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Australia and New Zealand Horizon Scanning Network

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AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon scanning technology Prioritising summary

Piezosurgery®

August 2008



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID S000078

NAME OF TECHNOLOGY PIEZOSURGERY® [MECTRON MEDICAL TECHNOLOGY, GENOA, ITALY]

PURPOSE AND TARGET GROUP THE DEVICE INTENDS TO REDUCE MORTALITY AND MORBIDITY RELATED TO DELICATE PROCEDURES REQUIRING OSTEOTOMY SUCH AS CRANIOFACIAL SURGERY

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | | | |
|-------------------------------------|--------------------|--------------------------|--|
| <input type="checkbox"/> | Yet to emerge | <input type="checkbox"/> | Established |
| <input type="checkbox"/> | Experimental | <input type="checkbox"/> | Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> | Investigational | <input type="checkbox"/> | Should be taken out of use |
| <input type="checkbox"/> | Nearly established | | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | | |
|-------------------------------------|----------------|-------------|--------|
| <input checked="" type="checkbox"/> | Yes | ARTG number | 109615 |
| <input type="checkbox"/> | No | | |
| <input type="checkbox"/> | Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
China		✓	
France	✓		
Germany	✓		
Italy	✓		
Korea		✓	
Netherlands		✓	
Switzerland		✓	
United States		✓	

IMPACT SUMMARY

The Piezosurgery® device (Mectron Medical Technology, Genoa, Italy) is a potentially more precise bone cutting instrument than conventional tools used in osteotomy and osteoplasty procedures. The device is intended for use in patients who require very fine and delicate bone surgery, such as maxillofacial and craniofacial surgery.

BACKGROUND

An osteotomy is a surgical procedure which involves cutting of bone to shorten, lengthen or change its alignment. It is often utilised to treat hallux valgus (bunions) and to straighten a bone that has healed incorrectly following a fracture. Meanwhile, osteoplasty refers to the surgical practice of bone grafting.

Surgeons face a variety of issues when performing osteotomy and osteoplasty, such as maintaining a clear surgical site, and the need for tools which allow multidirectional movement, while generating minimal heat (Hoigne et al 2007). Conventional tools used in osteotomy and osteoplasty include rotating/oscillating saws, drills, hammers and chisels (Blus & Szmukler-Moncler 2006; Hoigne et al 2006; Robiony et al 2007). While some instruments are time efficient (such as rotating and oscillating tools), the risk of damage to fine bone and soft tissue appears substantial and is speculated to be greater than what is actually reported in the literature (Nordera et al 2007; Salami et al 2007). This is a particular concern for surgeons who must navigate around extremely delicate structures during neurological, craniofacial, maxillofacial, oral and orthopaedic surgeries. Consequently, these procedures often rely heavily on a surgeon's competence and aptitude to apply conventional tools (Nordera et al 2007).

The Piezosurgery device was developed with the aim of enhancing the surgeon's ability to perform meticulous bone surgery, while reducing the risk of intraoperative and postoperative morbidity (Stubinger et al 2008). The tip of the Piezosurgery device oscillates at ultrasonic frequencies within a range of 25 to 29 kHz to cut bone. The system consists of a main unit, peristaltic pump (for cooling and removal of blood and wastes), foot switch, handpiece and tool inserts (flat, blunt, scalpel and sharp saw tipped) (Eggers et al 2004). Unlike conventional tools, the device can recognise changes in material density and deactivate itself when a change is encountered.

Piezoelectric surgery was originally performed by oral and maxillofacial surgeons for osteotomies, but its use is now spreading to other surgical fields, such as craniofacial procedures. The purported advantage of the Piezosurgery device over conventional tools is its ability to cut soft and hard tissues selectively, thus enabling the surgeon to confine tissue destruction to the areas planned and preserve adjacent structures, such as neurovascular tissue (Eggers et al 2004; Nordera et al 2007; Geha et al 2006; Salami et al 2008).

CLINICAL NEED AND BURDEN OF DISEASE

The potential application of the Piezosurgery device appears substantial due to the fact that it may be utilised in practically all procedures that require delicate and accurate cutting of bone, particularly musculoskeletal procedures of the head.

The National Hospital Morbidity Database of the Australian Institute of Health and Welfare (AIHW) indicates that there were approximately 14,190 surgical procedures performed on the head from 2006-2007. These craniofacial surgeries involved bones such as the maxilla, mandible, nasal, temporomandibular joint and zygomatic (AIHW: National Hospital Morbidity Database 2004-2005). It is likely that a substantial portion of these craniofacial surgeries could have utilised the Piezosurgery device.

DIFFUSION

Although the Piezosurgery device is registered on the Australian Register of Therapeutic Goods (ARTG no. 109615), no Australian studies have yet been published on the device. The Piezosurgery device was cleared for marketing (510k) by the United States Food and Drug Administration in June 2005 for bone cutting during oral surgery (Food & Drug Administration 2008).

