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Complex craniofacial advancement in paediatric patients: Piezoelectric and traditional technique evaluation

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A B S T R A C T

Purpose: The piezoelectric device allows bone cutting without damaging the surrounding soft tissues. The purpose of this study was to assess the role of this surgical instrument in paediatric craniofacial surgery in terms of safety and surgical outcomes.

Methods: Thirteen consecutive paediatric patients underwent craniofacial Le Fort osteotomies type III and IV. The saw was used on the right side in seven patients and on the left side in six patients; the piezoelectric instrument was used on the right side in six patients and on the left side in seven patients. Intraoperative blood loss, surgical procedure length, incision precision, postoperative haematoma and swelling, and nerve impairment were evaluated to compare the outcomes of both procedures.

Results: A longer surgical procedure was observed in 28% of the patients when using the piezoelectric device ($p = 0.032$), with an intraoperative blood loss reduction of 18% ($p = 0.156$). Greater precision in bone cutting was reported, together with a reduction in the requirement to protect and incise adjacent soft tissues during piezoelectric osteotomies. There was a lower incidence of postoperative haematoma and swelling following piezo-osteotomy, and a significant reduction in postoperative nerve impairment ($p = 0.002$).

Conclusions: The ultrasonic surgical device guaranteed a clean bone cut, preserving the integrity of the adjacent soft tissues beneath the bone. Although the time required for a piezoelectric osteotomy was longer, the total operation time remained approximately the same. In conclusion, the device's lack of power appears to be a minor problem compared with the advantages, and an ultrasonic device could be considered a valuable instrument for paediatric craniofacial advancement.

1. Introduction

Facial advancement is a routine procedure in paediatric craniofacial surgery that might require both cranial vault and facial osteotomies, and its aim is to improve facial asymmetry, orbital and intracranial volume, and facial appearance in patients with syndromic and non-syndromic craniosynostosis (Tessier, 1971). To perform facial advancement, saws, drills and chisels are usually used, and extended exposure of the osteotomy sites is required to ensure that the procedure is safe and precise. This type of surgical access for complex osteotomies could entail severe complications, such as haemorrhage, and neurological and ophthalmic damage (McCarthy et al., 1995a,b). Therefore, thus far, safety and precision have been the two main drivers in research to improve bone cutting in craniomaxillofacial surgery. Moreover, traditional saws and drills produce high temperatures during osseous drilling, due to their rotating movement; thus, their use may lead to marginal osteonecrosis and impair bone regeneration (Gleizal et al., 2007).

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Piezoelectric surgery has been presented as a novel technique for osteotomy, and it is supposed to protect soft tissues, allowing bone cutting by creating an electric field that changes polarity periodically, thus causing piezoelectric substances to start vibrating (Vercellotti et al., 2001). Ultrasonic surgery is a well-known technical procedure that has been used in dental practice since the 1940s (Lynn et al., 1942); thereafter, it has been applied to other oral surgical procedures (Gonzalez-Garcia et al., 2009; Gilles et al., 2013; Rullo et al., 2013), becoming competitive with traditional instruments in orthognathic surgery (Beziat et al., 2009; Hoffmann et al., 2013; Landes et al., 2014; Spinelli et al., 2014). In fact, piezoelectric devices have been shown to allow minimal soft-tissue injury and to increase the precision of osteotomy, thus ensuring better intraoperative and clinical results, such as: 1) reduction in intraoperative blood loss, 2) better cutting precision, 3) lower incidences of postoperative swelling and haematoma, and 4) a lower incidence of nerve damage together with a faster nerve recovery when impaired (Beziat et al., 2007a; Gilles et al., 2013; Spinelli et al., 2014). Therefore, based on the objective advantages ensured by this surgical device (Spinelli et al., 2014), its use has spread to other surgical specialties, such as neurosurgery and major maxillofacial surgical procedures (Kramer et al., 2006; Gleizal et al., 2007).

