	137.9 ± 41.5[a]	225.83 ± 9.17[b]	219.5 ± 49.9[b]	<.001*‡	<.001*‡	.927*
Length of procedure, minutes	22 (21-22.75)[a]	26 (23.75-28.5)[ab]	27,5 (26.5-31.5)[b]	.265*	.012*‡	.285*
Blood loss, mL	107.5 ± 28.98[a]	157.5 ± 61.51[ab]	194.16 ± 107.14[b]	.281*	.03*‡	.466*
Postoperative edema, cm^2	8.39 ± 6.42[a]	16.10 ± 6.37[ab]	19.84 ± 13.16[b]	.149*	.02*‡	.597*
Nasal mucosa perforation	2 (10%)	4 (16.70%)	6 (25%)	.445†	.445†	.445†

Note: Data are expressed as number (percentage), mean ± standard deviation, or median (first quartile to third quartile). Different superscript letters in the same row indicate statistically significant differences between groups.

* One-way analysis of variance.

† Pearson χ^2 test.

‡ Statistically significant result (*P* < .05).

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and conventional groups. Mean blood loss was lower in the bone scalpel group than in the other 2 groups. The number of lacerations of the nasal mucosa was lower in the bone scalpel group than in the other 2 groups. The mean amount of postoperative edema was lower in the bone scalpel group than in the other groups.

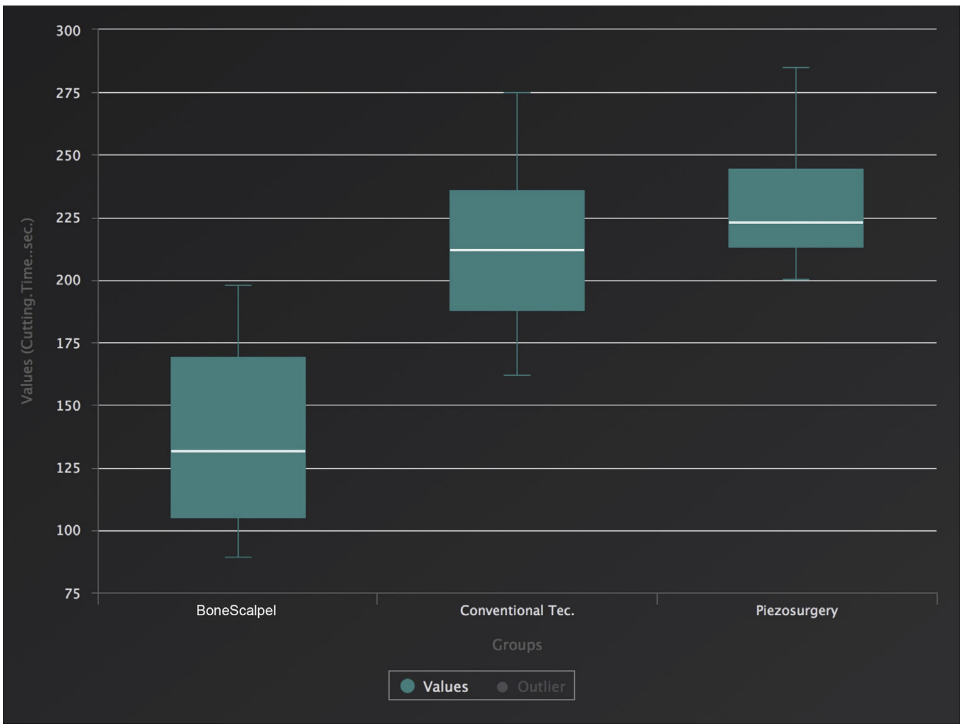

FIGURE 6. Cutting time in all groups. Tec., technique.

