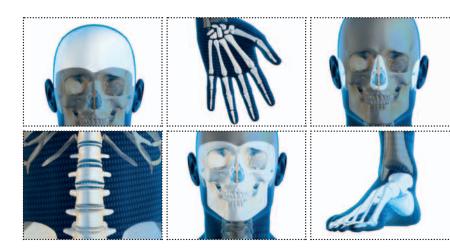
# **PIEZOSURGERY**<sup>®</sup>*medical*

# Scientific Abstracts



# Clinical benefits:

In all patients, the PIEZOSURGERY<sup>®</sup> instrument allowed an easy and precise handling during osteotomy with a reduced amount of trauma to adjacent soft tissues and with no complications.

Kramer F.J., Ludwig H.C., Materna T., Gruber R., Merten H.A., Schliephake H. Piezoelectric osteotomies in craniofacial procedures: a series of 15 pediatric patients. *J Neurosurg. 2006 Jan; 104(1 Suppl): 68-71.* 

Schaller et al. showed in five cases of pediatric skull base surgery that with a piezoelectric device, there was no osteonecrosis, less damage to the surrounding soft tissue, and better vision of the operative site.

**Gleizal A., Béra J.C., Lavandier B., Béziat J.L.** Piezoelectric osteotomy: a new technique for bone surgery – advantages in craniofacial surgery. *Childs Nerv Syst. 2007 May; 23(5): 509-513. Epub 2007 Mar 14.* 

#### **Histological benefits:**

**Results:** Histomorphological analyses demonstrated that more inflammatory cells were present in samples from drilled sites. Also, neo-osteogenesis was consistently more active in bone samples from the implant sites that were prepared using piezoelectric bone surgery. Moreover, bone around the implants treated with the piezoelectric bone surgery technique showed an earlier increase in BPM-4 and TGF-2 proteins as well as a reduction in proinflammatory cytokines. **Conclusion:** Piezoelectric bone surgery appears to be more efficient in the first phases of bone healing; it induced an earlier increase in BMPs, controlled the inflammatory process better, and stimulated bone remodeling as early as 56 days post-treatment.

Preti G., Martinasso G., Peirone B., Navone R., Manzella C., Muzio G., Russo C., Canuto R.A., Schierano G.

Cytokines and Growth Factors Involved in the Osseointegration of Oral Titanium Implants Positioned using Piezoelectric Bone Surgery Versus a Drill Technique: A Pilot Study in Minipigs. J Periodontol. 2007 Apr; 78(4): 716-22.

## Dear Surgeon,

Piezosurgery S.r.l. is devoted to the improvement of bone surgery, and our goal is to reduce pain while also shortening recovery time. We provide surgeons with leading edge technology that is helping revolutionize the way bone surgery is performed.

This collection of scientific abstracts will provide an overview of the existing clinical and histological evidence for PIEZOSURGERY<sup>®</sup>. Ten years ago, Dr. Tomaso Vercellotti developed the concept of piezoelectric bone surgery to overcome the limits of precision and intra-operatory safety existing in traditional bone cutting instruments.

Independent clinical studies have proven the benefits of PIEZOSURGERY<sup>®</sup> by Mectron, such as:

- highly precise
- minimal damage to the surrounding soft tissue
- minimal intra-operative bleeding
- no osteonecrosis
- better and faster healing
- minimal postoperative swelling

More than forty publications in international journals of Maxillofacial-, Neuro-, Otologic- and Orthopedic-Surgery state that PIEZOSURGERY<sup>®</sup> medical is, today, the only evidence based alternative to traditional bone surgical tools.

Sincerely, Your PIEZOSURGERY<sup>®</sup> team

PIEZOSURGERY® TECHNOLOGY		
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	Osseous Response Following Resective Therapy with PIEZOSURGERY <sup>®</sup> .	
	Int J Periodontics Restorative Dent. 2005 Dec;25(6):543-549.	8
	Preti G., Martinasso G., Peirone B., Navone R., Manzella C., Muzio G., Russo C.,	
	Canuto R.A., Schierano G.	
	Cytokines and Growth Factors Involved in the Osseointegration of Oral	
	Titanium Implants Positioned using Piezoelectric Bone Surgery Versus a	
	Drill Technique: A Pilot Study in Minipigs.	
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	J Oral Maxillofac Surg. 2007 Sep;(1 Suppl)65(9):39.e7-39.e8.	8
	Maurer P., Kriwalsky M.S., Block Veras R., Brandt J., Heiss C.	
	Light microscopic examination of rabbit skulls following conventional and	
	PIEZOSURGERY <sup>®</sup> osteotomy.	
	Biomed Tech (Berl). 2007;52(5):351-5.	9
	Cabaayan C. Janui (w. C. Jahayan M. Talaay M. Vayaallatti T. Maytin J.	
	Schaeren S., Jaquiéry C., Heberer M., Tolnay M., Vercellotti T., Martin I. Assessment of Nerve Damage using a novel ultrasonic device for bone cutting.	
	J Oral Maxillofac Surg. 2008 Mar;66(3):593-6.	10
		10
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	Piezoelectric bone surgery: a revolutionary technique for minimally invasive surgery	
	in cranial base and spinal surgery? Technical notes.	
	Neurosurgery. 2005 Oct ; 57(4 Suppl):E410 ; discussion E410.	11
	Kramer F.J., Ludwig H.C., Materna T., Gruber R., Merten H.A., Schliephake H.	
	Piezoelectric osteotomies in craniofacial procedures: a series of 15 pediatric patients.	
	J Neurosurg. 2006 Jan; 104(1 Suppl):68-71.	11
	Gleizal A., Béra J.C., Lavandier B., Béziat J.L.	
	Piezoelectric osteotomy: a new technique for bone surgery – advantages in	
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	Childs Nerv Syst. 2007 May;23(5):509-513. Epub 2007 Mar 14.	12
	Gleizal A., Béra J.C., Lavandier B., Béziat J.L.	
	Craniofacial approach for orbital tumors and ultrasonic bone cutting.	
	J Fr Ophtalmol. 2007 Nov;30(9):882-91.	12
OTOLOGIC SURGERY	Colomi A. Varcellatti T. Maro D. Dollaniana M	
OTOLOGIC SONGENT	Salami A., Vercellotti T., Mora R., Dellepiane M. Piezoelectric Bone Surgery in otologic surgery.	
	Otolaryngol Head Neck Surg. 2007 Mar;136(3):484-485.	13
		15
	Vercellotti T., Dellepiane M., Mora R., Salami A.	
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	Acta Otolaryngol. 2007 Sep;127(9):932-7.	13
	Blakenburg J.J., Both C.J., Borstlap W.A., Van Damme P.A.	
	Sound levels of the PIEZOSURGERY <sup>®</sup> . Risk of permanent damage to hearing.	
	Ned Tijdschr Tandheelkd. 2007 Nov;114(11):451-4.	13

	Salami A., Dellepiane M., Salzano F.A., Mora R.	
	PIEZOSURGERY <sup>®</sup> in the excision of middle-ear tumors: Effects on mineralized	
	and non-mineralized tissues.	
	Med Sci Monit. 2007 Dec;13(12):Pl25-29.	14
	Salami A., Mora R., Dellepiane M.	
	PIEZOSURGERY <sup>®</sup> in the exeresis of glomus tympanicum tumours.	
	Eur Arch Othorinolaryngol. 2008 Sep;265(9):1035-8. Epub 2008 Jan 4.	14
	Dellepiane M., Mora R., Salzano F.A., Salami A.	
	Clinical evaluation of piezoelectric ear surgery.	
	Ear Nose Throat J. 2008 Apr;87(4):212-3, 216.	14
	Salami A., Dellepiane M., Mora R.	
	A novel approach to facial nerve decompression: use of PIEZOSURGERY <sup>®</sup> .	
	Acta Otolaryngol. 2008 May;128(5):530-3.	15
	Salami A., Dellepiane M., Ralli G., Crippa B., Mora R.	
	Effects of PIEZOSURGERY <sup>®</sup> on the cochlear outer hair cells.	
	Acta Otolaryngol. 2009 May;129(5):497-500.	15
	Salami A., Dellepiane M., Salzano F.A., Mora R.	
	PIEZOSURGERY <sup>®</sup> in endoscopic dacryocystorhinostomy.	
	Otolaryngol Head Neck Surg. 2009 Feb;140(2):264-266.	15
	Crosetti E., Battiston B., Succo G	
	PIEZOSURGERY <sup>®</sup> in head and neck oncological and reconstructive surgery:	
	personal experience on 127 cases.	
	Acta Otorhinolaryngol Ital. 2009 Feb;29(1):1-9.	16
	Cuda D., Murri A., Tinelli N.	
	Piezoelectric Round Window Osteoplasty for Vibrant Soundbridge Implant.	
	Otol Neurotol. 2009 Sep;30(6):782-6.	16
	Bolger W.E.	
	Piezoelectric surgical device in endoscopic sinus surgery: an initial clinical experience.	
	Ann Otol Rhinol Laryngol. 2009 Sep;118(9):621-4.	17
	Salami A., Dellepiane M., Crippa B., Mora R.	
	A new method for osteotomies in oncologic nasal surgery: PIEZOSURGERY <sup>®</sup> .	
	Am J Otolaryngol. 2009 Mar 26. [Epub ahead of print]	17
	Salami A., Mora R., Mora F., Guastini L., Salzano F.A., Dellepiane M.	
	Learning curve for PIEZOSURGERY <sup>®</sup> in well-trained otological surgeons.	
	Otolaryngol Head Neck Surg. 2010 Jan;142(1):120-5.	17
MAXILLOFACIAL SURGERY	Eggers G., Klein J., Blank J., Hassfeld S.	
	PIEZOSURGERY®: an ultrasound device for cutting bone and its use and limitations	
	in maxillofacial surgery.	<i>.</i> -
	Br J Oral Maxillofac Surg. 2004 Oct;42(5):451-3.	18
	Robiony M., Polini F., Costa F., Vercellotti T., Politi M.	
	Piezoelectric bone cutting in multipiece maxillary osteotomies. Technical Note.	
	J Oral Maxillofac Surg. 2004 Jun;62(6):759-61.	18

Gruber R.M., Kramer F.J., Merten H.A., Schliephake H. Ultrasonic surgery – an alternative way in orthognathic surgery of the mandible. A pilot study. Int J Oral Maxillofac Surg. 2005 Sep;34(6):590-3.	19
Geha H.J., Gleizal A.M., Nimeskern N.J., Béziat J.L. Sensitivity of the Inferior Lip and Chin following Mandibular Bilateral Sagittal Split Osteotomy Using PIEZOSURGERY <sup>®</sup> . Plast Reconstr Surg 2006 Dec;118(7):1598-607.	19
Kotrikova B., Wirtz R., Krempien R., Blank J., Eggers G., Samiotis A., Mühling J. PIEZOSURGERY® — a new safe technique in cranial osteplasty? Int J Oral Maxillofac Surg. 2006 May;35(5):461-5. Epub 2006 Feb 24.	20
Béziat J.L., Vercellotti T., Gleizal A. What is PIEZOSURGERY <sup>®</sup> ? Two-years experience in craniomaxillofacial surgery. Rev Stomatol Chir Maxillofac. 2007Apr;108(2):101-7. Epub 2007 Mar 13.	20
Béziat J.L., Béra J.C., Lavandier B., Gleizal A. Ultrasonic osteotomy as a new technique in craniomaxillofacial surgery. Int J Oral Maxillofac Surg. 2007 Jun;36(6):493-500. Epub 2007 Mar 26.	21
Guo Z.Z., Liu X., Li Y., Deng Y.F., Wang Y. The use of PIEZOSURGERY® osteotomy in treatment of long-standing maxillary fractures: report of 12 consecutive patients. Shanghai Kou Qiang Yi Xue. 2007 Feb;16(1):97-9.	21
Robiony M., Polini F., Costa F., Toro C., Politi M. Ultrasound Piezoelectric Vibrations to Perform Osteotomies in Rhinoplasty. J Oral Maxillofac Surg. 2007 May;65(5):1035-8.	21
Robiony M., Polini F., Costa F., Zerman N., Politi M. Ultrasonic bone cutting for surgically assisted rapid maxillary expansion (SARME) under local anaesthesia. Int J Oral Maxillofac Surg. 2007Mar;36(3):267-9. Epub 2006 Nov 16.	22
Robiony M., Toro C., Costa F., Sembronio S., Polini F., Politi T. PIEZOSURGERY®: a new method for osteotomies in rhinoplasty. J Craniofacial Surg. 2007 Sep;18(5):1098-100.	22
Robiony M., Polini F., Costa F., Sembronio S., Zerman N., Politi M. Endoscopically-Assisted Intraoral Vertical Ramus Osteotomy and Piezoelectric Surgery in Mandibular Prognathism. J Oral Maxillofac Surg. 2007 Oct;65(10):2119-24.	23
Sakkas N., Otten J.E., Gutwald R., Schmelzeisen R. Transposition of the mental nerve by PIEZOSURGERY® followed by postoperative neurosensory control: A case report. Br J Oral Maxillofac Surg. 2008 Jun;46(4):270-1. Epub 2007 Aug 10.	23
Nordera P., Spanio di Spilimbergo S., Stenico A., Fornezza U., Volpin L., Padula E. The Cutting-Edge Technique for Safe Osteotomies in Craniofacial Surgery: The PIEZOSURGERY <sup>®</sup> Bone Scalpel.	
Plast Reconstr Surg. 2007 Dec;120(7):1989-95.	23