Accordingly, this paper is an extension of the authors' previous investigation on the comparison of ultrasonic surgical devices with a traditional saw in maxillofacial surgery (Spinelli et al., 2014). The clinical application was introduced and the safety of the ultrasonic device as an alternative tool in paediatric craniofacial surgery was evaluated. A comparative analysis was performed between the outcomes of both devices in thirteen children who required a Le Fort type III or type IV osteotomy to increase intracranial volume and improve their facial appearance.

2. Patients and methods

2.1. Patients

Thirteen children were prospectively enrolled between January 2013 and January 2014 with the consent of Meyer Hospital to undergo major surgical procedures to restore craniofacial malformations. All of the patients' parents signed an informed consent agreement to allow the surgical team, comprising neurosurgeons and maxillofacial surgeons, to operate.

Surgical indications included the presence of syndromic craniofacial malformations causing one or more of the following: airway, orbit, occlusal and facial aesthetic problems, with or without associated psychosocial problems. Obstructive sleep apnoea syndrome (OSAS) and severe exorbitism were the main indications for this surgery. The need to perform Le Fort type III or type IV osteotomies was another inclusion criterion presented by all of the 13 patients. On the other hand, a history of maxillofacial and/or neurosurgical procedures was considered to be an exclusion criterion.

The series included 13 patients, six of whom were female and seven of whom were male. Nine of the patients were affected by Crouzon syndrome, and the remaining four patients had Apert syndrome; all of them were confirmed by genetic investigation.

2.2. Surgical method

The procedures performed consisted of Le Fort type III osteotomy in nine of 13 cases, and a monobloc procedure or Le Fort type IV (monobloc advancement) osteotomy in four of 13 cases. The senior maxillofacial surgeon (GS) performed all of the 13 surgical craniofacial osteotomies and facial advancements, with collaboration by the neurosurgeon who operated on the cranial vault. The surgical technique was chosen based on the personal experience of the surgeon, by comparing surgical techniques reported in the literature (Ortiz-Monasterio et al., 1978; Nout et al., 2008; Nada et al., 2010; Laure et al., 2014).

Before the osteotomy, a narrow exposure of the bone site was performed using a periosteal elevator. Next, Le Fort III osteotomy was performed following exposure of the frontotemporal skull, lateral orbital region, nasion, zygomatic arch and zygomatic body via a coronal incision (Fig. 1); at the same time, through the gingivobuccal sulcus, the anterior surface of the maxilla was approached. The senior surgeon completed the facial osteotomies through the frontozygomatic suture, the medial wall and the floor of the orbit, and the nasion (Fig. 2). A cephalo-osteotome was used to divide the vomer and ethmoid bones on the midline.

Coronal and upper gingivobuccal sulcus incisions allowed access to the anterior cranial vault and midface, and a bifrontal craniectomy was performed in Le Fort IV osteotomies. After orbital wall osteotomy, an additional pterygomaxillary disjunction was performed to complete the en bloc facial mobilization.

The removed frontal bone and upper part were fixed with resorbable plates and screws. A rigid external distraction device (RED II System; KLS Martin, USA) was then symmetrically positioned bilaterally at the supraorbital bandeau and zygoma. The maxilla was also attached using a pair of external distraction devices. The surgeon drew a route from the temporal fossa, under the zygomatic arch, between the coronoid process and sphenoid bone, and then through the zygomatic-alveolar crest. Distraction vectors were set in an antero-inferior direction for the upper and lower parts.

In this setting, to compare the piezo-osteotomy characteristics with a traditional mechanical device, the surgeon (GS) performed a total of 13 procedures by using, for each hemifacial osteotomy, a traditional saw and a piezoelectric device alternately in each patient. On the other hand, bone cutting on the cranial vault was performed in each case with a high-speed drill (HiLAN, Aesculap, Tuttlingen, Germany). The ultrasonic scalpel operated at a non-modulated frequency of 22.5 kHz, and the amplitude of the vibrations ranged between 35 and 300 mm. Although soft tissues are not affected by slight touches by the instrument, its end becomes hot, requiring copious irrigation in order to avoid heat injury (Kramer et al., 2006) (Fig. 3).

