COMEG Medical Technologies is the Medical Division of the ACTEON Group.

• Over 40 years of experience in surgical endoscopy
• Focused specifically in Minimally Invasive Surgery (MIS)
• Global presence on 6 continents
• Meeting the specific needs for GYN, URO, ENT, LAP, ARTHRO, CAV, and PLASTIC surgery
• Intuitively connecting physicians with the appropriate solutions

COMEG designs intuitive solutions for minimally invasive surgery.

Safe and atraumatic ultrasonic piezo bone surgery Compendium
Ultrasonic Piezo Bone Surgery Performances

Keywords
Gene expression, Histology, MicroCT, Piezoelectric surgery, Piezotome®.

Abstract
Purpose:
This pilot study evaluated the molecular, histologic, and radiographic healing of bone to instrumentation with piezoelectric or high speed rotary (R) devices over a 3-week healing period.

Materials and methods:
Fourteen Sprague-Dawley rats (Charles River Laboratories International, Inc., Wilmington, MA, USA) underwent bilateral tibial osteotomies prepared in a randomized split-leg design using Piezotome® [P1] (Satelec® Acteon®, Merignac, France), Piezotome® 2 [P2] (Satelec® Acteon®), High-speed R instrumentation, or sham surgery (S).

At 1 week, an osteogenesis array was used to evaluate differences in gene expression while quantitative analysis assessed percentage bone fill (PBF) and bone mineral density (BMD) in the defect, peripheral, and distant regions at 3 weeks. Qualitative histologic evaluation of healing osteotomies was also performed at 3 weeks.

Results:
At 1 week, expression of 11 and 18 genes involved in bone healing was significantly (p < .05) lower following P1 and P2 instrumentation, respectively, relative to S whereas 16 and 4 genes were lower relative to R. No differences in PBF or BMD were detected between groups within the osteotomy defect. However, significant differences in PBF (p = .020) and BMD (p = .008) were noted along the peripheral region between P2 and R groups, being R the group with the lowest values. Histologically, smooth osteotomy margins were present following instrumentation using P1 or P2 relative to R.

Conclusion:
Piezoelectric instrumentation favors preservation of bone adjacent to osteotomies while variations in gene expression suggest differences in healing rates due to surgical modality. Bone instrumented by piezoelectric surgery appears less detrimental to bone healing than high-speed R device.

With both Piezotome® piezoelectric surgical units, osteotomy margins were smooth and much better defined, suggesting minimal postoperative necrosis of the marginal bone during healing process.

Osteotomies performed with Piezotome® 2 went faster than Piezotome® 1. However, the increase of power of generation 2 has no effect on bone tissues or healing process.

No genetic, histologic, or radiographic evidence of necrosis or exuberant inflammation over the 3 week healing period was found.

Increased Intraosseous Temperature Caused by ultrasonic Devices During Bone Surgery and the Influences of Working Pressure and Cooling Irrigation

Keywords
Cutting performance, Intraosseous temperature development, Ultrasonic bone surgery.

Abstract
Purpose:
The purpose of this study was to investigate the increases in intraosseous temperature generated by a modern ultrasonic device for bone surgery (UDBS) and the influences of working pressure and cooling irrigation on this temperature.

Materials and methods:
Twenty human mandibular bone specimens (20 x 15 x 5 to 7 mm) were used; three vertical cuts were performed for a duration of 12 seconds per cut. Each bone specimen was machined with a different combination of working pressure (1.5, 2.0, 3.0, 4.0, or 6.0 N) and cooling irrigation (0, 30, 60, or 90 mL/min), and intraosseous temperatures were measured.

Harmful temperature development was defined as an increase of more than 10°C for the 75th percentile and/or a maximum increase of more than 15°C. Cutting performance was also measured.

Results:
Harmless intraosseous temperature development was identified for working pressures of 1.5 N and 2.0 N with cooling irrigations of 30, 60, and 90 mL/min and for 3.0 N at 90 mL/min. The maximum temperature observed was 72°C (6.0 N with 60 mL/min). The mean cutting performance values were 0.21±0.02 mm/s for 6.0 N, 0.21±0.06 mm/s for 3.0 N, 0.20±0.01 mm/s for 4.0 N, 0.11±0.05 mm/s for 1.5 N, and 0.08±0.03 mm/s for 2.0 N.

Conclusion:
To prevent tissue damage in dental bone surgery, a minimum coolant amount of 30 mL/min is recommended. The working pressure should be chosen with great care because of its significant influence on intraosseous temperature. Doubling of the working pressure from 1.5 to 3.0 N requires a tripling of the coolant (30 to 90 mL/min) to prevent tissue damage. A working pressure above 3.0 N did not result in improved cutting performance.

F. Birkenfeld, M.E. Becker, S. Harder, R. Lucius, M. Kern
All 19 patients in this study underwent LeFort I segmented osteotomy with Piezotome®. It has been concluded that using the Piezotome® generator increased the security as there was no soft tissue lesion nor necrosis of the osteotomized segments. Throughout the procedure, full visibility and a stable view was achieved with minimal bleeding and adequate irrigation on the surgical site. Using a piezoelectric device optimized the surgical technique and with a minimal learning curve allowed to perform the maxillary osteotomy in an average time of 48 minutes.

S. Olate, L. Pozzer, A. Unibazo, C. Huentequeo-Molina, F. Martinez, M. de Moraes

Performance of Ultrasonic Devices for Bone Surgery and Associated Intraosseous Temperature Development

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The International Journal of Oral & Maxillofacial Implants Volume 24, Number 3, 2009

Keywords
Cutting performance, Intraosseous temperature development, Material testing, Ultrasonic bone surgery.