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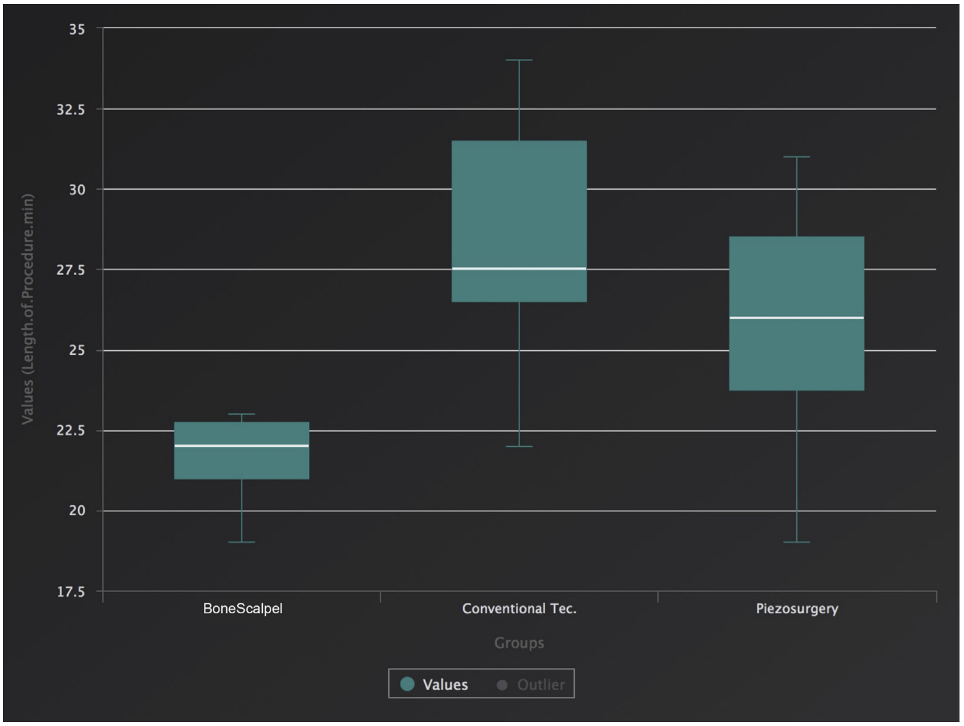

FIGURE 7. Length of procedure in all groups. Tec., technique.

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In the neurosurgical literature, high clinical success rates were shown for the ultrasonic bone scalpel.[14-16] However, very few studies on its use in orthognathic surgery have been performed. In orthognathic surgery, there are many studies comparing Piezosurgery and surgery with conventional instruments.[6,17-21] The advantages of Piezosurgery are the ability to adjust the vibration frequency, the

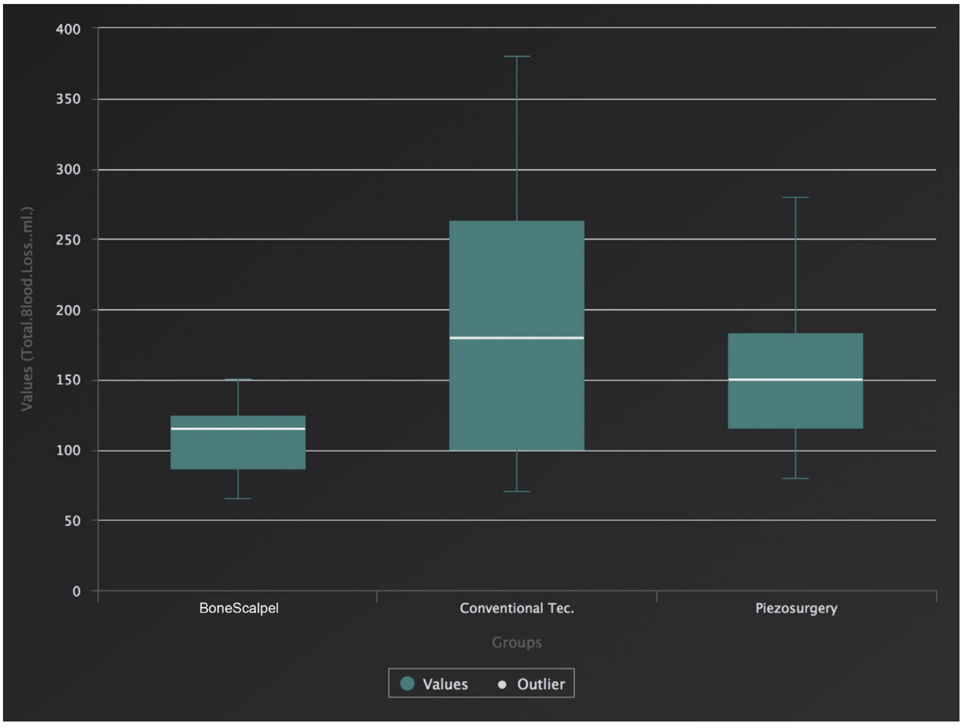

FIGURE 8. Total blood loss in all groups. Tec., technique.