2.3. Parameter assessment

Several parameters were analysed to assess each device's advantages and disadvantages:

1) Overall length of the procedure (OL): the operative time of the entire surgical procedure was evaluated objectively using OPERA software, a computer application that helps to record the operative time of all of the surgical steps for each side and device;
2) Length of the part of the procedure performed with the saw (OLS) and length of the part of the procedure performed with the piezoelectric instrument (OLP): the operative times of these parts were recorded objectively and obtained from the OL;
3) Total blood loss (TBL): intraoperative blood loss was evaluated as the volume (mL) collected by the same type of calibrated suction instrument during each surgical procedure. A standard volume of 0.9% saline solution was used to cool the bone and clean the surgical site, and it was counted and subtracted from the total amount of surgical fluid suctioned. This procedure was performed on each side and for each surgical device considering the blood loss on the side operated with the saw (BLS) and blood loss on the side operated with the piezosurgical instrument

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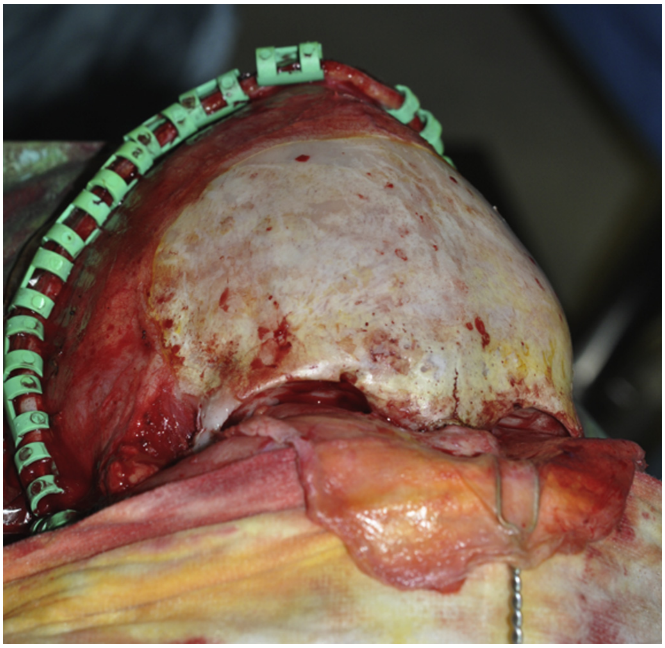

Fig. 1. Coronal flap harvested during Le Fort III osteotomy with exposure of the frontotemporal skull, lateral orbital region and the nasion.

Fig. 2. Medial orbital wall osteotomy by piezoelectric device which ensures a reduction in injury of the nasal mucosa.

(BLP). Gauzes were used to cover and keep the contralateral osteotomy side dry while the osteotomy was performed on the other side, in order to minimize blood leakage.

4) Complication rate: evaluation of the occurrence of severe complications, such as haemorrhage, sepsis, ophthalmic and neurological damage, and the occurrence of wound infection, dehiscence of the wound, soft-tissue damage (i.e., dura mater injury), suboptimal aesthetic results, and unresolved airway problems;
5) Postoperative swelling (HS) and the presence of residual haematoma (HP): these were evaluated using a quantitative method by comparing each side at 1 and 3 months after surgery;
6) Grade of nerve sensation: this was calculated using a neurosensory test performed at 3 months follow-up on the side operated with the saw (GNSS) and on the side operated with the piezoelectric device (GNSP). The same person (GM) performed all of the tests, which were carried out in a quiet room with the patient relaxed, eyelids closed, in a semi-sitting position, after explaining and performing the test on the hand (free from any sensory disturbance). Reference points were determined over the inferior lip and chin. The right and left sides were examined separately. Patients were asked to evaluate, when possible, sensory recovery according to a scale from 1, which meant complete anaesthesia, to 5, meaning normal sensation (Beziat et al., 2007b).