	Landes C.A., Stübinger S., Rieger J., Williger B., Ha T.K., Sader R.	
	Critical evaluation of piezoelectric osteotomy in orthognathic surgery:	
	operative technique, blood loss, time requirement, nerve and vessel integrity.	
	J Oral Maxillofac Surg. 2008 Apr;66(4):657-74.	24
	Costa F., Robiony M., Salvo I., Toro C., Sembronio S., Politi M.	
	Simultaneous functional endoscopic sinus surgery and esthetic rhinoplasty	
	in orthognathic patients.	
	J Oral Maxillofac Surg. 2008 Jul;66(7):1370-7.	25
	Bader G., Morais D.	
	PIEZOSURGERY <sup>®</sup> for genioglossal advancement in treatment of obstructive	
	sleep apnea syndrome.	
	Rev Stomatol Chir Maxillofac. 2008 Dec;109(6):375-8. Epub 2008 Aug 21.	25
	Landes C.A., Stübinger S., Ballon A., Sader R.	
	Piezoosteotomy in orthognathic surgery versus conventional saw and	
	chisel osteotomy.	
	Oral Maxillofac Surg. 2008 Sep;12(3):139-47.	25
	González-Lagunas J., Mareque J.	
	PIEZOSURGERY <sup>®</sup> : its role in TMJ surgery.	
	It J Maxillofac Surg 2008 Dec;19(3):119-21.	26
	González Lagunas J., Molina Montes J., Mareque Bueno J.	
	Extraoral uses of a piezoelectric surgical cutting tool.	
	Rev Esp Cir Oral y Maxilofac 2009 Jan;31(1):26-31.	26
	Muñoz-Guerra M.F., Naval-Gías L., Capote-Moreno A.	
	Le Fort I osteotomy, bilateral sinus lift, and inlay bone-grafting for	
	reconstruction in the severely atrophic maxilla: a new vision of the sandwich	
	technique, using bone scrapers and PIEZOSURGERY®.	
	J Oral Maxillofac Surg. 2009 Mar;67(3):613-8.	27
	Béziat J.L., Faghahati S., Ferreira S., Babic B., Gleizal A.	
	Intermaxillary fixation: technique and benefit for piezosurgical sagittal	
	split osteotomy.	
	Rev Stomatol Chir Maxillofac. 2009 Nov;110(5):273-7. Epub 2009 Oct 20.	27
ORTHOPEDIC SURGERY	Vercellotti T., Crovace A., Palermo A., Molfetta A.	
	The Piezoelectric Osteotomy in Orthopedics: Clinical and Histological	
	Evaluations (Pilot Study in Animals).	
	Mediterranean Journal of Surg Med 2001; 9: 89-95.	28
	Hoigne D.J., Stübinger S., Von Kaenel O., Shamdasani S., Hasenboehler P.	
	Piezoelectric osteotomy in hand surgery: first experiences with a new technique.	
	BMC Musculoskelet Disord. 2006 Apr 12; 7:36.	28
	Battiston B., Tos P., Conforti G., Vercellotti T.	
	PIEZOSURGERY <sup>®</sup> in hand surgery.	
	Riv Chir Mano 2006; 43(3):268-270.	29

Int J Periodontics Restorative Dent. 2005 Dec;25(6):543-549.

## Vercellotti T., Nevins M. L., Kim D. M., Nevins M., Wada K., Schenk R. K., Fiorellini J. P. Osseous Response Following Resective Therapy with PIEZOSURGERY<sup>®</sup>.

ENGLISH

#### Abstract

A piezoelectric instrument vibrating in the ultrasonic frequency range was investigated for its potential use in periodontal resective therapy. The rate of postoperative wound healing (baseline and 14, 28, and 56 days after surgery) in a dog model following surgical ostectomy and osteoplasty was the marker used to compare the efficacy of this instrument (PS) with a commonly used carbide bur (CB) or a diamond bur (DB). The surgical sites treated by CB or DB lost bone, in comparison to baseline measurements, by the 14th day, while the surgical sites treated by PS revealed a gain in the bone level. By day 28, the surgical sites treated by all three instruments demonstrated an increased bone level and regeneration of cementum and periodontal ligament. However, by day 56, the surgical sites treated by CB or DB evidenced a loss of bone, versus a bone gain in the PS-treated sites. Thus, it appears that PS provided more favorable osseous repair and remodeling than CB or DB when surgical ostectomy and osteoplasty procedures were performed. Therefore, PS could be regarded as being efficacious for use in osseous surgery.

#### Preti G., Martinasso G., Peirone B., Navone R., Manzella C., Muzio G., Russo C., Canuto R.A., Schierano G.

Cytokines and Growth Factors Involved in the Osseointegration of Oral Titanium Implants Positioned using Piezoelectric Bone Surgery Versus a Drill Technique: A Pilot Study in Minipigs.

**ENGLISH** J Periodontol. 2007 Apr;78(4):716-22.

#### Abstract

Background: Most dental implants are positioned using a drilling surgery technique. However, dentistry recently experienced the implementation of piezoelectric surgery. This technique was introduced to overcome some of the limitations involving rotating instruments in bone surgery. This study used biomolecular and histologic analyses to compare the osseointegration of porous implants positioned using traditional drills versus the piezoelectric bone surgery technique.

Methods: Porous titanium implants were inserted into minipig tibias. Histomorphology and levels of bone morphogenetic protein (BMP)-4, transforming growth factor (TGF)-B2, tumor necrosis factor-alpha, and interleukin-1ß and -10 were evaluated in the peri-implant osseous samples.

Results: Histomorphological analyses demonstrated that more inflammatory cells were present in samples from drilled sites. Also, neo-osteogenesis was consistently more active in bone samples from the implant sites that were prepared using piezoelectric bone surgery. Moreover, bone around the implants treated with the piezoelectric bone surgery technique showed an earlier increase in BMP-4 and TGF-B2 proteins as well as a reduction in proinflammatory cytokines.

**Conclusion:** Piezoelectric bone surgery appears to be more efficient in the first phases of bone healing; it induced an earlier increase in BMPs, controlled the inflammatory process better, and stimulated bone remodeling as early as 56 days post-treatment.

#### Stübinger S., Goethe J.W.

## Bone Healing After PIEZOSURGERY<sup>®</sup> and its Influence on Clinical Applications.

ENGLISH J Oral Maxillofac Surg. 2007 Sep;(1 Suppl)65(9):39.e7-39.e8.

#### Abstract

Statement: Osteotomies are well-established procedures in oral and maxillofacial surgery for either corrective measures or for gaining access to subjacent hard and soft tissues. Yet surgical reconstruction of bony defects can often be very challenging as thin and fragile bony structures are especially prone to fracture due to bulky cutting tips or massive application of pressure by conventional mechanical instruments. By employing the new technique

of PIEZOSURGERY<sup>®</sup> such complications can be overcome. It was the aim of this animal study to analyse the bone remodelling process after ultrasound osteotomy in the sheep tibia under functional loading after 8 and 12 weeks and to evaluate its impact on clinical applications.

**Materials and methods:** In 12 sheep the PIEZOSURGERY<sup>®</sup> device (Mectron, Italy) was used to perform a midshaft osteotomy of the tibia diaphysis. The instrument operates with modulated ultrasound and thereby generates micromovements between 60 and 200 mm/sec. Physiological sodium chloride solution of approx. 4°C was used as an irrigant. For all osteotomies bone saw OT7 with parameters mode boosted burst c and pump 5 were used according to the manufacturer's recommendation.

All osteotomies were performed by one surgeon in a latero-lateral movement as well as in a turning guidance around the bone.

Method of data analysis: After 2 and 3 months specimen were evaluated by radiographic and histologic analysis (toluidin-blue-staining, fuchsin-vitalstaining). A complete, semi-quantitative and histomorphometrical evaluation was undertaken including fluorochromatic stainings indicative for bone remodeling. Data were compared to results gained by analogous experiments performed with other osteotomy techniques. **Results:** Piezoelectric osteotomy permitted a micrometric, selective cut and a clear surgical site by the cavitation effect created by irrigation/cooling solution and oscillating tip. No excessive bleeding was encountered. The evaluation of the PIEZOSURGERY® specimen proved 8 weeks as well as 12 weeks after surgery an ingrowth of vital bone-forming tissue into the osteotomy gap. The remodelling in the compact bone was undisturbed and the osteotomy gap was filled with new bone. Additional radiological findings supported these findings. The bone fragments were completely healed, the bone marrow cavity restored as well as the external callus formation was subsided undergoing piezoelectric surgery. In general bone healing was faster than known from conventional methods.

**Conclusion:** PIEZOSURGERY<sup>®</sup> definitely enhances handling of delicate structures in the oral and maxillofacial region. Concerning osteotomies of thin and fragile bones, application of ultrasound is assessed to be superior to other mechanical instruments, because of easy handling, efficient bone ablation and minimal accidental harm to adjacent soft tissue structures. As bone healing is not disturbed by the PIEZOSURGERY<sup>®</sup>, but even seems to be improved, this method will have a major influence on new minimally invasive bone surgery techniques with special regard to biomechanics.

## Maurer P., Kriwalsky M.S., Block Veras R., Brandt J., Heiss C. Light microscopic examination of rabbit skulls following conventional and PIEZOSURGERY<sup>®</sup> osteotomy.

DEUTSCH Biomed Tech (Berl). 2007;52(5):351-5.

#### Zusammenfassung

Hintergrund: Das seit kurzem im klinischen Gebrauch befindliche ultraschallgestützte Osteotomieverfahren PIEZOSURGERY®, stellt eine Alternative zu den konventionellen Verfahren der Osteotomie dar. Ziel der vorliegenden Studie war es, mittels auflichtmikroskopischer Untersuchungsmethoden einen morphologischen Vergleich konventioneller Osteotomiemethoden (Lindemannfräse und Mikrostichsäge) mit dem neuen, ultraschall-gestützten Verfahren hinsichtlich der Oberflächenmorphologie durchzuführen. Material und Methode: Zwölf frisch euthanasierten Kaninchen wurden Knochenstücke normierter Größe von der Schädelkalotte entnommen. Folgende Osteotomieverfahren kamen zum Einsatz: rotierendes Instrument (Lindemannfräse), Mikrosäge, PIEZOSURGERY<sup>®</sup> mit den Aufsätzen OT6 und OT7. Die für die Osteotomie benötigten Zeiten wurden gemessen. Die osteotomierten Oberflächen wurden auflichtmikroskopisch bei 40-facher und 100-facher Vergrößerung untersucht.

#### Abstract

Introduction: The novel ultrasonic osteotomy technique (PIEZOSURGERY®) is an alternative to conventional osteotomy devices. The aim of the present study was to carry out morphological comparison of the bone surface using conventional osteotomy techniques in comparison to the rather new ultrasonic osteotomy technique by means of a reflected-light microscopic examination. Materials and methods: Following the sacrifice of 12 rabbits, 24 standardized bone samples were removed from the skull. The osteotomy devices used were a rotating instrument (Lindemann bur), an oscillating micro-saw, and an ultrasonic osteotomy device (PIEZOSURGERY<sup>®</sup>) with insert tips OT6 and OT7. The times needed for osteotomy were measured. The bone surfaces were examined using a reflected-light microscope with a magnification of 40x and 100x.

