External osteotomy in rhinoplasty: Piezosurgery vs osteotome☆

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A R T I C L E I N F O

Article history:
Received 13 February 2015

A B S T R A C T

Purpose: To achieve the desired outcome in rhinoplasty depends on many factors. Osteotomy and surgical reshaping of nasal bones are important steps that require careful planning and execution. The availability of different tools raises the question of which one provides significant advantages for both technique and surgical outcome. Our prospective randomized pilot study compared the outcome of post-traumatic rhinoplasty performed with two different external techniques: ultrasound osteotomic cut using the Piezosurgery Medical Device (Mectron, Carasco, Italy) and traditional external osteotomy.
Material and methods: Forty-four lateral osteotomies of the nasal wall were performed in twenty-two patients. In twelve patients the osteotomies were conducted with a 2-mm traditional osteotome (control group), while in the remaining ten patients these were done with the Piezosurgery Medical Device (experimental group).
Results: At the postoperative evaluation, significantly lower pain, edema and ecchymosis were noticed in the experimental group ($p < 0.05$). Moreover, the endoscopic evaluation showed fewer mucosal injuries in the experimental group ($p < 0.05$), whereas bleeding, symmetry of the pyramid and presence of external scars, were similar in the two groups.
Conclusions: In the present study, Piezosurgery Medical Device allowed for safe lateral osteotomies in rhinoplasty preliminarily demonstrating the potential to reduce some of the most frequent complications of rhinoplasty.

1. Introduction

Lateral osteotomy is generally the last step in rhinoplasty. After hump removal, the nose appears wider and the dorsal roof becomes open. Lateral osteotomy is performed to close the dorsal roof, to narrow and refine the nasal pyramid and to straighten the nasal bones [1]. In this phase, it is important to achieve adequate mobilization of the bony skeleton minimizing the damage to the supporting soft tissue and avoiding excessive narrowing in order not to compromise the nasal physiology. Current methods rely on mechanical energy to perform osteotomies, but extensive trauma of the nasal mucosa may contribute to the prolonged postoperative ecchymosis and edema and comminuted fracture of the

☆ Disclosure statement: The authors declare that there is no conflict of interest.

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nasal bones may lead to suboptimal cosmetic outcome [1]. The ideal technique for lateral nasal osteotomy should maintain the integrity of the nasal mucosa and the periosteal attachment of the bony lateral wall of the nose, and it should also be safe, precise and reproducible. There is still considerable debate over the optimal method and approach to perform lateral osteotomies. They may be carried out using an internal approach, through the nose or the mouth, or with an external percutaneous approach using a 2-mm wide osteotome[2,3]. Both approaches are widely practiced, and the surgeon's choice is generally based on his own preference and experience. Many authors have compared the two approaches in order to highlight their benefits and limitations [4]. In our past experience, external osteotomy has proved to result in unnoticeable cutaneous scars one month after surgery, limited bleeding and edema and minimal periorbital ecchymosis with the preservation of the nasal mucosa[1].

A breakthrough in osteotomy was provided by the advent of the Mectron Piezosurgery Medical Device (PMD), an innovative instrument based on piezoelectric ultrasonic vibrations which has successfully been used to perform both closed and open rhinoplasty procedures, with fewer related complications[5,6]. The main benefits of this device are the harmless effect on soft tissues, the minimal bleeding and bruising, and the small pressure required to create bony cuts, which can destabilize the bony and the cartilaginous parts of the nose. The ability to minimize tissue trauma with its associated morbidity and the cutting effectiveness make the piezosurgery an attractive option for lateral osteotomies in rhinoplasty.

Authors skilled in maxillofacial surgery and rhinoplasty have performed lateral osteotomies and removal of the bony-cartilaginous hump by using piezoelectric technology rather than the classic osteotome[5,6]. Our literature research however failed to find a study in which a control group was enrolled.

This preliminary study analyzes the outcome of two different osteotomic techniques for lateral osteotomy: ultrasound osteotomic cut versus traditional external osteotomy.