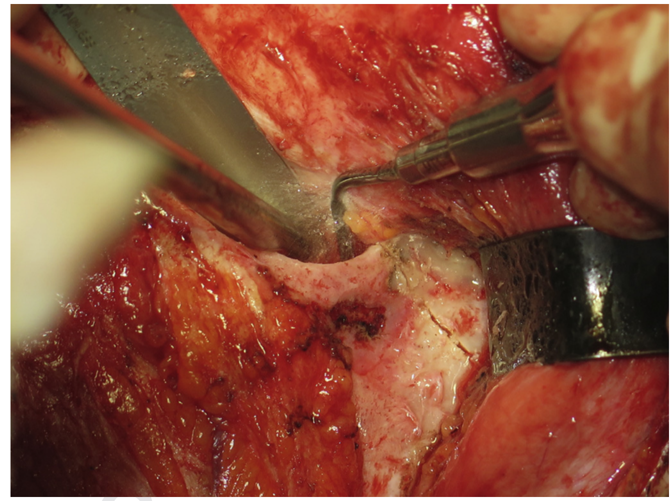

Fig. 3. Copious irrigation of the piezoelectric blade in order to avoid heat injury of the surrounding soft tissue.

2.4. Statistical analysis

The mean, standard deviation (SD) and median were calculated for data variables. Statistical analyses were performed using STATA (Stata Corporation, College Station, TX, USA). A *p*-value less than 0.05 was considered statistically significant.

3. Results

Each patient was investigated to assess any differences between the two techniques and consequences in terms of the final results. The saw was used on the right side in seven patients and on the left side in six patients; the piezoelectric instrument was used on the right side in six patients and on the left side in seven patients. Surgery was performed at a mean age of 7.3 years (range: 3–16). The mean follow-up time was 14.5 months (range: 11–23).

Overall, the piezoelectric osteotomies performed in nine patients were easier and more precise than those performed using a traditional saw. The movement and pressure of the osteotome against the bone surfaces was less complicated than when using the saw; in fact, only a little pressure was necessary to cut cranial bones precisely using the piezoelectric device, and no counteracting actions were required to perform the osteotomies in contrast to procedures performed using conventional instruments. In addition, the risk of accidental dislocation of the osteotome was very low using macrovibrations.

Continuous irrigation of the osteotomies was needed to cool the adjacent bones and remove bone debris; on the other hand, bone surface exposure was less extensive during piezoelectric osteotomies, thus reducing the risk of soft-tissue trauma and the length of the single surgical procedure. No damage to adjacent soft tissues was observed.

Table 1
Patient data and the major surgical aspects and differences between the two techniques. BLP: blood loss during the surgery performed with the piezosurgical instrument; BLS: blood loss during the surgery performed with the saw; OLP: overall length of the surgery performed with the piezosurgical instrument; OLS: overall length of the surgery performed with the saw.

Patient	Sex	Diagnosis	Age at surgery (years months)	Type of surgery	OLS	OLP	BLS	BLP
1	F	Apert	5 y 7 m	Monobloc	170	220	820	440
2	M	Crouzon	5 y 5 m	Le Fort III	100	180	970	730
3	M	Crouzon	5 y 5 m	Monobloc	130	140	680	550
4	F	Crouzon	2 y 9 m	Le Fort III	50	60	280	240
5	M	Crouzon	9 y 4 m	Le Fort III	90	150	390	210
6	M	Crouzon	7 y 2 m	Le Fort III	70	110	520	290
7	M	Crouzon	9 y	Le Fort III	70	160	200	180
8	M	Crouzon	16 y 3 m	Monobloc	110	100	880	910
9	F	Apert	13 y 4 m	Monobloc	130	210	510	260
10	M	Apert	4 y	Le Fort III	60	80	720	630
11	F	Crouzon	11 y 8 m	Le Fort III	110	120	610	580
12	F	Crouzon	6 y 3 m	Le Fort III	50	80	310	320
13	F	Apert	5 y 3 m	Le Fort III	80	150	710	420

Specifically, intraoperative parameters included the estimation of the surgical procedure length (minutes and hours) and evaluation of blood loss during surgery (mL). These data are shown in Table 1 together with the patient data.