**Results:** Osteotomy with PIEZOSURGERY<sup>®</sup> is significantly more time consuming than osteotomy with conventional methods (p<0.05). Following Ergebnisse: Die ultraschallgestützte Osteotomie benötigte signifikant mehr Zeit als die konventionellen Osteotomieverfahren (p<0,05). In den Untersuchungen liess sich an den nativ belassenen Knochenproben nach Einsatz des ultraschallgestützten Osteotomieverfahrens der typische Aufbau der Schädelkalotte mit Tabula externa, Diploe und Tabula interna nachvollziehen. Hingegen wiesen die spongiösen Strukturen der Diploe nach Einsatz der konventionellen Osteotomieverfahren deutliche Veränderungen auf. Die Spongiosaräume waren mit Knochendebris gefüllt, und trabekuläre Strukturen waren zerstört. Insbesondere nach Einsatz der Mikrostichsäge imponierte die Oberfläche verdichtet und wies Sägerillen auf.

Schlussfolgerung: In der vorliegenden Untersuchung konnten eindeutige morphologische Unterschiede zwischen den Knochenoberflächen nach konventionellen Osteotomieverfahren und dem ultraschallgestützten Verfahren aufgezeigt werden. Es ist denkbar, dass diese den Ablauf der Knochenheilung nach der Osteotomie beeinflussen. Weiterführende Studien zur Knochenheilung nach Einsatz unterschiedlicher Osteotomietechniken erscheinen notwendig.

osteotomy with the ultrasonic device, the reflectedlight microscopic examinations of the unmodified bone samples revealed typical bone structure of the calvaria, including compacta externa, diploe and compacta interna. On the contrary, following osteotomy with the conventional devices, the diploe structure presented distinct modifications. The cancellous spaces were filled with bone debris, and the cancellous structure was demolished. The samples prepared by the micro-saw technique showed a superficially condensed and grooved surface.

**Conclusion:** In the present study, well-defined differences were observed following osteotomy with conventional devices and osteotomy with the ultrasonic device. The integrity of the bony structure observed after the ultrasonic technique could benefit the bone healing process. Further studies dealing with the bone healing process after using different osteotomy techniques are recommended.

## Schaeren S., Jaquiéry C., Heberer M., Tolnay M., Vercellotti T., Martin I. Assessment of Nerve Damage using a novel ultrasonic device for bone cutting. **ENGLISH** J Oral Maxillofac Surg. 2008 Mar;66(3):593-6.

#### Abstract

In oral, maxillofacial, and spinal surgery, osteotomy often must be performed in close vicinity to nerve tissue, with the potential risk of transient or permanent neurologic injuries (eq, to trigeminal nerve branches). Traditional tools, such as rotating burs and oscillating saws, are highly effective in cutting bone tissue but are not selective for bone, and thus can produce significant harm to surrounding soft tissues, especially nerves. PIEZOSURGERY® (Mebiotec, Sestri Levante, Italy), a device for bone-cutting based on low-frequency (25 to 29 kHz) ultrasonic vibrations, has recently been introduced in oral and maxillofacial surgery. This device can improve the control and precision of osteotomy and improve bone healing due to reduced local trauma. A recent in vitro study of the use of PIEZOSURGERY® for transposition of the inferior alveolar nerve in the mandibles of cadaver sheep showed that this technique caused roughening of the epineurium without affecting deeper structures and induced less injury than a conventional rotary bur. A pilot clinical study found that PIEZOSURGERY<sup>®</sup> reduced neurosensory disturbances in orthognathic surgery of the mandible. To the best of our knowledge, no experimental in vivo study has yet demonstrated that bone cutting using PIEZOSURGERY® prevents damage to soft tissue, especially nerves. The aim of the present study was to assess the potential damage of PIEZOSURGERY® to a peripheral nerve on direct contact, in 2 possible scenarios. The first scenario corresponds to the situation in which the surgeon does not immediately realize the contact with the nerve and continues to apply the same force used for cutting bone (working force) for an estimated reaction time of 5 seconds. The second scenario corresponds to an accidental slip of the device on the bone tissue, causing a direct hit on the nerve with a higher force (peak force), estimated to be twice the working force, but for a shorter time (1 second). The rat sciatic nerve was selected for the study because it is an established model for studying sensory and motor nerve damage and recovery and also is of equivalent size of branches of human trigeminal nerve.

## Schaller B.J., Gruber R., Merten H.A., Kruschat T., Schliephake H., Buchfelder M., Ludwig H.C.

Piezoelectric bone surgery: a revolutionary technique for minimally invasive surgery in cranial base and spinal surgery? Technical notes.

ENGLISH Neurosurgery. 2005 Oct ; 57(4 Suppl):E410 ; discussion E410.

#### Abstract

**Objective:** Piezoelectric surgery represents an innovative, ultrasonic surgery technique for performing a safe and effective osteotomy or osteoplasty that contrasts with the traditional hard and soft tissue management methods with rotating instruments.

**Methods:** Because of its physical and mechanical properties, the definitive clinical advantage of piezoelectric bone surgery with regard to precision cutting lies in the sparing of vital neurovascular bundles or general soft tissue and better visualization of the surgical field, thus suggesting its great safety. Piezoelectric bone surgery has been previously described only in oral and maxillofacial operative procedures in adults.

**Results:** Five children between the age of 6 and 84 months were operated on for craniosynostosis, tethered cord, and an extraconal intraorbital tumor. The usefulness of piezoelectric bone surgery during neurosurgical procedures is presented for these cases. This technique is especially recommended when there are anatomic difficulties because of poor intraoperative visibility or the presence of delicate anatomic structures. **Conclusion:** The present preliminary report (comprising illustrative case reports) demonstrates and introduces for the first time the utility of piezoelectric bone surgery in cranial base and spinal surgery in children. Until now, there has been no documented neurosurgical experience of this technique even in adults.

## Kramer F.J., Ludwig H.C., Materna T., Gruber R., Merten H.A., Schliephake H. Piezoelectric osteotomies in craniofacial procedures: a series of 15 pediatric patients.

ENGLISH J Neurosurg. 2006 Jan; 104(1 Suppl):68-71.

#### Abstract

Frontoorbital advancement has become a standard method both to increase intracranial volume and to improve facial appearance in patients with syndromal or nonsyndromal craniosynostosis. Relevant complications of this procedure include severe hemorrhage and trauma to intracranial, orbital, or facial soft tissues, which mostly arise during the process of bone exposure or osteotomy. To minimize the risk of soft tissue injury and to increase the precision of the osteotomy, the authors applied a piezoelectric osteotome for frontoorbital advancement in 15 patients with craniosynostosis seen consecutively (mean age 11.3 months). They demonstrated that this new device can cut cranial bones using ultrasonic microvibrations created by piezoelectric effects. In all patients, this instrument allowed an easy and precise handling during osteotomy with a reduced amount of trauma to adjacent soft tissues and with no complications. Although the time required for piezoelectric osteotomy was longer compared with conventional techniques, the total operation time remained approximately the same because the preparation requirements are less extensive. Postoperatively, bone regeneration was uneventful. The authors conclude that this new technique of piezoelectric osteotomy is a valuable tool for cranio-facial reconstructive surgery in pediatric patients.

## Gleizal A., Béra J.C., Lavandier B., Béziat J.L. Piezoelectric osteotomy: a new technique for bone surgery – advantages in craniofacial surgery.

ENGLISH Childs Nerv Syst. 2007 May;23(5):509-513. Epub 2007 Mar 14.

#### Abstract

Introduction: Ultrasonic bone cutting is a new surgical technique used in dentistry to section hard tissues without damaging adjacent soft tissues. We hypothesized that such a device could also be useful in craniofacial surgery, particularly during the removal of the superior orbital roof during craniofaciostenosis surgery. Materials and methods: An ultrasonic device was employed in different craniofacial surgical procedures: 1. to remove the superior orbital roof in 30 cases of craniofaciostenosis,

2. to perform a Le Fort III osteotomy for the treatment of Crouzon syndrome in two patients,

3. to cut the parietal and frontal bone in 30 cases of craniofaciostenosis.

The integrity of soft tissues and surgical time was evaluated.

Results: Functional results were good without any soft tissue damage appreciated. The overall operative time, however, was increased.

Conclusions: PIEZOSURGERY® is a new technical procedure, which can be advantageous for bone cutting in multiple situations with minimal to no damage in adjacent soft tissues.

## Gleizal A., Béra J.C., Lavandier B., Béziat J.L. Craniofacial approach for orbital tumors and ultrasonic bone cutting. FRANÇAIS J Fr Ophtalmol. 2007 Nov;30(9):882-91.

#### Résumé

Introduction: L'exérèse des tumeurs du cône postérieur de l'orbite pose un problème d'abord difficile. Le but de cette étude a été d'évaluer l'intérêt des voies d'abord cranio-faciales et de juger de l'apport de la PIEZOSURGERY<sup>®</sup> lors de leur réalisation pratique. Matériel et méthode: Cinquante-sept tumeurs du cône postérieur de l'orbite ont été abordées par voie latérale externe ou par voie trans-sinusienne frontale en fonction de la localisation de la tumeur. Les ostéotomies orbitaires ont été réalisées soit par découpe mécanique classique, soit par PIEZOSURGERY<sup>®</sup>. Dans chaque cas ont été notés les éléments correspondant à l'exérèse tumorale et les caractéristiques de la découpe, et notamment sa précision et son impact sur l'os et les tissus mous environnants. Résultats: Les voies cranio-faciales de réalisation simple et rapide donnent sous microscope opératoire un jour excellent selon un axe favorable sur tout le cône postérieur. Le recours, pour les déposes osseuses, à la PIEZOSURGERY<sup>®</sup> simplifie et sécurise grandement leur realization par son respect total des parties molles, dure-mère et péri-orbite en particulier. Ce respect évite de devoir protéger les parties molles, ce qui compense l'allongement du temps opératoire qu'entraîne la moindre puissance de la section ultrasonique.

Conclusion: Cette étude montre l'intérêt des voies d'abord cranio-faciales pour l'exérèse des tumeurs du cône postérieur de l'orbite et objective la supériorité de la découpe osseuse ultrasonique lors de leur réalisation sur les découpes mécaniques classiques.

#### Abstract

Background: Removal of orbital tumors is a difficult problem. The goal of this study was to evaluate the advantages of the craniofacial approach to remove such tumors and to evaluate ultrasonic bone cutting during the procedure.

Method: The authors reviewed their experience with 57 tumors of the posterior cavity using lateral craniofacial and frontal transsinus approaches. Orbital osteotomies were performed with mechanical instruments or piezoelectric bone surgery as a minimally invasive surgery. For each case, the quality of bone cutting and soft tissue damage were evaluated.

**Results:** Craniofacial approaches are simple and fast. Under the microscope, they provide a good view of the entire posterior orbital cavity. Using PIEZOSURGERY<sup>®</sup>, the functional results are good with no soft tissue damage. These advantages balance with the increased operative time required by ultrasonic bone cutting.

Conclusion: This study shows the advantages of craniofacial approaches for removal of posterior orbital tumor. Moreover, the present preliminary report introduces and demonstrates the utility of piezoelectric bone surgery in craniofacial approaches for orbital tumors.

## Salami A., Vercellotti T., Mora R., Dellepiane M. Piezoelectric Bone Surgery in otologic surgery.

ENGLISH

Otolaryngol Head Neck Surg. 2007 Mar;136(3):484-485.

No Abstract avilable

## Vercellotti T., Dellepiane M., Mora R., Salami A. Piezoelectric Bone Surgery in otosclerosis.

ENGLISH Acta Otolaryngol. 2007 Sep;127(9):932-7.

#### Abstract

Conclusion: This test of the PIEZOSURGERY® medical device for osteoplasty of the external auditory duct posterior wall and stapedotomy highlighted the advantages of this device. The device's accuracy and selectivity render it superior to conventionally rotating instruments in otologic surgery. The precise nature of the instrument allows exact, clean, and smooth cut geometries during surgery, without any visible injury to the adjacent soft tissue. Objective: The aim of this work was to test the PIEZOSURGERY® device as a new and alternative method to conventional bone tissue management in otologic surgery and in particular in stapedotomy and the external auditory duct posterior wall.