2. Patients and methods

This prospective randomized pilot study involved patients that underwent rhinoplasty surgery at the ENT Department of the Cattinara Hospital in Trieste, Italy. The study ran from January through September 2013.The study protocol was approved by the Institutional Review Board of the University of Trieste (No. 54); patients were informed about the purpose of the study and gave their written consent to join the experimentation. All procedures were carried out by a single surgeon.

2.1. Patient selection

Our institute is a public hospital in which rhinoplasty surgery is performed with a morphofunctional intent and not merely for aesthetic purposes. The inclusion criteria were, therefore, history of maxillofacial trauma with specific nasal involvement, consensual deviation of both the nasal septum and pyramid, presence of a wide nasal dorsum and prominent hump and associated nasal respiratory dysfunction. Patients who had already undergone a previous rhinoplasty procedure, or who presented a narrow nasal dorsum and a minimal hump were excluded.

The study included 22 patients, 10 men and 12 women, who were randomly assigned to two groups: experimental group (G1, n = 10), in which the osteotomies were performed with PMD, and control group (G2, n = 12), in which the osteotomies were performed with traditional 2-mm wide osteotome. Allocation to groups was carried out by opening opaque sealed envelopes and was concealed from the investigators.

2.2. Anesthesia and surgical technique

All procedures were performed under general anesthesia and the rhinoplasty surgery was always a morphofunctional type encompassing the septoplasty and conducted with a closed technique. The first steps were the removal of the dorsal hump and the medial nasal osteotomy. Lateral osteotomy was performed with an external percutaneous approach using the selected instrument.

In the experimental group the surgeon performed a 2-mm long incision 8–10 mm below and medially to the medial canthus, involving the skin, the underlying superficial muscular aponeurotic system tissues and the periosteum (Fig. 1). A curved, narrow and unguarded MT1S-10 tip of the PMD was placed through the pilot incision up to the nasal bone. Before activation, the tip was manually pushed cranially and caudally into the incision to produce minimal periosteal detachment, restricted to the ideal line of the lateral osteotomy without the need to create a subperiosteal tunnel. The vibrating chisel was then activated and moved continuously along the ideal osteotomy line, exerting gently pressure on the bony surface, to create a continuous section line (Figs. 2 and 3). In some selected wider noses, the surgeon can choose to perform a second caudal incision to extend the osteotomy to the lower portion of the maxilla (Fig. 4).

In the control group, the 2-mm wide osteotome was used with a traditional technique that has already been described [1].

At the end of the procedure, each nasal fossa was packed with Merocel (Medtronic Xomed Inc, Jacksonville, FL) and Silastic sheeting was placed as a septal splint secured with a through-and-through suture. Externally, a plaster cast was applied to protect the nasal pyramid.

Fig. 1 – Cutaneous incision.

Fig. 2 – Insertion of the activated tip to perform the lateral osteotomy.

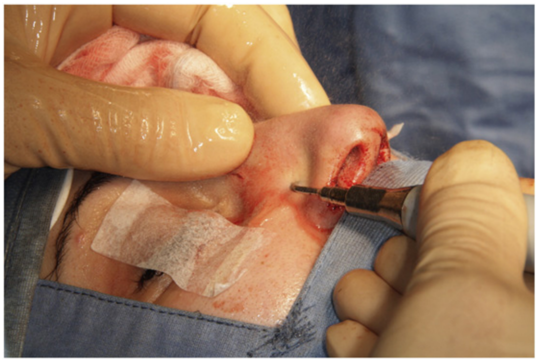

Fig. 4 – Second caudal incision in a case presenting wide nasal dorsum.

After surgery we prescribed antibiotic therapy for 6 days and painkillers for 4 days (i.v. Acetaminophen 1 g in association with Tramadol 100 mg diluted in 100 ml saline solution thrice a day).

2.3. *Post-operative management and follow-up*

Post-operative management was also standardized. All patients were instructed to keep the semi-seated position; cold compresses were applied to the eyes and continuously changed during the first 24 h. The nasal packs were removed on the fourth day after surgery, the septal splint together with the plaster cast on the seventh day.