To date, the majority of studies investigating the use of the Piezosurgery device are case reports and case studies from Germany, Italy and the United States.

COMPARATORS

The comparators to Piezosurgery include conventional equipment used in osteotomy and osteoplasty procedures, such as rotating or oscillating drills, saws, chisels and hammers.

SAFETY AND EFFICACY ISSUES

One nonrandomised comparative study with historical controls (Landes et al 2008) and five case series studies (Blus and Szmukler-Moncler 2006; Geha et al 2006; Nordera et al 2007; Salami et al 2007; Vercellotti et al 2007) were retrieved for inclusion in this summary. Results were presented as mean \pm standard deviation where possible.

Oral and Maxillofacial Surgery

The prospective study (with historical controls) by Landes et al (2008) investigated whether Piezoelectric osteotomy could replace the conventional saw in orthognathic surgery for repositioning one or both jaws. Between December 2005 and December 2006, 50 patients (26 males, 24 females; average age 21 ± 3 years (range 16 to 46)) with 106 osteotomies were operated on using the Piezosurgery device. The control group consisted of 86 patients (36 female, 50 male; average age 27 ± 5 years (range 17–38 years)) with 212 osteotomies that were operated on during December 2000 to December 2005 using a conventional saw and drill. No comparisons between the preoperative characteristics of control and study patients were presented.

Average blood loss was significantly lower in the piezosurgery group (n=26) compared with the conventional bimaxillary group (n=65) (541 ± 150 mL versus 773 ± 344 mL;

p=0.001). Two control patients required blood transfusion due to blood loss greater than 1500ml. The time required for bimaxillary standard osteotomy using the Piezosurgery device was 238±61 minutes compared with 227±73 minutes in the control group (p=0.45). For isolated Le Fort I osteotomies, the time requirements were 77±32 minutes versus 96±32 minutes, respectively (p=0.03). Three months postoperatively, 5% of Piezosurgery patients treated for stagittal split osteotomy had negative neurosensory test results, which indicated no damage was incurred to the inferior alveolar nerve, compared with 15% of the conventional osteotomy patients (p=0.0003).

Geha et al (2006) investigated the recovery of sensitivity in the inferior alveolar nerve after osteotomy using the Piezosurgery device. Twenty-one patients (six men and 15 women, mean age 28.2 years) were enrolled in this prospective study, and underwent bimaxillary osteotomy, including bilateral sagittal split osteotomy, for the correction of dentoskeletal deformities. Patients had either class II or III malocclusion and/or mandibular laterodeviation or obliquity. The Piezosurgery device was used to perform the sagittal splits. The inferior alveolar nerve was evaluated objectively with clinical neurosensory testing (including pin-prick sensation, light touch sensation and two-point discrimination tests) and subjectively before the procedure and on days 5, 7 and 10, as well as at 2 months after treatment. At 10 days post-treatment (n=20), the authors observed normal results for: 1) pin-prick sensation in 90% of patients, 2) light touch sensation in 82% and 3) two-point discrimination tests in 70%. A combination of the tests revealed 75% to 80% complete neurosensory recuperation at the second postoperative month. Recovery of inferior alveolar nerve function could be seen in 77.5% of sides assessed by neurosensory tests and 55% of sides assessed subjectively. The Piezosurgery device was able to split the mandible (down to the basilar border) in 26 out of 40 sagittal splits, or 13 (65%) of cases. In the remaining patients, the split was incomplete and reached varying depths past the inferior alveolar nerve without attaining the posteroinferior basilar border.

In a prospective case series study undertaken by Blus and Szmukler-Moncler (2006), the Piezosurgery device was used over a 3.5 year period in 57 patients to perform ridge-split procedures. The patients, of whom 50.9% were women, were aged between 23 and 82 years (mean age 50.2). The aim of this study was to place 78 implants in the mandible and 152 in the maxilla to restore full arches (n=9), hemi-arcades (3), partial bridges (43) and single crowns (24). The average initial ridge width was 3.2 mm and the average final ridge was 6 mm. The average split length was 15.1 mm. Blus and Szmukler-Moncler (2005) successfully placed 228 implants (99.1%); two implants (0.9%) were unable to be placed. During second stage surgery, eight (3.5%) implants failed, all in the maxilla, while 96.5% of implants succeeded. No implants were lost after loading and remained in place at two months. Over three years, life table analysis of loaded implants demonstrated a cumulative survival rate of 100%.