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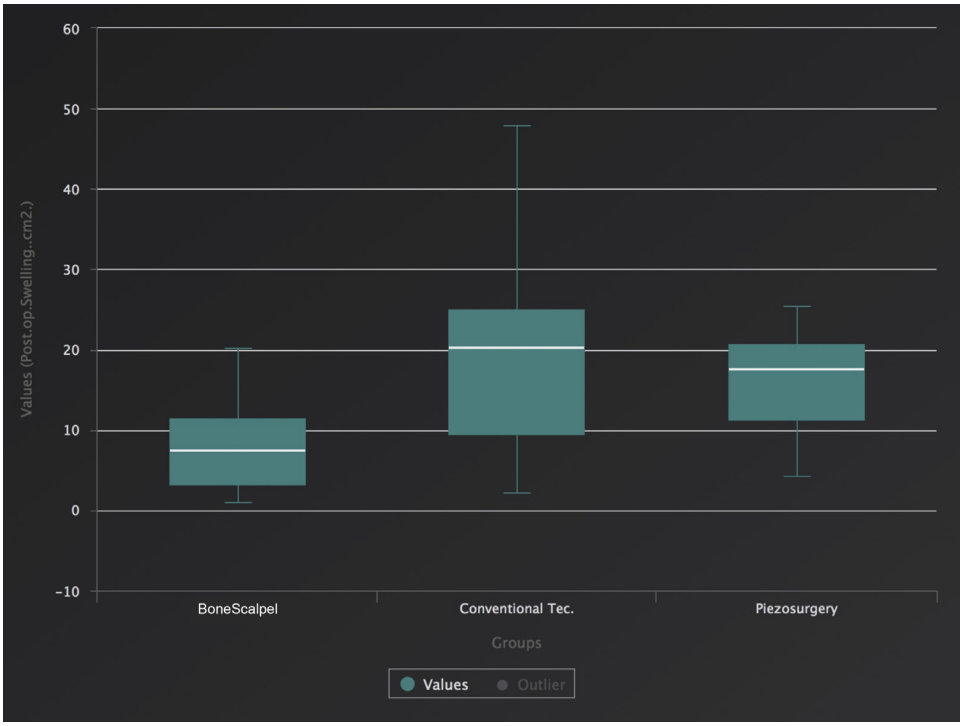

FIGURE 9. Postoperative (Post-op) edema in all groups. Tec., technique.

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minimal risk of damage to the soft tissue, and the increase in the field of view of the surgeon by reducing the amount of bleeding during the operation.[4,5,22] On the other hand, most of these studies reported that the longer cutting time on cortical bone is considered more disadvantageous compared with the conventional instruments.[6,21] However, in a systematic review published by Pagotto et al,[17] no difference in operation time was found between Piezosurgery and conventional osteotomies. According to the results of our study, the Piezosurgery technique had a longer cutting time than the conventional technique, but this difference was not statistically significant. In addition, the length of the procedure was shorter in the Piezosurgery group, in contrast to the cutting time. The main reason for this result may be that Piezosurgery provides less soft tissue injury at the site of the operation. The most important disadvantage of Piezosurgery is that the cutting power in the cortical bone is not as adequate as that of conventional instruments. The results of this study showed that the cutting time and the length of the procedure were significantly shorter in a Le Fort I osteotomy using the ultrasonic bone scalpel compared with the other instruments ($P < .05$). The ultrasonic bone scalpel can eliminate the disadvantage of slow bone cutting of ultrasonic devices by making a faster cut than can be made with a Piezosurgery device. The main reasons for the faster cut are that the ultrasonic bone scalpel has a greater cutting surface area like a reciprocal saw and cuts the mineralized tissue at a rate of up to 300 μm/second whereas the Piezosurgery instrument cuts at a rate of up to 200 μm/second. Dammous et al[10] reported that there was no significant difference between the bone scalpel and the conventional technique in terms of the cutting time in a Le Fort I osteotomy in their cadaveric study. In our prospective clinical study, the ultrasonic bone scalpel showed a statistically significantly shorter cutting time than the Piezosurgery and conventional instruments ($P < .001$).