Materials and methods: The PIEZOSURGERY® medical device is a piezoelectric ultrasonic bone-cutting surgical instrument designed to perform sharp cutting actions. The equipment consists of two piezoelectric hand-pieces and two insets that are connected to a main unit, which supplies power and has holders for the hand-piece and irrigation fluids. PIEZOSURGERY® uses low frequency ultrasonic waves (24.7-29.5 kHz), the applied power can be modulated between 2.8 and 16 W, and the machine is programmed in accordance with the density of the bone cut. The microvibrations that are created in the piezoelectric hand-piece cause the inserts to vibrate linearly between 60 and 210 µm and allow a selective cut of mineralized tissues without trauma to soft tissues. The interoperative irrigation cools down the bone surface and make the operating site blood-free. Twenty patients affected by otosclerosis underwent treatment utilizing the device.

Results: In all the patients treated, the characteristics of the ultrasonic frequencies allowed rapid and easy intraoperative management, without any visible injury to the adjacent soft tissue. No side effects were detected.

## Blakenburg J.J., Both C.J., Borstlap W.A., Van Damme P.A. Sound levels of the PIEZOSURGERY<sup>®</sup>. Risk of permanent damage to hearing.

NEDERLANDS Ned Tijdschr Tandheelkd. 2007 Nov;114(11):451-4.

#### Zusammenfassung

In het verleden is regelmatig onderzoek gedaan naar het geluidsniveau van allerhande boorapparatuur en de gevolgen daarvan voor behandelaars die deze apparatuur regelmatig gebruiken. Het onderhavige onderzoek richtte zich op de mogelijke permanente gehoorschade die men zou kunnen oplopen tijdens het gebruik van een nieuw ontwikkeld instrument, de PIEZOSURGERY<sup>®</sup>. Hiertoe zijn metingen verricht in een gestandaardiseerde omgeving en opstelling, waarbij gebruik is gemaakt van onderkaken van varkens en een weegschaal om verschillende drukstadia te kunnen meten. De grenswaarden van de toegestane geluidsblootstelling zijn berekend. Daarnaast is een illustratieve vergelijking gemaakt tussen de hoogte van het geluidsniveau van conventionele boormachines en de PIEZOSURGERY<sup>®</sup>. Bij gebruik van de PIEZOSURGERY<sup>®</sup> gedurende minder dan 90 minuten per werkdag blijkt geen gevaar te bestaan voor permanente gehoorschade. Hiermee ligt het risico van de PIEZOSURGERY<sup>®</sup> iets onder dat van de conventionele boorapparatuur.

#### Abstract

In the past, research has regularly been carried out concerning the sound levels of various drilling devices and the impact these have on those who regularly use these devices. The present research is concerned with the possible permanent damage to hearing which can occur during the use of a newly developed instrument, the PIEZOSURGERY®. Measurements have been performed in a standardized set-up in which use is made of the lower jaws of pigs and a weight scale for measuring various degrees of pressure. The boundary values of the permissible exposure to noise were determined. The values of the PIEZOSURGERY<sup>®</sup> were compared with conventional drilling machines. It was concluded that using the PIEZOSURGERY<sup>®</sup> for less than 1.5 hours per day implies no risk of permanent damage to hearing. This means that the risk in the case of PIEZOSURGERY® is somewhat lower than that of conventional drilling devices.

## Salami A., Dellepiane M., Salzano F.A., Mora R. PIEZOSURGERY<sup>®</sup> in the excision of middle-ear tumors: Effects on mineralized and non-mineralized tissues.

ENGLISH Med Sci Monit. 2007 Dec;13(12):PI25-29.

#### Abstract

**Background:** PIEZOSURGERY<sup>®</sup> is a new instrument able to cut bone without necrosis and non-mineralized tissue damage. The aim of this study was to test the PIEZOSURGERY<sup>®</sup> as a new and alternative method for the excision of middle-ear tumors and to analyze its effects on soft tissues.

**Material/methods:** The PIEZOSURGERY<sup>®</sup> device was used to excise eight glomus tympanicum tumors and two primary B-cell lymphomas of the middle ear. The piezoelectric device uses low-frequency ultrasonic waves (24.7–29.5 kHz); the applied power can be modulated between 2.8 and 16 W and is programmed in accordance to the density of the bone. The equipment consists of two hand-pieces, two inserts, and two peristaltic pumps. The microvibrations that are created in the piezoelectric hand-piece cause the inserts to vibrate linearly by between 60 and 210 µm.

**Results:** PIEZOSURGERY<sup>®</sup> provided excellent control in all the patients, without bleeding and harmful effects on the adjacent structures of the middle and inner ear.

**Conclusions:** PIEZOSURGERY<sup>®</sup> is a new and revolutionary osteotomy technique utilizing the microvibrations of scalpels at ultrasonic frequency, so that soft tissue will not be damaged even upon accidental contact with the cutting tip. The vibration frequency of PIEZOSURGERY<sup>®</sup> is optimal for mineralized tissue and does not cut the adjacent soft tissue, minimizing the risk of harming the adjacent tissues. This renders the piezoelectric device ideal for application at the border between hard and soft tissues as in the excision of a middle-ear tumor.

## Salami A., Mora R., Dellepiane M.

## PIEZOSURGERY<sup>®</sup> in the exeresis of glomus tympanicum tumours.

ENGLISH Eur Arch Othorinolaryngol. 2008 Sep;265(9):1035-8. Epub 2008 Jan 4.

#### Abstract

The glomus tumor is a middle ear neoplasm commonly delayed in diagnosis. Surgery and radiation are often recommended as therapy; in the literature are no reported series of piezoelectric excision of glomus tympanicum tumors. This paper reviews a series of ten patients in whom successful resection of the type A glomus tympanicum tumours was achieved with the use of PIEZOSURGERY<sup>®</sup>. PIEZOSURGERY<sup>®</sup> is a new instrument able to cut the bone without necrosis and non-mineralized tissues damage. In all the patients PIEZOSURGERY<sup>®</sup> provided excellent control of glomus tympanicum tumors without without side effects on the soft tissues.

## Dellepiane M., Mora R., Salzano F.A., Salami A. Clinical evaluation of piezoelectric ear surgery.

ENGLISH Ear Nose Throat J. 2008 Apr;87(4):212-3, 216.

#### Abstract

We evaluated the use of piezoelectric surgery (PIEZOSURGERY®; Mectron Medical Technology; Carasco, Genoa, Italy) as a means of avoiding some complications of osteotomy and osteoplasty in otologic surgery, particularly in classic canal-wall-up mastoidectomy. Piezoelectric surgery is a recently developed system for cutting bone with microvibrations created by the piezoelectric effect. This effect occurs when an electric current is passed through certain ceramics and crystals, causing them to oscillate at ultrasonic frequencies. Our study population was made up of 20 adults with unilateral chronic otitis media. In all patients, piezoelectric surgery allowed for effective, precise, safe, easy, and rapid intraoperative management. In particular, the instrument's precision allowed surgeons to make exact, clean, and smooth cuts without causing any injury to adjacent soft tissue. No complications were noted. We conclude that the piezoelectric device is superior to conventionally rotating instruments for performing classic canal-wall-up mastoidectomy.

## Salami A., Dellepiane M., Mora R.

A novel approach to facial nerve decompression: use of PIEZOSURGERY<sup>®</sup>.

ENGLISH Acta Otolaryngol. 2008 May;128(5):530-3.

#### Abstract

**Conclusions:** The safety of PIEZOSURGERY<sup>®</sup> as regards soft tissues in facial nerve decompression was confirmed. No side effects were detected during unintentional contact with the nerve.

**Objectives:** The aim of this work was to test PIEZOSURGERY<sup>®</sup> as a new and alternative method to conventional bone tissue management in facial nerve decompression by posterior tympanotomy.

**Patients and methods:** We used PIEZOSURGERY<sup>®</sup> under general anaesthesia on 10 patients affected by facial paralysis following temporal bone fractures. The equipment consists of two hand-pieces, two inserts and two peristaltic pumps connected to the control unit. The device uses low frequency ultrasonic waves (24.7-29.5 kHz), the applied power can be modulated between 2.8 and 16 W, and the machine is programmed in accordance with the density of the bone. The microvibrations that are created in the piezoelectric hand-piece cause the inserts to vibrate linearly between 60 and 210 μm.

**Results:** PIEZOSURGERY<sup>®</sup> proved effective in sclerotic and pneumatic mastoid. This approach results in significantly less operative blood loss and better visibility in the surgical field compared with conventional methods. Its safety as regards soft tissues was confirmed: no side effects were detected during unintentional contact with the nerve. All patients presented a complete recovery from facial paralysis at the last follow-up.

## Salami A., Dellepiane M., Ralli G., Crippa B., Mora R. Effects of PIEZOSURGERY<sup>®</sup> on the cochlear outer hair cells.

ENGLISH Acta Otolaryngol. 2009 May;129(5):497-500.

#### Abstract

**Conclusions:** The absence of audiologic side effects highlights the reduced trauma of the piezoelectric cut, demonstrates the superiority of the PIEZOSURGERY<sup>®</sup> device in terms of safety and protection of anatomical structures and confirms its applicability in all the otologic techniques tested.

**Objectives:** The aim of the present study was to estimate the effect of PIEZOSURGERY<sup>®</sup> on the cochlea and in particular on the cochlear outer hair cells.

**Patients and methods:** We selected 60 patients with a history of otologic surgery with PIEZOSURGERY<sup>®</sup>. Before and 6 months after surgery, all the patients underwent the following instrumental examinations: pure-tone audiometry, tympanometry, transient evoked otoacoustic emissions (TEOAEs), distortion product otoacoustic emissions (DPOAEs) and auditory brainstem response (ABR).

**Results:** PIEZOSURGERY<sup>®</sup> showed its safety on the inner ear and in particular on the cochlear outer hair cells: for each instrumental examination (pure-tone audiometry, tympanometry, TEOAE, DPOAEs and ABR), no patients presented postoperative worsening.

## Salami A., Dellepiane M., Salzano F.A., Mora R. PIEZOSURGERY<sup>®</sup> in endoscopic dacryocystorhinostomy.

ENGLISH Otolaryngol Head Neck Surg. 2009 Feb;140(2):264-266.

No Abstract avilable

## **Crosetti E., Battiston B., Succo G.** PIEZOSURGERY<sup>®</sup> in head and neck oncological and reconstructive surgery: personal experience on 127 cases.

ENGLISH Acta Otorhinolaryngol Ital. 2009 Feb;29(1):1-9.

#### Abstract

Piezoelectric bone surgery, known simply as PIEZOSURGERY®, is a new technique of osteotomy and osteoplasty, which requires the use of microvibrations of ultrasonic frequency scalpels. The principle of PIEZOSURGERY® is ultrasonic transduction, obtained by piezoelectric ceramic contraction and expansion. The vibrations thus obtained are amplified and transferred onto the insert of a drill which, when rapidly applied, with slight pressure, upon the bony tissue, results, in the presence of irrigation with physiological solution, in the cavitation phenomenon, with a mechanical cutting effect, exclusively on mineralized tissues. Personal experience with the use of PIEZOSURGERY® in head and neck oncological and reconstructive surgery is relatively recent, having been developed in 2002-2006, and, so far, involves 127 cases; preliminary results are interesting and improving in the, hopefully, developmental phases of inserts with specific geometrics on account of the characteristics of the various aspects of surgical ENT operations. Furthermore, with piezoelectric surgery it has been possible to perform precise osteotomy lines, micrometric and curvilinear with absolute confidence, particularly in close proximity to the vessels and nerves and other important facial structures (dura mater). There can be no doubt, since this is a new cutting method, that PIEZOSURGERY® involves a different learning curve compared to other techniques, requiring obstacles of a psychological nature to be overcome as well as that concerning surgical expertise. Given the numbers of cases treated and the relative power of this instrument, analysis of complications, intra-operative time (which would appear, on average, to be 20% longer) and, therefore, morbility, shows interesting potentiality of the technique. This new ultrasound cutting method will, no doubt, in the future, be increasingly used in ENT surgery, particularly with improvements in power and geometry of the inserts, with possible applications also in neurosurgery, paediatric surgery and orthopedics, branches in which a selective action upon the mineralized tissues is of fundamental importance.

## Cuda D., Murri A., Tinelli N. Piezoelectric Round Window Osteoplasty for Vibrant Soundbridge Implant.

ENGLISH Otol Neurotol. 2009 Sep;30(6):782-6.