Middle Ear Surgery

In the case series reported by Vercellotti et al (2007), the Piezosurgery device was used for osteoplasty of the external auditory duct posterior wall and stapedotomy for hearing loss due to otosclerosis in 20 patients: 8 males and 12 females aged between 42 and 57 years (mean 52.8). Patients were examined at one and six months post-treatment. The average

length of the posterior bony duct wall removed using the device was 2.6 mm, and the average time for osteoplasty was 2 minutes. No tissue damage was noted. At 15 days after surgery, otomicroscopic evaluation showed a normal tympanic membrane. Before surgery, 16 patients had a type C tympanogram and no surgical reflexes, while 4 patients had normal ear drum movement (type A tympanogram) with stapedial reflexes present. One month after surgery, impedanzometry revealed a type A tympanogram and the absence of the stapedial reflex in four patients. In these patients, auditory brainstem response (ABR) (an objective measure of hearing) and electronystamographic measurements of vestibular function were unchanged, indicating that the use of piezosurgery did not negatively affect patient hearing.

In a prospective case series study (n=10) undertaken by Salami et al (2007), the Piezosurgery device was used to remove glomus tympanic tumors in eight patients and primary B-cell lymphomas of the middle ear in two patients. The average age of the patients was not reported. Patients were followed up at one, six, and 12 months postoperatively. There were no cases of bleeding or damage to nearby structures of the middle or inner ear. Also there were no occurrences of sensorineural hearing loss, tinnitus, neural deficit or side effects during the follow-up period (Salami et al 2007). Impedanciometry revealed a type A tympanogram, and ABR and electronystamographic measurements showed no difference to preoperative scores. One month postoperatively, two patients affected by B-cell non-Hodgkin's lymphoma were treated with external-beam radiation. At 12 months magnetic resonance imaging revealed no tumour recurrences. For all patients, pure-tone audiometry showed a mean hearing improvement of at least 15.5 dB at the 12-month follow up.

Craniofacial Surgery

Nordera et al (2007) treated 15 patients prospectively (10 male, 5 female) between 18 months and 65 years of age. The patients underwent various craniofacial procedures. Eight patients affected by bilateral Basedow's exophthalmos were treated with three-wall orbital decompression to achieve adequate room for the enlarged intraorbital tissue. Two patients suffering from class III malocclusion, were treated by mandibular setback with a standardised sagittal split osteotomy of both mandibular rami. Three patients underwent removal of a sphenoid wing meningioma that was causing optic field impairment. Two children underwent cranioplasty: an 18-month-old with scaphocephaly and a 42-month-old with a complex craniosynostosis. All osteotomies were performed with the Piezosurgery bone scalpel. The follow-up was performed between 6 and 18 months postoperatively. According to Nordera et al (2007) no sensory loss was reported in the infraorbital nerve area after orbital decompression for Basedow's exophthalmos. The osteotomies were performed without any complication such as tearing of the dura mater or nerve impairment. In the three cases of meningioma, two patients regained visual field completely, whereas the third showed no improvement of visual acuity. All surgical procedures were completed successfully.

COST IMPACT

The cost of the Piezosurgery device is approximately US\$7000 (Hoigne et al 2007), depending on the package bought. After the initial set-up, there is an additional maintenance cost for the cooling liquid at an estimated value of a 'few dollars' (Hoigne et al 2006). It is not clear how often this replacement is required.

Another cost impact worth mentioning is the potentially slower speed of the Piezosurgery device (Nordera et al 1992; Stubinger et al 2008; Eggers et al 2004). The extra time needed compared to an oscillating drill has been estimated by Nordera et al (1992) to be up to 10%, and for very thick bone up to 20%. This appears to be the main disadvantage of the Piezosurgery device, and must be taken into account with the initial set-up cost of the device. Further studies would be required to verify this potential advantage.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved materials.

OTHER ISSUES

It is worth noting that the majority of clinical applications of Piezosurgery have been undertaken in Italy (the country of residence of the designer) and Germany. While Piezosurgery has the potential to diffuse into a wide range of surgical applications (such as orthopaedic surgery, neurosurgery and otolaryngology); the current focus for the Piezosurgery device is oral and maxillofacial procedures. It is important to note that, one study stated that patients with pacemakers would be at risk with this surgical device if they did not have an anti-interference filter fitted (Nordera et al 2007).

SUMMARY OF FINDINGS

Conclusions from the comparative study and five case series suggest that Piezosurgery is a safe alternative to conventional tools used in osteotomy and osteoplasty procedures. Minimal faults or flaws have appeared with usage of this device in the included studies. It would seem that Piezosurgery is a promising tool for use in osteotomy, particularly where the preservation of thin and fragile bone structures is important. Despite this, with scarce experimental or controlled trial evidence available on the Piezosurgery device it is difficult to determine its efficacy relative to existing practice. Further large-scale clinical trials would help to determine the effectiveness of Piezosurgery in osteotomy procedures. Bearing this in mind, it is likely the device could be applied to a wider range of procedures.

HEALTHPACT ACTION

Based on the poor quality of evidence available (Level III-3 and lower) and the low likelihood of healthcare issues, Piezosurgery will be archived.

NUMBER OF STUDIES INCLUDED

Total number of studies	6
Level III-3 intervention evidence	1
Level IV intervention evidence	5

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SEARCH CRITERIA TO BE USED

Piezosurgery

USBS

Ultrasonic Bone Surgery