The total operation time remained fairly constant because of the increased time required for piezoelectric osteotomy even if the latter needed a shorter time for exposure of the osteotomy bone site. In fact, the OL of the procedure had a mean value of 5 h and 38 min; SD 1 h and 51 min (range: 3–9 h). The mean procedure duration time required to perform osteotomies using a traditional saw (OLS) was 93.35 min; SD 35.72 (95% CI: 72.26–115.43; range: 50–170). However, the OLP of osteotomies performed using a piezoelectric device presented a longer mean time of 135.38 min; SD 49.77 (95% CI: 105.31–165.46; range: 60–220), which was also statistically significant ($p = 0.032$).

The mean TBL for the overall procedure, including both side osteotomies, was 1440 mL (range: 520–2320), with a mean overall blood loss value on the traditional side osteotomy of 584.62 mL, SD 241.30 (95% CI: 438.80–730.43; range: 200–970), instead of a mean BLP value, on the piezoelectric side osteotomy, of 445.00 mL, SD 234.00 (95% CI: 307.63–578.52; range: 180–910). Whilst lower blood loss during the procedure was found with the piezoelectric device, this was not statistically significant ($p = 0.156$).

The post-operative complications (Table 2) consisted of two cases of wound infections and two cases of cranial cerebrospinal fluid (CSF) leakage. In all cases, conservative treatment was the first choice, consisting of antibiotic treatment for the wound infection, according to the microbiologist's advice, and keeping a flat position in bed for the CSF leakage. No further surgical treatment was required in any of those cases, and the complications were resolved with no consequences. One patient developed a late complication that consisted of suboptimal midface advancement at 6-month follow-up with evidence of almost complete ossification of the osteotomies. A second operation was planned and was performed with good results.

At the 1-month postoperative follow-up, all of the patients were evaluated for evidence of a residual haematoma: none of the sides operated on using the piezoelectric instrument showed any sign of a haematoma; however, a haematoma was still evident in two of 13 cases on the side operated on using the saw. In addition, at the 3-month clinical follow-up, all of the patients were evaluated for residual swelling and nerve sensation. Evidence of swelling was still present in four of the 13 patients on the side operated with the saw, and two patients presented with soft-tissue swelling on the side operated with the piezoelectric instrument.

Regarding the grading of nerve sensation, on the side treated with the saw, one patient was graded a level 5, four at level 4, four at level 3, three at level 2, and one at level 1. On the other hand, the level of sensation on the piezoelectric side was graded at level 5 in eight out of 13 patients, level 4 in three patients, and level 3 in two patients; no patient had level 2 or 1 sensation on the piezoelectric-treated side. These values presented a significant result of $p = 0.002$.

All of these results are shown in Table 2.

Table 2
Postoperative surgical evaluation. CSF leak: cranial cerebrospinal fluid leak; GNSP: grade of the nerve sensation on the side operated with the saw at the 3-month follow up; GNSS: grade of the nerve sensation on the side operated with the saw at the 3-month follow up; PHP: residual haematoma at the 1-month follow-up on the side operated with the piezoelectric instrument; PHS: residual haematoma at the 1-month follow-up on the side operated with the saw; PSP: residual swelling at the 3-month follow-up on the side operated with the piezoelectric instrument; PSS: residual swelling at the 3-month follow-up on the side operated with the saw.