#### Abstract

**Objective:** To evaluate the PIEZOSURGERY<sup>®</sup> (PZS) ultrasonic bone dissector as an alternative to conventional drilling to implant the Vibrant Soundbridge transducer in the round window (RW) niche. **Study design:** Prospective noncontrolled study. Audiologic and surgical records analysis. **Methods:** Eight patients with mixed hearing loss and previous unsuccessful otologic surgeries were recruited.

A transcanal or transmastoid approach was used. Round window osteoplasty was performed with the PZS device to implant the VBS floating mass transducer for cochlear stimulation.

**Results:** The osteoplasty was performed safely with PZS, and all patients were successfully implanted. No sensorineural hearing deterioration occurred in all but 1 patient. The postoperative air conduction threshold was slightly higher than preoperatively because of minor middle ear transfer function changes. After fitting, patients continue to wear their speech processors full-time. The aided speech discrimination scores at conversational level ranged from 65 to 100%. Aided hearing threshold was 32.2 dB HL (preoperative threshold under earphones, 62.8 dB HL). One patient affected by congenital aural atresia had a posterior canalithiosis on the operated side that was successfully treated by the repositioning maneuver. **Conclusion:** The PZS device proved to be effective for RW osteoplasty; floating mass transducer was successfully implanted in all patients. Audiologic results are comparable to those obtained from traditionally operated patients. Relative to conventional drilling, the PZS allows a safer osteoplasty because it does not produce any rotation or torque that reduces the risk of RW membrane injury. Although hearing was preserved in our sample, the potential inner ear risks need to be further evaluated in both experimental and clinical fields.

## **Bolger W.E.**

## Piezoelectric surgical device in endoscopic sinus surgery: an initial clinical experience.

ENGLISH Ann Otol Rhinol Laryngol. 2009 Sep;118(9):621-4.

#### Abstract

Revision endoscopic sinus surgery presents special challenges, such as the need to remove thick osteoneogenic bone close to the orbit or skull base. Currently available drills and microdebriders have shortcomings for this task, including risk to the underlying periorbita or dura. Recently, piezoelectric ultrasound technology has been used to remove bone while preserving adjacent soft tissue structures. This technology has been effective in several areas of the body, and it logically follows that it may have beneficial rhinologic applications. The purpose of this medical communication is to report an initial clinical experience with piezoelectric technology in revision sinus surgery. The piezoelectric surgical device was used during revision endoscopic sinus surgery in 14 patients in the author's practice from June 2006 to January 2009. All patients had an underlying bone component to their sinus condition, such as osteoneogenesis adjacent to the orbit or skull base. The piezoelectric surgical device performed successfully in removing osteoneogenic bone, and no complications were noted from its use. Piezoelectric surgical technology generates low-frequency ultrasound that dissects bone and appears to offer an option to mechanical drill instrumentation when used during endoscopic sinus surgery to address thick osteoneogenic bone. The clinical experience reported herein shows initial feasibility of the technology in selected cases of sinus surgery. On the basis of the favorable observations from this clinical experience, further exploration and discussion would appear to be valuable.

#### Salami A., Dellepiane M., Crippa B., Mora R.

A new method for osteotomies in oncologic nasal surgery: PIEZOSURGERY®. ENGLISH Am J Otolaryngol. 2009 Mar 26. [Epub ahead of print]

#### Abstract

Objective: PIEZOSURGERY® is a recently developed system for cutting bone without necrosis and nonmineralized tissues damage. The aim of this work has been to test PIEZOSURGERY® as a new bony scalpel in nasal surgery. Methods: In this nonrandomized study, we have performed PIEZOSURGERY® in the excision of malignant nasal tumors through a paralateronasal approach. We have used PIEZOSURGERY® on 10 patients affected by nasal adenocarcinoma. The piezoelectric device uses low-frequency ultrasonic waves (24.7–29.5 kHz); the applied power can be modulated between 2.8 and 16 W and is programmed in accordance to the density of the bone. The equipment consists of 2 hand pieces, 2 inserts, and 2 peristaltic pumps; the microvibrations that are created in the piezoelectric hand piece cause the inserts to vibrate linearly between 60 and 210 µm.

Results: In all the patients, PIEZOSURGERY® provided excellent control without bleeding and harming effects on the adjacent structures. No patients experienced adverse effects.

Conclusion: PIEZOSURGERY<sup>®</sup> is a new and revolutionary osteotomy technique using the microvibrations of scalpels at ultrasonic frequency, so that soft tissue will not be damaged even upon accidental contact with the cutting tip. The safety of PIEZOSURGERY® as regards soft tissues was confirmed. No adverse effects were detected during unintentional contact with the tumor, nerve, vessel, and mucoperiosteum; this renders the piezoelectric device ideal for this application.

## Salami A., Mora R., Mora F., Guastini L., Salzano F.A., Dellepiane M. Learning curve for PIEZOSURGERY<sup>®</sup> in well-trained otological surgeons.

ENGLISH Otolaryngol Head Neck Surg. 2010 Jan;142(1):120-5.

#### Abstract

Objective: PIEZOSURGERY® is an ultrasound instrument (24.7-29.5 kHz) capable of cutting bone without necrosis and nonmineralized tissue damage. The aim of this work has been to determine the time required for a well-trained surgeon to perform ontological surgery with the piezoelectric device.

Study design: Case series with planned data collection. Sixty-three patients affected by otosclerosis and 63 by chronic otitis media were enrolled. For each disease, patients were divided into three numerically equal groups, with each group assigned to a well-trained otological surgeon. Patients underwent stapedotomy (n = 63) and intact canal wall tympanoplasty (n = 63) with the piezoelectric device.

Setting: ENT Department, University of Genoa (Italy).

**Subjects and methods:** We recorded "skin-to-skin" operation time, surgical success, surgical complication, and hospital stay duration. Before and one year after surgery, all patients underwent pure-tone audiometry, tympanometry, recording of transient-evoked otoacoustic emission, recording of distortion product otoacoustic emission, auditory brainstem response, and electronystamographic recording.

**Results:** In each surgical technique, the piezoelectric device provided excellent control without side effects on the adjacent structures of the middle and inner ear.

**Conclusion:** The piezoelectric device is a new bony scalpel that uses microvibrations at ultrasonic frequency so that soft tissue (nerve, vessel, dura mater, etc) will not be damaged even on accidental contact with the cutting tip. A feature of the piezoelectric device is its good manageability, which makes it easy for a well-trained otological surgeon to create a straight osteotomy line without any learning period: this renders the piezoelectric device suitable for bone surgery.

#### MAXILLOFACIAL SURGERY

Eggers G., Klein J., Blank J., Hassfeld S. PIEZOSURGERY<sup>®</sup>: an ultrasound device for cutting bone and its use and limitations in maxillofacial surgery.

**ENGLISH** Br J Oral Maxillofac Surg. 2004 Oct;42(5):451-3.

#### Abstract

PIEZOSURGERY<sup>®</sup> uses modulated ultrasonic vibration to allow controlled cutting of bony structures. Delicate bony structures can be cut easily and with great precision, without destruction of soft tissue. We have found this device useful when exact cutting of thin bones is essential. However, it is of only limited use in cutting thick bones and in regions with limited access.

#### Robiony M., Polini F., Costa F., Vercellotti T., Politi M.

#### Piezoelectric bone cutting in multipiece maxillary osteotomies. Technical Note.

ENGLISH J Oral Maxillofac Surg. 2004 Jun;62(6):759-61.

## Abstract

PIEZOSURGERY® (patented by Mectron Medical Technology, Carasco [Genova], Italy.) is a new innovating technique used to perform safe and effective osteotomies using piezoelectric ultrasonic vibrations. It was first reported for preprosthetic surgery, alveolar crest expansion, and sinus grafting. We introduce and report the use of PIEZOSURGERY® for multipiece maxillary osteotomies, to overcome many of the complications of this delicate surgery on hard and soft tissues. Because of its micrometric and selective cut, the piezoelectric device produces safe and precise osteotomies without any osteonecrosis damage. This device works only on mineralized tissues, sparing soft tissues and their blood supply.

Among various surgical phases, osteotomy is one of the most technique-sensitive procedures in maxillofacial surgery. Osteotomies are usually conducted close to delicate anatomic structures, such as vestibular and lingual/ palatal soft tissues that provide bone vascularization through the periosteum. Furthermore, bone is a hard tissue and many cutting or drilling osteotomes are very crude tools. In particular, rotating instruments are potentially injurious, due to the production of excessively high temperatures during osseous drilling, which can produce marginal osteonecrosis and impair bony regeneration. It is widely and strongly recommended to use a careful surgical technique and to reduce the amount of frictional heating with saline solution irrigation. Among cutting techniques, PIEZOSURGERY® is a new and innovating method that uses piezoelectric ultrasonic vibrations to perform precise and safe osteotomies, due to its characteristics of a micrometric and selective cut. It was first invented by Tomaso Vercellotti, MD, DDS, to overcome the limits of traditional instruments in oral bone surgery. The purpose of this report was to present the use of the piezoelectric cut in segmental maxillary Le Fort I osteotomy, a field in which effectiveness, precision, and safety of osteotomies are of paramount importance.

## Gruber R.M., Kramer F.J., Merten H.A., Schliephake H. Ultrasonic surgery – an alternative way in orthognathic surgery of the mandible. A pilot study.

ENGLISH Int J Oral Maxillofac Surg. 2005 Sep;34(6):590-3.

#### Abstract

The aim of this report is to present preliminary results and experiences using an ultrasonic bone-cutting device in bilateral sagittal split osteotomies of the mandible (BSSRO) with particular attention to possible damages to the inferior alveolar nerve (IAN). Seven patients with class II or class III malocclusion were treated by BSSRO with a conventional combined orthognathic and surgical approach. The osteotomy was carried out using an ultrasonic bone-cutting device. Subjective neurosensory deficits of the inferior alveolar nerve were assessed on 14 sides. Compared to the conventional techniques using saws, chisels and burs, the use of the ultrasonic device was more time-consuming, but the osteotomies were carried out at a high level of precision. In addition, this procedure offered the advantage of a blood-free surgical field and thus provided good control of the surgical procedure. Subjective neurosensory disturbances of the IAN showed a continuous decrease from 57.1% (eight sides) 2 months after the surgical procedure to 14.3% (2 sides) after 5 months and to 7.1% 7 months after BSSRO. Within the seven patients of this pilot study associated neurosensory disturbances were low. A possible advantage in terms of nerve protection is subject to a prospective study.

## Geha H.J., Gleizal A.M., Nimeskern N.J., Béziat J.L. Sensitivity of the Inferior Lip and Chin following Mandibular Bilateral Sagittal Split Osteotomy Using PIEZOSURGERY®.

ENGLISH Plast Reconstr Surg 2006 Dec;118(7):1598-607.

#### Abstract

Background: Bimaxillary osteotomy, including bilateral sagittal split osteotomy, is the most commonly performed orthognathic surgical intervention in Europe and the United States. Neurosensory perturbation in the territory of the inferior alveolar nerve is a reported adverse effect of bilateral sagittal split osteotomy. PIEZOSURGERY<sup>®</sup> is a relatively new technique that allows bone to be cut while preserving soft tissues, including nerves. The purpose of this study was to assess inferior alveolar nerve function through clinical neurosensory testing after bilateral sagittal split osteotomy using PIEZOSURGERY®.

Methods: Between February and September of 2004, 20 patients (40 sides) presenting with dentoskeletal deformities underwent bimaxillary osteotomy, including bilateral sagittal split osteotomy. The Mectron PIEZOSURGERY® device was used to perform all sagittal splits, with distraction being performed between the two bone valves. The inferior alveolar nerve was evaluated both objectively with clinical neurosensory testing, including pin-prick sensation, light touch sensation, and two-point discrimination tests, and subjectively at the following time points: preoperatively; at days 5, 7, and 10, postoperatively; and at the second month post-operatively.

Results: The anatomical integrity of the inferior alveolar nerve was respected in all cases. Observed normal results for the different tests at 10 days were 90, 82, and 70 percent, respectively, for pin-prick sensation, light touch sensation, and two-point discrimination. By computing scores for different clinical neurosensory tests, the authors observed between 75 and 80 percent complete neurosensory recuperation as early as the second postoperative month.

Conclusions: PIEZOSURGERY® used for bilateral sagittal split osteotomy allows prompt recovery of inferior alveolar nerve neurosensory function within 2 months. No comparison is possible with the results using the standard technique for bilateral sagittal split osteotomy.