We collected data regarding the time of surgery noted in the operating room form, the post-operative course and the follow-up period. Particularly, during the hospitalization we daily checked the following criteria regarding the post-operative course: pain, edema and periorbital ecchymosis, post-operative bleeding, symmetry and solidity of the bony nasal pyramid and visible scars were evaluated by a blinded operator at a distance of one meter from the patient.

- We noted the presence or the absence of edema and ecchymosis as ordinary variables:
  0 = absent; 1 = low (edema and ecchymosis limited to the zygomatic region); 2 = severe (extended edema and raccoon eyes).

Fig. 3 – The handpiece is turned to extend the osteotomy to the nasal root.

- Post-operative bleeding was considered as positive when anterior or posterior epistaxis occurred.
- Pain was assessed using the visual analog scale (VAS) [7]. A VAS score of 3 or higher required the administration of analgesic therapy, whereas a VAS score lower than 3 corresponded to slight discomfort rather than actual pain.

Four days after removal of the packings, patients underwent nasal endoscopy to evaluate any mucosal injury which might be attributed to either of the two techniques. This evaluation was carried out by the blinded operator, together with the solidity and the symmetry of the pyramid and the cutaneous scars appearance one month after surgery.

2.4. *Statistical analysis*

Statistical analysis was performed by using the software Statistical Package for Social Sciences v.15 (SPSS Inc., Chicago, IL). Comparisons between the two groups for each nominal variable were performed using a Fisher exact test; for VAS scores, grading of edema and ecchymosis using a Mann–Whitney test. Data concerning the duration of surgery with the two instruments were tested for normality of distribution and equality of variances with a Shapiro–Wilk test and a Levene test, respectively. As a result, the significance of the difference in duration of surgery was assessed by means of a Mann–Whitney test. The level of significance for all tests was $p < 0.05$.

3. Results

Periorbital edema and ecchymosis were present in the early post-operative period (within four days) in 10 patients (83%) operated on using the 2-mm osteotome, and in 2 patients (20%) belonging to the experimental group; this difference was statistically significant ($p < 0.05$) (Figs. 5–8).

Eighty percent of the patients in the experimental group reported minimal discomfort (VAS < 3) so that they generally refused analgesics, which were instead necessary in the majority of patients (75%) in the control group and this difference was statistically significant ($p < 0.05$).

Fig. 5 – Representative case performed with 2-mm osteotome. Frontal view before surgery.

The endoscopic evaluation in the control group revealed 5 cases of mucosal injury presenting dot-like lesions anteriorly to the middle turbinate head, whereas no damages were observed in the experimental group; this difference was statistically significant ($p < 0.05$).

No post-operative hemorrhage occurred.

With regard to the duration of surgery, the use of the osteotome allowed a slightly shorter operative time (12.8 ± 1.4) compared to average time of surgery in the experimental group (13.8 ± 1.3) but the difference was not statistically significant ($p = 0.1$).

Cutaneous scars at the entry point of PMD appeared minimal at the end of surgery and were invisible one month after surgery (Figs. 9 and 10). During the postoperative clinical follow-up after one month we noted that all the fractures were well consolidated, and a perfect symmetry of the nasal pyramid was achieved in all patients with no visible cutaneous scarring.

4. Discussion

Historically, two techniques have been used to facilitate lateral nasal osteotomy; the intranasal continuous method and the transcutaneous perforating method [3,8–10]. Rohrich

Fig. 6 – Representative case performed with 2-mm osteotome. Frontal view 4 days after surgery: periorbital edema and ecchymosis are observable bilaterally.

Fig. 7 – Representative case performed with PMD. Frontal view before surgery.

et al. compared the two techniques in a cadaver study and the blinded endoscopic evaluation showed less intranasal trauma and minimal morbidity (hemorrhage, edema and ecchymosis) associated with the external approach [11,12]. The same results were confirmed *in vivo* in another study conducted in our institute by Giacomarra et al. [1] and we are still following this tendency.