Patient	Complications	PHS	PHP	PSS	PSP	GNSS	GNSP
1	CSF leak	No	No	Yes	Yes	2	5
2	Wound infection	Yes	No	No	No	3	5
3		No	No	No	No	4	5
4	Suboptimal result	No	No	Yes	No	1	3
5		No	No	No	No	2	4
6		No	No	No	No	2	3
7		No	No	No	No	3	4
8	Wound infection	Yes	No	Yes	Yes	3	5
9	CSF leak	No	No	Yes	No	3	5
10		No	No	No	No	5	5
11		No	No	No	No	4	5
12		No	No	No	No	4	4
13		No	No	No	No	4	5

4. Discussion

Paediatric patients affected by craniofacial malformations show several clinical conditions. In particular, obstructive sleep apnoea syndrome (OSAS) is one of the major indications for children to undergo this type of surgery because it causes obstructive hypoventilation, rather than clinical features, and it may lead to failure to thrive, feeding difficulties, recurrent infections, disturbed cognitive function, developmental delay, cor pulmonale or infant sudden death (Nixon et al., 2005).

Mobilization of the midface is an extensive procedure, carrying a high degree of morbidity due to blood loss. Major complications occur in nearly 7% of all paediatric tracheotomy procedures in the early post-operative phase and in nearly 5% of procedures in the late post-operative phase (Tantinikorn et al., 2003; Nout et al., 2010). Moreover, patients with craniofacial dysostosis present a higher risk for other airway abnormalities, such as laryngo-tracheo-

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broncho-malacia. Thus, timely facial advancement ensuring enlargement of the nasopharynx and palatopharyngeal space can allow faster decannulation (Boston and Rutter, 2003); additionally, a shorter time of endotracheal intubation reduces the incidence of related morbidity. Moreover, frequent desaturation, together with changes in the blood pressure and cerebral perfusion, may cause deterioration of vision with the possible presence of papilloedema, which could occur in approximately 10–15% of untreated craniofacial dysostosis patients (Tay et al., 2006).

Thus, facial advancement has become a widely accepted treatment option for the correction of facial hypoplasia and related functional and aesthetic problems, and the long-term surgical outcomes have grown worldwide together with improvements in the technique, surgical equipment and perioperative care. In fact, surgeons have looked for less invasive techniques to limit morbidity. The greatest advance has been the advent of distraction osteotomies, which have eliminated the need for immediate advancement, graft harvesting and immediate internal stabilization.

From a technical point of view, the first instrument that aimed to change the manner in which osteotomy was performed has been the piezoelectric device, which increases the precision of bone cutting, ensuring a lower incidence of adjacent soft-tissue damage due to less extensive soft-tissue dissection and a reduction in surgical trauma (Kramer et al., 2006; Robiony et al., 2004; Vercellotti, 2004).

This comparative study examined the safety and efficacy of ultrasonic vibration instruments in major paediatric craniofacial surgery, and reports on the possible suitability of the piezoelectric device in these surgical procedures; its usefulness has already been demonstrated in other types of bone surgery.

It was found that the conventional osteotomy technique requires extensive protection of adjacent tissue, resulting in an extended operation time on the traditional saw facial side, which was balanced by a longer osteotomy time on the piezoelectric side; thus, the overall surgical time using the piezoelectric device was not significantly different to that using traditional instruments. In fact, in this series, the mean procedure duration time by piezo-osteotomy increased by 28% compared with traditional surgery ($p = 0.032$).

Osteotomies, both on the cranial vault and the face, pose at least three main risks: bleeding, damage to the soft tissues underneath the bone, and osteonecrosis. Traditional cutting instruments have improved over time, and of course, together with the learning curve of the operator, those risks have been reduced dramatically but not completely. Piezosurgery was presented as a new technique that would further reduce all of the above mentioned risks.