## Kotrikova B., Wirtz R., Krempien R., Blank J., Eggers G., Samiotis A., Mühling J. PIEZOSURGERY® - a new safe technique in cranial osteplasty?

ENGLISH Int J Oral Maxillofac Surg. 2006 May;35(5):461-5. Epub 2006 Feb 24.

#### Abstract

Résumé

All surgical interventions on the neurocranium bear the risk of injury of the dura mater and development of a cerebrospinal fluid fistula. Therefore, despite careful preparation, damage to the dura mater cannot always be omitted. Especially after surgery and in patients with increased intracranial pressure (craniosynostoses) there is a high risk of perforating the dura. In this article a new surgical technique for osteotomy (PIEZOSURGERY®) that avoids perforation of the dura is presented. Ultrasonic microvibrations allow a selective cut of only mineralized structures without damage to the soft tissue. Even in case of accidental contact the dura remains undamaged. This advantage is also useful for bone splitting, to separate the tabula externa from the tabula interna in situ, without any risk of dura perforation even in case of the very thin bones in an infantile skull. The present work shows the applicability of piezoelectric surgery in high-risk patients after osteotomy, avoiding perforation of the dura mater.

## Béziat J.L., Vercellotti T., Gleizal A. What is PIEZOSURGERY<sup>®</sup>? Two-years experience in craniomaxillofacial surgery. FRANÇAIS Rev Stomatol Chir Maxillofac. 2007Apr;108(2):101-7. Epub 2007 Mar 13.

Introduction: La PIEZOSURGERY® est une nouvelle technique de découpe ultrasonique essentiellement utilisée en chirurgie buccale et préimplantaire pour réaliser de petits gestes osseux sans endommager les tissus mous. Le but de cette étude a été de juger de son intérêt en chirurgie craniomaxillofaciale. Matériel et méthode: Pour cela, nous avons réalisé en deux ans avec le matériel ultrasonique de la Société Mectron: a) 144 ostéotomies Le Fort I, 140 expansions palatines après ostéotomie Le Fort I, deux disjonctions palatines isolées et 134 clivages sagittaux mandibulaires ; b) deux ostéotomies Le Fort III, c) cinq ostéotomies segmentaires et trois ostéotomies basilaires de symétrisation ; d) 12 prélèvements unicorticaux de calvaria ; 20 ostéotomies orbitaires et cing frontales pour craniofaciosténose; e) dix abords craniofaciaux transsinusiens ou latéraux du cône postérieur de l'orbite : f) et quatre abords transsinusiens frontaux de la base du crâne. Résultats: L'analyse de cette expérience fait apparaître les résultats suivants: a) la PIEZOSURGERY® a permis des découpes osseuses extrêmement précises et complètes supprimant la nécessité de terminer les sections osseuses à l'ostéotome; b) elle a respecté parfaitement les tissus mous: muqueuse palatine, périorbite, et dure-mère en particulier; c) elle apréservé les nerfs, notamment alvéolaires inférieurs; d) enfin si elle augmentait, surtout lors de la période d'apprentissage, le temps de réalisation des ostéotomies, le temps opératoire global du fait de la disparition des contraintes de protection des parties molles, a été identique ou diminué. Discussion: La PIEZOSURGERY® apparaît comme une nouvelle technique de découpe osseuse ultra-

#### Abstract

Introduction: PIEZOSURGERY® is a new surgical technique used in dentistry to section hard tissues without damaging adjacent soft tissues. We hypothesized that such a device could also be useful in craniofacial and orthognathic surgery. Material and method: An ultrasonic device (Mectron) was employed in different craniofacial surgical procedures: a) to perform 144 Le Fort I osteotomies, 140 palatal expansions after Le Fort I osteotomies, and 134 bilateral sagittal osteotomies; b) to perform a Le Fort III osteotomy for treatment of Crouzon syndrome in 2 patients; c) to perform 5 segmental osteotomies and 3 osteotomies of the inferior edge of the mandible for facial asymmetry; d) to perform 12 cases of unicortical calvarial bone grafting; e) to remove the superior orbital roof in 20 cases of craniofaciostenosis and the frontal bone in 5 cases; f) to remove the external wall of the orbit or the anterior and posterior wall of the frontal sinuses in 10 cases of orbital cavity tumors; g) to approach the skull base through the frontal sinuses in 4 cases. Integrity of soft tissues and surgical time were evaluated.

Results: Analysis of the results showed that PIEZOSURGERY®: a) allows very precise cutting; b) avoids bone cutting using an osteotome; c) spares soft tissue such as brain, dura-mater, palatal mucosa, and the inferior alveolar nerve; d) increases the time of bone cutting but not the overall operative time because of the absence of soft tissue protection. Discussion: PIEZOSURGERY<sup>®</sup> is a new technical procedure, which can be advantageous for bone cutting in many situations, sparing adjacent soft

sonique particulièrement intéressante en chirurgie craniomaxillofaciale puisqu'elle supprime deux des dangers majeurs des découpes mécaniques: les plaies des parties molles et les atteintes nerveuses. Elle se révèle de plus beaucoup plus précise dans sa réalisation. La puissance encore modérée de l'appareil n'est qu'un inconvénient minime par rapport à ses avantages.

tissues such as brain, palatal mucosa, and the inferior alveolar nerve from any damage. The device's lack of power appears to be a minor problem compared with the advantages.

## Béziat J.L., Béra J.C., Lavandier B., Gleizal A. Ultrasonic osteotomy as a new technique in craniomaxillofacial surgery.

ENGLISH Int J Oral Maxillofac Surg. 2007 Jun;36(6):493-500. Epub 2007 Mar 26.

#### Abstract

Ultrasound osteotomy is a new surgical technique used in dentistry to section hard tissues without damaging adjacent soft tissues. It was hypothesized that this could also be useful in craniofacial and orthognathic surgery. An ultrasonic device was employed in the following craniofacial surgical procedures: 144 Le Fort I osteotomies, 140 palatal expansions after Le Fort I osteotomies and 140 bilateral sagittal osteotomies; 2 Le Fort III osteotomies for treatment of Crouzon syndrome in two patients; 12 cases of unicortical calvarial bone grafting; removal of superior orbital roof in 25 cases of craniofaciostenosis; removal of external wall of the orbit in 10 cases of orbital cavity tumour; removal of anterior and posterior walls of the frontal sinuses in four cases of orbital cavity tumour. Integrity of soft tissues and surgical time were evaluated. Functional results were good without any soft-tissue damage being observed, but the overall operative time was increased. Ultrasound osteotomy is a new technical procedure that is advantageous for bone cutting in multiple situations, with minimal to no damage in adjacent soft tissues such as brain, palatal mucosa and the inferior alveolar nerve.

## Guo Z.Z., Liu X., Li Y., Deng Y.F., Wang Y. The use of PIEZOSURGERY® osteotomy in treatment of long-standing maxillary fractures: report of 12 consecutive patients.

ENGLISH Shanghai Kou Qiang Yi Xue. 2007 Feb;16(1):97-9.

#### Abstract

Purpose: To evaluate the clinical applicability of PIEZOSURGERY® osteotomy: a new safe technique in managing long standing maxillary fractures.

Methods: 12 patients with long-standing maxillary fractures were surgically treated using Le Fort I osteotomy. During operation, PIEZOSURGERY<sup>®</sup> osteotomy was used for bone cutting and splitting. After repositioning, the bone segments were rigidly fixed with micro Ti-plate, Ti-mesh. All the patients were followed up for 6 to 12 months, and the functional and esthetic results were evaluated.

Results: Ultrasonic microvibrations allow accurate bone cutting without oscillating injuries to the soft tissue. All the wounds healed primarily without complications. The postoperative occlusion and appearance were satisfactory. Conclusions: Maximal recovery of mastication and appearance can be achieved by using PIEZOSURGERY® osteotomy with fixation materials such as Ti-plates and Ti-meshes in selected patients with long-standing maxillary fractures.

## Robiony M., Polini F., Costa F., Toro C., Politi M. Ultrasound Piezoelectric Vibrations to Perform Osteotomies in Rhinoplasty. ENGLISH J Oral Maxillofac Surg. 2007 May;65(5):1035-8.

#### Abstract

Among various surgical phases, osteotomy is one of the most technique-sensitive procedures in esthetic facial surgery. The bone-cutting strongly conditions the clinical outcome of the patient, not only in terms of surgical results but also in terms of safety and lack of complications. In rhinoplasty, lateral osteotomy technique should not only be precise, reproducible, and safe; it should also minimize postoperative sequelae, including ecchymosis and edema. Indications for lateral osteotomy include closure of a dorsal open roof, narrowing of the nasal pyramid, and straightening of the nasal bones. The aim of this surgical step is to mobilize the nasal bones and to simultaneously maintain the esthetic contour. Two basic techniques for lateral osteotomy have evolved, the internal (endonasal) continuous technique and the external (percutaneous) perforating method. Rohrich et al compared the 2 techniques in the fresh cadaver nose using a blinded endoscopic evaluation of the nasal mucosa, showing that the external perforated osteotomy results in a more controlled fracture with less intranasal trauma and can minimize the associated morbidity (hemorrhage, edema, and ecchymosis) in the rhinoplasty patient, and fewer mucosal tears. On the other side, minor technical problems could be reported with such a perforating external approach, as the risk of periorbital ecchymosis, due to the blinded use of the chisel on hard and soft nasal tissues, or the irregularity of the osteotomy line, obtained with the serial perforations, which could require a greater deal of pressure to infracture nasal bones. The PIEZOSURGERY® Medical Device® (PMD) is an ultrasonic bone-cutting surgical instrument, designed to perform sharp osteotomies. Its micrometric and selective action allows efficient cut of the mineralized tissues, with minimal trauma to the soft tissues. The aim of this report is to introduce the use of the PMD in rhinoplasty, in order to provide a more delicate and handy tool for the lateral percutaneous osteotomies, as an alternative to the standard chisel. Technical characteristics, indications, advantages, and limitations are discussed.

## Robiony M., Polini F., Costa F., Zerman N., Politi M. Ultrasonic bone cutting for surgically assisted rapid maxillary expansion (SARME) under local anaesthesia.

ENGLISH Int J Oral Maxillofac Surg. 2007Mar;36(3):267-9. Epub 2006 Nov 16.

#### Abstract

Ultrasonic bone-cutting surgery has been recently introduced as a feasible alternative to the conventional tools of cranio-maxillo-facial surgery, due to its technical characteristics of precision and safety. The device used is unique in that the cutting action occurs when the tool is employed on mineralized tissues, but stops on soft tissues. This technical note illustrates the use of PIEZOSURGERY® for all osteotomies of surgically assisted rapid maxillary expansion (SARME). The procedure, including pterygo-maxillary detachment, can be completed under local anaesthesia. Other advantages include minimal risk of jeopardizing critical anatomic structures (e.g. palatine artery), minimal intraoperative bleeding and postoperative swelling, and minimal thermal damage to bone surfaces. Narrow and rectilinear osteotomies can be easily performed with varying vibrating scalpels, at the cost of a longer operative time.

## Robiony M., Polini F., Costa F., Toro C., Politi M. PIEZOSURGERY<sup>®</sup>: a new method for osteotomies in rhinoplasty.

**ENGLISH** J Craniofacial Surg. 2007 Sep;18(5):1098-100.

#### Abstract

Two basic techniques for lateral osteotomy have been developed to date; the internal (endonasal) continuous technique and the external (percutaneous) perforating method. Numerous investigators have subjectively reported that the application of the two techniques results in less postoperative ecchymosis and edema compared to the use of other techniques, but an alternative and gentle method for performing lateral osteotomy or bony hump removal has not been proposed yet. The authors present a new soft technique to perform nasal osteotomy in rhinoplasty using piezoelectric ultrasonic vibrations, and emphasize the advantages of this method.

## Robiony M., Polini F., Costa F., Sembronio S., Zerman N., Politi M. Endoscopically-Assisted Intraoral Vertical Ramus Osteotomy and Piezoelectric Surgery in Mandibular Prognathism.

ENGLISH J Oral Maxillofac Surg. 2007 Oct;65(10):2119-24.