Shortening the operation time reduces the risk of complications due to general anesthesia. The safety of airway control and successful cardiopulmonary regulation are directly related to a short operation time. The amount of blood loss was reported to increase by 18% when the operation time was over 3 hours in orthognathic surgery.[23] In this study, the effect of the instrument type used in a Le Fort I osteotomy on the amount of intraoperative blood loss also was investigated. In many studies comparing different instruments in the literature, intraoperative blood loss has been calculated as the difference between the total amount of physiological fluid and the total amount of aspirated fluid during the operation.[6,8,24] In this study, the amount of intraoperative blood loss was significantly lower in patients who underwent osteotomy using the ultrasonic bone scalpel compared with the other 2 instruments. Mean blood loss in the bone scalpel group decreased by 31% and 45%, respectively, compared with the Piezosurgery and conventional techniques. In parallel to this study, a study by Silva et al[12] reported a 49% reduction in the average volume of blood loss using the ultrasonic bone scalpel compared with a reciprocal saw in temporomandibular joint surgery. Pagotto et al[17] compared Piezosurgery and conventional instruments in orthognathic surgery in a meta-analysis study and reported that the amount of total blood loss was lower when the Piezosurgery device was used. Moreover, it has been reported that the bone scalpel significantly reduces blood loss compared with conventional instruments in neurosurgical operations.[9] The lower amount of blood loss also reduces the necessity for blood transfusion and its associated risks and increases the quality of the view of the surgical field during the operation. In this study, significantly less blood loss was obtained in a Le Fort I osteotomy using the ultrasonic bone scalpel compared with the other instruments. The main reason for this result may be the shortening of the osteotomy and the operation time.

Silva et al[12] reported that there was a reduction in the requirement to protect adjacent soft tissues during bone cutting. Laceration of the nasal mucosa during a Le Fort I osteotomy increases bleeding, negatively affects the quality of the view of the surgical field, and leads to prolongation of the operation time. In this study, only 2 of the 20 osteotomies using the ultrasonic bone scalpel had lacerations in the nasal mucosa. However, laceration of the nasal mucosa may occur during osteotomy, as well as during dissection and downfracture of the maxilla.

Soft tissue damage, excessive bleeding, and prolonged operation time affect postoperative edema. Spinelli et al[6] reported in their study that ultrasonic systems reduce postoperative swelling. However, in the literature, there are few studies investigating the effect of the instrument used during osteotomy on edema in orthognathic surgery.[15] The effect of the ultrasonic bone scalpel on postoperative edema in orthognathic surgery was first shown in our study. According to the results of this study, postoperative swelling was the least in the bone scalpel group. The incidence of postoperative swelling after osteotomy was significantly lower in the bone scalpel group than in the conventional group ($P = .025$).

The strengths of this study include the prospective, randomized study design; the comparable results to those of previous studies; the fact that all osteotomies were performed in all patients by the same surgeon; and the multivariate statistical analysis. The weaknesses of the study include the limited study sample and single-blind design. In addition, differences in bone quality, bleeding, and the postoperative edema response among patients may affect the results of the study.

The ultrasonic bone scalpel is a safe and effective ultrasonic bone-cutting instrument that can be used to facilitate osteotomies in orthognathic surgery. This instrument significantly reduces the cutting time compared with the other osteotomy devices commonly used in orthognathic surgery. Future studies are needed to investigate the effectiveness of the ultrasonic bone scalpel with large sample sizes and different osteotomy types and variables.

Supplementary Data

Supplementary Video associated with this article can be found in the online version at https://doi.org/10.1016/j.joms.2019.09.021.

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