According to the author's experience, the piezoelectric device dramatically reduced the need for soft-tissue protection. The latter was true particularly concerning the face; it was not chosen for use on the cranial vault as previous studies have reported a relatively higher risk of dural tear than with rotating trephine instruments (Gleizal et al., 2007). The reason for the higher risk may be associated with a lack of experience using the piezoelectric instrument on the cranial vault, which requires a very long learning curve. In this setting, there are a few topics to address: on the one hand, a different 'feeling' of bone touch compared with the sensation felt when using a traditional instrument; on the other hand, the difference in the manoeuvres needed to help the cutting instrument itself. In other words, conventional osteotomies need the constant physical pressure of the saw on the bone surface to increase the speed and effectiveness of the cut, possibly limiting bone cutting precision and possibly being linked to a higher risk of osteotome dislocation. This occurs less frequently in piezo-osteotomies, where the handle guides the osteotome to allow for precise curved cutting as well. If the same pressure were applied to piezoelectric osteotomy this could produce a reduction of the speed and an increase in the risk of tissue warming and osteonecrosis. If the pressure is excessive, it can also produce suboptimal cutting results and increase the risk of bleeding (Blus and Szmukler-Moncler, 2006; Kramer et al., 2006; Gleizal et al., 2007).

The problem of blood loss, which is of particular concern in children, was addressed with special interest and revealed that piezo-osteotomies were effective in reducing bleeding even if the final comparison between the two procedures did not show a statistically significant result ($p = 0.156$).

From a long-term results point of view, this series considered the duration of post-operative haematoma at 1-month after surgery, residual swelling at the 3-month follow-up, and the incidence of sensitive nerve impairment, a well-known possible complication for this type of surgery. Haematomas at 1-month follow-up, and swelling at the 3-month follow-up, were less common on the side operated on with the piezoelectric device than on the side operated on with traditional cutting instruments. These results have not been discussed previously for advancement surgery in complex craniostenosis, but they might be an interesting indirect outcome in evaluating the results of surgery. Less significant haematoma and swelling may be due to reduced soft-tissue incisions and the lower blood loss recorded during piezoelectric surgery. Concerning the risk of nerve injury, the results showed a statistically significant difference in the reduction of nerve impairment on the piezoelectric side ($p = 0.002$), in accordance with the data reported in the literature that are mainly focused on orthognathic surgery (Westermark et al., 1999; Landes et al., 2008; Gruber et al., 2005; Beziat et al., 2007b).

To conclude the discussion, a possible disadvantage of the quality of the piezo-osteotomy could be the thin cut produced in the bone compared with traditional rotating instruments. Although the cut is effective, re-ossification occurred too early in the youngest patient. The early bone fusion was probably due to two main reasons: the presence of a thinner osteotomy cut made on the piezoelectric side; and the regenerating properties of the bone, particularly in children, being too fast to allow adequate growth when a thin cut is coupled with the absence of an effective hyperdistraction system.

5. Conclusion

Several questions concerning the piezo-osteotomy technique still require further study; such studies are few in number due to the rarity of the associated pathologies.

In our experience, the piezoelectric device appears to be a reliable instrument that offers good results both in terms of complications and outcome. The device is easy to use, ensuring precise bone cutting together with tissue selectivity, producing no visible adjacent soft-tissue injury.

Although the time of the procedure is relatively lengthened by the use of the ultrasound device, even this limited series revealed that the length of time reduced quite quickly with experience, and that some of the advantages over the traditional cutting system are effective in the surgery of the orbital part of the treatment of complex craniostenosis.

Therefore, the authors conclude that a piezoelectric osteotomy could be considered a safe procedure which has advantages in paediatric craniofacial major surgery.

Conflict of interest statement

All of the authors have disclosed no financial or personal relationships with other individuals or organizations that could inappropriately influence their work.

Financial disclosure

None of the authors have financial conflicts or interests to report in association with the contents of this paper.

Q3 Previous presentations

None.

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