Up to now, we have performed the lateral osteotomies exclusively with the manual osteotome; a step forward has been made with the introduction of the PMD. This device is able to convert the electric current into ultrasonic waves by means of a dedicated transducer. The waves are transmitted to a handpiece where they generate vibration of the chisel located at its tip. The PMD is provided with two handpieces and with two peristaltic pumps connected to the control unit, allowing the user to carry out a continuous operation without interruptions to replace or insert new tips.

The control of the PMD occurs via a graphic user interface, where the operator can select and adjust the following parameters: tip type, vibration intensity (in a scale from 1 to 7), irrigation level (in a scale from 1 to 5) and bone type (cortical or medullar).

Fig. 8 – Representative case performed with PMD. Frontal view 4 days after surgery: absence of periorbital edema and ecchymosis.

Fig. 9 – Surgical wounds in case of double incision.

PMD has a selective and micrometric action that allows efficient cutting of mineralized tissues and no harm of soft tissues; this means that with the PMD the osteotomy can be conducted leading the tip of the instrument even close to delicate anatomical structures (vessels, nerves and mucous membranes) with minimal risk of their injury.

Moreover, it has already been demonstrated histologically that bony surfaces cut with PMD present absence of coagulation necrosis with preservation of osteocytes [13,14]. This feature attests to the potential of PMD to perform osteotomy keeping low the risk of osteonecrosis thanks to the micrometric and selective cutting action [14,15].

In contrast with other authors who claimed that the PMD necessarily creates a greenstick fracture [5,6], in our pilot study the osteotomies performed with the PMD appeared to be more precise, linear and efficient than those performed with the traditional osteotome. It was seen especially when a thick bony component required a complete detachment from the nasal process of the maxilla and any greenstick fracture occurred. The osteotomy carried out with the PMD results in a continuous fracture line, so one could speculate that the use of a piezoelectric device could be more indicated in subjects with thicker nasal bones and a wide nasal dorsum; on the contrary, lateral external osteotomies performed with the osteotome could be reserved for patients with a narrow nasal dorsum and thin nasal bones, because in these cases there might be unevenness in fracture lines.

Consistent with the literature [5,6], the experimental group reported fewer complications such as edema and periorbital ecchymosis as well as a substantial reduction in post-operative pain.

Fig. 10 – Surgical wound in case of single incision.

Furthermore, it is important to note that all our cases were post-traumatic and the tissues were often in suboptimal conditions. In such cases, it is common to find abundant scar tissue with major adhesions involving the nasal mucosa, soft tissues and cartilage, which complicate the surgical identification of anatomical structures and the dissection of soft tissues; additionally, there is often major deviation of the nasal septum which requires a more invasive surgical procedure. All of these factors increase the risk of bleeding, which may be massive and require substantial nasal packing. This leads to further congestion with reduced hematic and lymphatic drainage, so that patients who undergo morphofunctional rhinoplasty generally experience slower healing compared to those receiving rhinoplasty exclusively for aesthetic purposes. Nonetheless, the results achieved with the PMD seem to be very encouraging.

In 50% of patients in the experimental group a slight increase in operative time was observed (average 8 min). The need for the surgeon to become acquainted with the proper use of the device –which was however user-friendly– could explain this finding.

Considering PMD cost, this device has a price around 50.000 Euro and the cost of each tip is about 155 Euro. Nowadays, it is suitable to get the device loan for use and the cost of the tips could easily be recovered in global saving.

The main limit of this pilot study is the low number of cases enrolled; prospective randomized trials involving a greater number of patients are necessary to analyze surgical parameters and post-operative complications related to postoperative quality of life.

5. Conclusion

The PMD allows to spare all soft tissues and it focuses the action exclusively on mineralized tissues thus preserving the nasal mucosa. In this pilot study the PMD showed its potential to keep low the incidence rate of postoperative pain, edema and ecchymosis achieving a good symmetry of the nasal pyramid. Cutaneous scars were not visible one month after surgery.

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