#### Abstract

In corrective surgery for mandibular prognathism, intraoral vertical ramus osteotomy (IVRO) is a simple technique that divides the mandibular ramus from the sigmoid notch down to the angular region, with many advantages over sagittal split ramus osteotomy (SSRO) in terms of lower incidence of inferior alveolar nerve damage and improved temporomandibular joint (TMJ) function. A minimally invasive approach to the facial skeleton through endoscopic assistance has gained acceptance recently. Such an approach allows the surgeon to treat several pathologies in the maxillofacial area with effectiveness and minimal morbidity: orbital surgery, fracture repair, salivary gland surgery, paranasal sinuses functional surgery. Most indications arise from orthognathic surgery (eg, Le Fort I osteotomies) and from surgical treatment of mandibular subcondylar fractures. Endoscopically assisted fracture repair of the mandible is one of the most popular indications of this minimally invasive approach because it allows excellent visibility and an effective anatomic restoration with limited-access incisions. It also minimizes the risks of an external repair (facial nerve injury and cutaneous scars). In recent years, the use of ultrasonic waves for bone cutting has also been introduced in oral and maxillofacial surgery, with favorable clinical results, due to its technical characteristics of precision and safety. Piezoelectric surgery has been indicated for all the osteotomies in which respect of surrounding soft tissues is strongly recommended to decrease the risk of damage to the most critical structures (nerves, vessels, mucosa). The aim of this technical report is to introduce and to illustrate the advantages of the combination of these technical innovations with IVRO: endoscopic assistance, through the classical "intraoral" and minimally invasive approach and piezoelectric bone cutting.

## Sakkas N., Otten J.E., Gutwald R., Schmelzeisen R. Transposition of the mental nerve by PIEZOSURGERY® followed by postoperative neurosensory control: A case report. ENGLISH Br J Oral Maxillofac Surg. 2008 Jun;46(4):270-1. Epub 2007 Aug 10.

#### Abstract

Transposition of the mental nerve is a preprosthetic procedure that is effective for patients with hyperaesthesia caused by the effect of a dental prosthesis on the alveolar ridge. We present the case of a 74-year-old woman with pain and hyperaesthesia of the right inferior alveolar nerve caused by a dental prosthesis. Caudal transposition of the right mental nerve by PIEZOSURGERY® resulted in postoperative neurosensory controls of the lower lip showing normal nerve function 2 months later.

Nordera P., Spanio di Spilimbergo S., Stenico A., Fornezza U., Volpin L., Padula E. The Cutting-Edge Technique for Safe Osteotomies in Craniofacial Surgery: The PIEZOSURGERY<sup>®</sup> Bone Scalpel.

ENGLISH Plast Reconstr Surg. 2007 Dec;120(7):1989-95.

#### Abstract

The risk of dura mater damage is reduced by the new generation of drills for craniotomy and by the new application of endoscopic techniques. Anecdotal reports describing intraoperative injury of the soft tissue resulting from the use of drills and saw may be found in the current literature. Appropriate decompression of cranial nerves is now safer as a result of the most updated technologies. All surgeons - neurosurgeons; plastic; maxillofacial; and ear, nose and throat - dealing with craniotomies or with cranial nerve decompression are aware that soft-tissue and nerve damage is still possible during osteotomy. The instruments used are drills or saws regardless of whether the bone thickness is greater than 10 mm or just 0.5 mm. Craniotomy and nerve decompression are highly demanding procedures from the very beginning, and utmost care is always required

during the osteotomy. Actually, the rate of soft-tissue damage (dural tear, nerve injury) seems to be higher than that reported in the literature. Our impression is based on our clinical experience and on personal reports by several colleagues. Currently, the available instruments for performing osteotomies involve the use of drills and saws (reciprocating or oscillating). Drills constitute a major element in the evolution of craniofacial surgery. They are constantly becoming more specialized and miniaturized, with several heads and tips for different purposes that efficiently cut the bone. However, drills and saws may also cut the soft tissues below or besides the bone because a rotating tip or a sawing blade usually does not stop on contact with structure of different density. These instruments therefore require a long period of training for appropriate and safe use. We wondered whether it would not be easier and safer to perform osteotomies with an instrument able to selectively cut only the bone structure. Could such an instrument decrease the stress for the surgeon? Would the instrument have a short learning curve? In the present article, we introduce to the practice of craniofacial surgery and neurosurgery a new ultrasound instrument that has previously been used for maxillary sinus osteotomies by oral surgeons. Ultrasonic cutting of soft and hard tissues is not an original idea. However, the present instrument is more powerful and precise than the previous generation. The characteristics of the PIEZOSURGERY® bone scalpel seemed so important to us that we wanted to share our preliminary results with our colleagues, even if the present series has a limited number of cases.

Landes C.A., Stübinger S., Rieger J., Williger B., Ha T.K., Sader R. Critical evaluation of piezoelectric osteotomy in orthognathic surgery: operative technique, blood loss, time requirement, nerve and vessel integrity. **ENGLISH** J Oral Maxillofac Surg. 2008 Apr;66(4):657-74.

#### Abstract

Purpose: Piezo-osteotomy feasibility as a substitute for the conventional saw in orthognathic surgery was evaluated regarding operative technique, blood loss, time requirement, and nerve and vessel integrity. Patients and methods: Fifty patients had orthognathic surgery procedures in typical distribution using piezosurgical osteotomy: 22 (44%) monosegment, 26 (52%) segmented Le Fort I osteotomies; 48 (48%) sagittal split osteotomies, 6 (12%) symphyseal, and 4 (4%) mandibular body osteotomies. Controls were 86 patients with conventional saw and chisel osteotomies: 57 (66%) monosegment, 25 (29%) segmented Le Fort I osteotomies, 126 (73%) sagittal split, and 4 (5%) symphyseal osteotomies.

Results: Piezosurgical bone osteotomy permitted individualized cut designs, enabling segment inter-digitation after repositioning. Angulated tools weakened the pterygomaxillary suture; auxiliary chisels were required in 100% of cases for the nasal septum, and lateral nasal walls as 46% pterygoid processes. After downfracture, the dorsal maxillary sinus wall and pterygoid processes were easily reduced. Hemorrhage was successfully avoided with average blood loss of  $541 \pm 150$  mL versus  $773 \pm 344$  mL (P = .001) for a conventional bimaxillary procedure. Sagittal mandibular osteotomy required considerable time (auxiliary saw in 13%); the lingual dorsal osteotomy was mostly performed tactile. Time investment remained unchanged: 227 ± 73 minutes per bimaxillary standard osteotomy versus 238 ± 61 minutes (P = .5); clinical courses and reossification were unobtrusive. Alveolar inferior nerve sensitivity was retained in 95% of the study collective versus 85% in the controls (P = .0003) at 3 months postoperative testing.

Conclusions: Piezoelectric osteotomy reduced blood loss and inferior alveolar nerve injury at no extra time investment. Single cases require auxiliary chiseling or sawing. Piezoelectric drilling for screw insertion and complex osteotomy designs may be developed to maintain bone contact or inter-digitation after repositioning and minimize need for osteofixation.

## Costa F., Robiony M., Salvo I., Toro C., Sembronio S., Politi M. Simultaneous functional endoscopic sinus surgery and esthetic rhinoplasty in orthognathic patients.

ENGLISH J Oral Maxillofac Surg. 2008 Jul;66(7):1370-7.

#### Abstract

Purpose: Patients treated for dentofacial deformities may be predisposed to aggravated sinonasal disease postoperatively, particularly if concurrent rhinoplasty is performed. The authors present their experience with simultaneous rhinoplasty, maxillary/mandibular osteotomies, and functional endoscopic sinus surgery (FESS). Patients and Methods: Thirteen patients were treated with simultaneous rhinoplasty, maxillary/mandibular osteotomies, and FESS from January 2002 to December 2005. An operative algorithm for patients with dentofacial deformities requiring rhinoplasty was developed. The surgical procedure was performed under general anesthesia with nasotracheal intubation and maxillary/mandibular osteotomies first. Nasotracheal intubation was then converted to orotracheal intubation and FESS was performed. The third step was correction of the esthetic deformities of the nose through an open approach.

Results: In all cases, it was possible to successfully complete the combined operation. Median operation time was: 2 hours and 18 minutes for orthognathic bimaxillary surgery, 54 minutes for rhinoplastic surgery; and 23 minutes for FESS. All the patients had good esthetic and functional results and were free from symptoms consistent with previous rhinosinusitis.

Conclusion: The combination of orthognathic surgery, rhinoplasty, and FESS in selected cases is safe and effective.

#### Bader G., Morais D.

## PIEZOSURGERY® for genioglossal advancement in treatment of obstructive sleep apnea syndrome.

FRANÇAIS Rev Stomatol Chir Maxillofac. 2008 Dec;109(6):375-8. Epub 2008 Aug 21.

#### Résumé

La langue participe à l'obstruction des voies aériennes supérieures, lors du syndrome d'apnées obstructives du sommeil (SAOS). Les génioglosses sont les muscles les plus antérieurs de la langue et sont fixés au niveau des apophyses géni sur la face interne de la symphyse mandibulaire. L'avancée des génio-tubercules permet d'élargir l'espace retrobasilingual et d'améliorer le SAOS. La piézochirurgie limite les risques de lésions des apex dentaires. Le parfait contrôle de la profondeur de coupe et la très faible incidence des inserts sur les tissus mous limitent considérablement les risques de lésions du plancher buccal.

#### Abstract

The tongue is a frequent cause of upper airway obstruction in obstructive sleep apnea syndrome. The genioglossi muscles are the front-most muscles of the tongue, attached to the geniotubercle on the inner cortical of the mandibular symphisis. The collapsibility of the tongue can be managed with genioglossus advancement. PIEZOSURGERY® can decrease the risk of apical dental lesion. The perfect depth control during osteotomy and absence of soft tissue lesion considerably limit the risks of oral floor lesion.

## Landes C.A., Stübinger S., Ballon A., Sader R. Piezoosteotomy in orthognathic surgery versus conventional saw and chisel osteotomy.

ENGLISH Oral Maxillofac Surg. 2008 Sep;12(3):139-47.

#### Abstract

Introduction: Piezoosteotomy was assessed as alternative osteotomy method in orthognathic surgery regarding handling, time requirement, nerve and vessel impairment.

Materials and methods: In this comparative clinical experience, 90 patient's orthognathic surgery procedures were performed in typical distribution prospectively by piezoosteotomy: 34 (38%) monosegment, 47 (52%)

segmented LeFortl osteotomies, 94 (52%) sagittal split osteotomies, 11 (12%) symphyseal, and 4 (2%) mandibular body osteotomies. As controls served 90 retrospective patients with conventional saw and chisel osteotomy: 58 (64%) monosegment, 27 (30%) segmented LeFortl osteotomies, 130 (72%) sagittal split, and 4 (4%) symphyseal osteotomies.

Results and discussion: Piezoosteotomies were individually designed to interdigitate the jaw segments after repositioning. The pterygomaxillary suture weakened angulated tools; auxiliary chisels were required in 100% of cases for the nasal septum and lateral nasal walls, in 33% for pterygoid processes. The dorsal maxilla as the pterygoid process were easily reduced; 15% mandibular osteotomies required sawing, while the lingual dorsal osteotomy was performed by manual feedback due to limited visibility. Bloodloss decreased from average 537±208 ml vs. 772±338 ml (p= 0.0001). Operation time remained unchanged: 223±70 min vs. 238±60 min (p=0.2) for a conventional bimaxillary procedure. Clinical courses and reossification were unobtrusive. Alveolar inferior nerve sensitivity was retained in 98% of the piezoosteotomy collective versus 84% of controls (p=0.0001) at 3 months postoperative testing.

Conclusion: Piezoelectric osteotomy did not prolong the operation and reduced blood loss as alveolar nerve impairment. A few patients required additional sawing or chisel. Piezoelectric screw insertion as complex osteotomies may be initiated to simplify the procedure and increase segment interdigitation after repositioning as to minimize the osteofixation time and dimensions.

## González-Lagunas J., Mareque J. PIEZOSURGERY<sup>®</sup>: its role in TMJ surgery.

ENGLISH It J Maxillofac Surg 2008 Dec;19(3):119-21.

#### Abstract

This article presents the authors' experience with the use of a piezoelectric device to perform different osteotomies during open temporomandibular (TMJ) surgery. In the last six months six patients underwent TMJ open surgery with a piezoelectric device in order to perform osteotomies both in the condyle and in the articular eminence. This surgical instrument allows to trace an accurate osteotomy line, without injuring the adjacent soft tissues. PIEZOSURGERY® has gained popularity during the last few years due to the accurate and safe cutting of bone achieved without the risk of injuring the neighboring soft tissues. Most of the applications in oral and maxillofacial surgery have included its use in cases when bone cutting was performed near nerves or other weak structures as the sinus membrane.

The aim of this paper is to present authors' experience in six cases of TMJ surgery, where PIEZOSURGERY® allows a safe bone cutting in the vicinity of important vascular structures.

## González Lagunas J., Molina Montes J., Mareque Bueno J. Extraoral uses of a piezoelectric surgical cutting tool.

ESPAÑOL Rev Esp Cir Oral y Maxilofac 2009 Jan;31(1):26-31.

#### Resumen

Presentamos nuestra experiencia con el empleo de un bisturí piezoeleéctrico con el fin de efectuar diferentes osteotomias extraorales, Estas indicaciones no se han presentado previamente en la literatura. En lus últimos 6 meses hemos utilizado este intrumento para efectuar osteotomías en el cóndilo y en la eminencia articular, para tomar injerto de calota craneal y para realizar las osteotomias de la rinoplastia. Este instrumento permite una inea de osteotomia precisa sin el riesgo de lesionar los tejidos blandos vecinos. Se discuten las ventajas e inconvenientes del instrumento según el procedimento realizado.

#### Abstract

We report our experience with the use of a piezoelectric surgical cutting tool in performing extraoral osteotomies. These indications have not been reported previously in the literature. In the last 6 months we have used this instrument to perform osteotomy on the temporomandibular condyle and articular eminence, to obtain grafts from the skull, and to perform osteotomy for rhinoplasty. This instrument can be used to makes an osteotomy cut without risk of injuring adjacent soft tissues. Its advantages and disadvantages are discussed in accordance with the procedure performed.

#### Muñoz-Guerra M.F., Naval-Gías L., Capote-Moreno A.

Le Fort I osteotomy, bilateral sinus lift, and inlay bone-grafting for reconstruction in the severely atrophic maxilla: a new vision of the sandwich technique, using bone scrapers and PIEZOSURGERY®. ENGLISH J Oral Maxillofac Surg. 2009 Mar;67(3):613-8.

#### Abstract

Severe atrophy of the edentulous maxilla and progressive pneumatisation of the maxillary sinus can compromise the insertion of dental implants. In this context, ideal implant positioning is limited by inadequate height, width, and quality of the bone. Le Fort I osteotomy and interpositional bone graft is an excellent treatment concept for the dental rehabilitation of patients with atrophied maxilla and reversed intermaxillary relationship. In this report, we indicate the transcendent aspect of elevation and preservation of maxillary sinus and nasal mucosa, modifying the sandwich technique by the useful of bone scrapers and PIEZOSURGERY®. The procedure is described including a 1-stage approach using cortico-cancellous bone blocks through which implants are placed. In the extremely atrophied alveolar process of the maxilla, this technique provides the desired gain of bone, allows for the ideal placement of dental implants, and improves any discrepancy between the upper and lower arches.

## Béziat J.L., Faghahati S., Ferreira S., Babic B., Gleizal A. Intermaxillary fixation: technique and benefit for piezosurgical sagittal split osteotomy.

FRANÇAIS Rev Stomatol Chir Maxillofac. 2009 Nov;110(5):273-7. Epub 2009 Oct 20.

#### Résumé

Introduction: Le but de ce travail était de préciser la technique et l'intérêt du clivage sagittal par découpe ultrasonique en maintenant un blocage maxilloman-dibulaire durant sa réalisation. Matériel et method: Nous avons analysé 25 ostéotomies bimaxillaires soit 50 clivages sagittaux réalisés par cette technique. Elle a comporté, d'une part, le maintien durant tout le clivage d'un blocage maxillomandibulaire et d'autre part la réalisation d'un clivage en cinq étapes. Nous avons noté pour chaque cas le type de la dysmorphose, la surface du clivage obtenu et le temps de sa réalisation à côté des éléments d'information classiques type sexe, âge, etc. Ces données ont été comparées aux résultats d'une série antérieure de patients également opérés avec la PIEZOSURGERY® mais sans bloquer le patient durant le clivage. Résultats: Le maintien du blocage maxillomandibulaire durant le clivage ultrasonique diminue d'un tiers la durée du clivage, permet d'obtenir neuf fois sur dix un clivage complet, bord basilaire inclus n'a pas d'effet négatif en particulier sur le matériel orthodontique. Discussion: L'utilisation de la PIEZOSURGERY® est un progrès considérable en chirurgie orthognathique de par sa précision et son respect des parties molles. Elle impose en revanche le plus souvent de modifier la technique classique prévue pour la découpe mécanique. Le recours à un blocage maxillomandibulaire pendant le clivage ultrasonigue est une modification technique simple et remarquablement efficace.

#### Abstract

Introduction: The aim of this study was to assess piezosurgical sagittal split osteotomy with peroperative inter maxillary fixation. Material and method: We studied 25 bimaxillary osteotomies, 50 sagittal split osteotomies performed with this technique. It included both maxillomandibular fixation during all the split osteotomy and performing split osteotomy in five steps. For each case, we noted the type of dysmorphia, the size of split osteotomy and the time required for surgery, along with common data such as sex, age, etc. The data was compared to results of a previous series of patients also operated with PIEZOSURGERY® but without peroperative maxillomandibular fixation. **Results:** Using peroperative maxillomandibular fixation during piezosurgical bilateral sagittal osteotomy decreases the length of surgery by 33%, allows 9 times out of 10 for complete splitting, including the basilar edge, has no adverse effect especially on orthodontic material. Discussion: PIEZOSURGERY<sup>®</sup> is a great progress for orthognatic surgery because of its precision and ability to preserve soft tissues. But it requires modification of the usual technique for mechanical section. Using peroperative inter maxillary fixation during ultrasonic splitting is a remarkably effective and easy technical modification.

## Vercellotti T., Crovace A., Palermo A., Molfetta A. The Piezoelectric Osteotomy in Orthopedics: Clinical and Histological Evaluations (Pilot Study in Animals).

ITALIANO Mediterranean Journal of Surg Med 2001; 9: 89-95.

#### Riassunto

In Ortopedia la corretta esecuzione di ogni intervento chirurgico richiede una meticolosa conoscenza di anatomia, l'impiego di una procedura ben pianificata e il corretto uso di strumenti specifici che consentono di raggiungere il livello di precisione necessario. Lo scopo di questo articolo è di valutare i risultati di un nuovo strumento piezoelettrico in Chirurgia Ortopedica nei casi in cui ci siano difficoltà anatomiche dovute alla particolare delicatezza della struttura: ad una mancanza di visibilità intraoperatoria, alla vicinanza del midollo spinale o del fascio vascolo nervoso e dove l'uso degli strumenti tradizionali risulta di difficile controllo nell'eseguire l'oteotomia e pertanto risulta difficile e spesso rischioso per le possibili complicanze post-chirurgiche. Sono state seguite 3 chirurgie ortopediche su cani affetti da differenti patologie usando un nuovo apparecchio chirurgico (Mectron PIEZOSURGERY®). Le valutazioni cliniche intra-operatorie sono state eseguite per determinare che il taglio piezoelettrico, il quale è selettivo e micrometrico, è efficace sul tessuto osseo, ma inattivo sui tessuti molli, inoltre il campo chirurgico esangue ha offerto una maggiore visibilità intra-operatoria da quella che si riscontra con l'uso degli strumenti tradizionali. Gli esami istologici sulla superficie del taglio di tutti i segmenti osteotomizzati hanno evidenziato la presenza di osteociti vitali (nucleati) a dimostrazione della ridotta traumaticitàdel taglio piezoelettrico. Tutte le chirurgie sono state monitorate nel periodo di guarigione e con un'assenza di complicazioni post-operatorive e un veloce recupero delle funzioni.

#### Abstract

In Orthopedic surgery, the correct execution of each operation requires a meticulous knowledge of anatomy, a well planned surgical procedure and the correct use of specific instruments that allow the necessary level of precision required. The purpose of this paper is to evaluate the results of a new piezoelectric instrument in orthopaedic surgery in cases where there are anatomic difficulties due to the particular fineness of the structure, a lack of intra-operative visibility or due to the adjacency to the spinal cord or vascular nervous tract, where the use of other osteotomy instruments prove to be difficult to control and often risky. Three orthopaedic surgeries were performed on dogs affected by different pathologies using a new surgical device (Mectron PIEZOSURGERY®). Intra-operative clinical evaluations were undertaken to determine the characteristics of the micro-metric and selective piezoelectric cut, which is effective on bone tissue but inactive on soft tissues. The operating site was blood-free with greater intra-operatory visibility than that offered by traditional instruments. The histological examinations carried out on the cut surfaces of all the osteomitized segments show the presence of live osteocytes. This proves the reduced trauma of the piezoelectric cut. All the surgeries were followed by an excellent post-operative healing period with an absence of complications and a fast recovery of functions.

## Hoigne D.J., Stübinger S., Von Kaenel O., Shamdasani S., Hasenboehler P. Piezoelectric osteotomy in hand surgery: first experiences with a new technique.

ENGLISH BMC Musculoskelet Disord. 2006 Apr 12; 7:36.

#### Abstract

**Background:** In hand and spinal surgery nerve lesions are feared complications with the use of standard oscillating saws. Oral surgeons have started using a newly developed ultrasound bone scalpel when performing precise osteotomies. By using a frequency of 25–29 kHz only mineralized tissue is cut, sparing the soft tissue. This reduces the risk of nerve lesions. As there is a lack of experience with this technique in the field of orthopaedic bone surgery, we performed the first ultrasound osteotomy in hand surgery.

**Method:** While performing a correctional osteotomy of the 5th metacarpal bone we used the PIEZOSURGERY<sup>®</sup> Device from Mectron [Italy] instead of the usual oscillating saw. We will report on our experience with one case, with a follow up time of one year.

Results: The cut was highly precise and there were no vibrations of the bone. The time needed for the

operation was slightly longer than the time needed while using the usual saw. Bone healing was good and at no point were there any neurovascular disturbances.

**Conclusion:** The PIEZOSURGERY<sup>®</sup> Device is useful for small long bone osteotomies. Using the fine tip enables curved cutting and provides an opportunity for new osteotomy techniques. As the device selectively cuts bone we feel that this device has great potential in the field of hand- and spinal surgery.

## Battiston B., Tos P., Conforti G., Vercellotti T. PIEZOSURGERY<sup>®</sup> in hand surgery.

ITALIANO Riv Chir Mano 2006; 43(3):268-270.

#### Riassunto

La PIEZOSURGERY<sup>®</sup> è una nuova tecnica per osteotomie ed osteoplastiche che utilizza un innovativo apparecchio chirurgico ad ultrasuoni. Grazie a questa tecnica è possibile ottenere una maggiore precisione e sicurezza nella chirurgia ossea attraverso uno strumento con puntali che agiscono con vibrazione di una frequenza di 29 kHz e un range tra 60 e 200 Hz. Le micro vibrazione consentono una sezione selettiva solo delle strutture mineralizzate senza danno per i tessuti molli. Le vibrazioni micrometriche assicurano un'azione di taglio precisa che non causa necrosi ossea da calore. Allo stesso tempo il fenomeno fisico della cavitazione mantiene un campo chirurgico privo di sangue. La maneggevolezza del sistema e l'assenza di micro vibrazioni consentono di effettuare tagli ossei precisi e vere e proprie osteoplastiche. Questi vantaggi in una chirurgia come quella della mano sono molto importanti per evitare danni alle tante strutture delicate vicino all'osso e per consentire ricostruzioni chirurgiche precise.

#### Abstract

PIEZOSURGERY<sup>®</sup> is a new technique for osteotomy and osteoplasty utilizing an innovative ultrasonic surgical apparatus. The use of this technique may give us greater precision and safety in bone surgery by means of an instrument characterized by inserts acting by piezoelectric ultrasonic vibrations of a frequency of 29 kHz and a range between 60 and 200 Hz. The microvibrations allow a selective cut of only mineralized structures without damaging soft tissues. The micrometric vibrations ensure precise cutting action without causing bone necrosis by heating. At the same time the physical phenomenon of cavitations maintains a blood-free site. This manageable system and the absence of microvibrations allow precise bone cuts and real osteoplasties. These advantages in hand surgery are very important to avoid lesions to be numerous bone neighboring structures and to allow precise osseous reconstructions.

# **PIEZOSURGERY**<sup>®</sup>*medical*



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