Abstract
Purpose:
The purpose of this study was to evaluate and to compare the bone-cutting performance and intraosseous temperature development of three modern ultrasonic devices for bone surgery (UDBS).

Materials and methods:
The following UDBS and associated cutting tips [strucks bone saws] were used in this study: [1] Piezosurgery® II professional, tip OT 7 (Mectron®); [2] Piezotome®, tip BS1 (Acteon®) and [3] Surgysonic®, tip ES007 [American dental system/Günther Jernei]. In the experimental setup UDBS, handpieces were immobilized, and bone specimens from the mid-diaphysis of a bovine femur were moved in a longitudinal direction under the cutting tip to a standardized depth of 3.0 mm. Statistical analysis was performed using the Wilcoxon rank sum test.

Results:
The median increase (25th through 75th percentiles) of the local intraosseous temperature was 3.0°C (2.2°C to 4.2°C) for the Surgysonic®, 2.2°C (1.8°C to 3.2°C) for the Piezosurgery® II, 1.1°C (0.7°C to 1.6°C) for the Piezotome®. The median cutting performance was 0.31 mm/s (0.11 to 0.46 mm/s) for the Piezotome®, 0.25 mm/s (0.23 to 0.27 mm/s) for the Piezosurgery® II and 0.04 mm/s (0.03 to 0.05 mm/s) for the Surgysonic®.

Conclusion:
Among the three tested UDBS, the Piezotome® and the Piezosurgery® II showed a significantly higher cutting performance than the Surgysonic®. The Piezotome® produced the smallest increase in intraosseous temperature.

Acteon® & Mectron® showed a significantly higher cutting performance, whereas Acteon® produced the least increase of intraosseous temperature. Differences in the cutting performance and intraosseous temperature development of the tested devices seemed to be influenced by the design of the cutting tips of the bone saws used in this investigation. On Acteon® device, was observed a deeper penetration into the bone. Its cutting tip showed more homogenous and sharper spike geometry and more roughened spike surfaces than other cutting tips.
The mandibular constriction is a surgical technique aiming to manage the skeletal transversal discrepancies which associated to the ultrasonic generator allow to get a thin and straight cut.

Osteotomy in mandibular condylectomy is traditionally performed with a saw, drill, or chisel and often associated to complications due to the proximity with major vascular structures such as the maxillary artery. Piezotome® applied to this surgery enhances the visualization and allows for full control during the osteotomy. Soft tissue is preserved and no necrosis was observed in the residual bone which could lead to improve bone healing and a reduction in the postoperative patient’s symptoms. Thus, piezoelectric application to this surgery is considered safe and efficient.

Keywords
Mandibular condylectomy, Visual clarity, Control, Bleeding control, Soft tissue preservation, Piezoelectric ultrasonic system

Abstract
Condylar hyperplasia is a well-known pathologic entity with an established treatment protocol. Traditionally, saws and drills have been used in the condylar osteotomy. The use of ultrasonic systems has optimized many procedures in the maxillofacial area; however, exploration of the use of this technique for condylectomy has been limited. Ultrasonic systems offer several advantages, such as a decrease in the risk of blood vessel damage and clarity of the osteotomy. The present report addressed the scope of condylar osteotomy using ultrasonic systems.
108 patients were treated for cosmetic reduction rhinoplasty performed by three different surgical disciplines: Cosmetic-, ENT-, and Maxillofacial surgeons who each used different instruments (Piezotome® vs conventional), techniques and approaches. Rhinoplasty performed with Piezotome allows immediate post-surgical morbidity reduction: almost a complete absence of ecchymosis and edema and significant pain reduction were observed as bone cutting is precise and soft tissue is preserved, indeed, the periosteum is intact both on a histological and functional level. Therefore, the nasal bone stability is preserved. According to the results of the study, Piezotome appears to be the surgical instrument of choice for cosmetic surgery on facial bones and increases patient’s satisfaction with the final results.
Rhinoplasty

Rhinoplasty surgeries have evolved with the use of piezo and specifically designed tips for rhinoplasty. A major change is the extensive exposure of the skin envelope in rhinoplasty and thanks to piezo, the underlying cartilage and mucosa are untouched; thus preserving bone stability and reducing the risk of nasal bone collapsing in the airway. The wide exposure also increases the visibility which makes it easier for surgeons to assess and surgically correct the bony vault prior to and after the osteotomies are performed as a result of the full visibility and thus a greater control. Piezo-rhinoplasty is particularly adapted when bones are close to delicate soft structures such as skin, mucosa or flimsy cartilage as they remain protected and offer more precise results without significant risk of osteonecrosis.

Conclusion:
Based on the authors’ experience, adoption of PEI is justified and offers more precise analysis and surgical execution with superior results in altering the osseocartilaginous vault. With extensive exposure, surgeons can make an accurate diagnosis of bony deformity and safely contour the bones to achieve narrowing and symmetry of the bony dorsum. Stable osteotomies can be performed under direct vision with precise mobilization and control. As a result of PEI, the upper third of the rhinoplasty operation is no longer shrouded in mystery.
"M+ has Restored my Love of my Job"

v.Prof.Dr.Dr. Troedhan - MD, DMD, PhD, Vienna, AUSTRIA
Specialist in Cranio-Maxillo-Facial surgery - Specialist in Dentistry & Periodontology

"Patients are not consumers. They are human beings, who should be treated with the utmost respect. Using Piezotome® instruments in my cranio-maxillo-facial (CMF) operations enables me to reduce their pain and apprehension, and has restored my love of the job."

Angelo Troedhan, who is based in Austria, has been working as a CMF surgeon for 28 years. His CMF operations range from impacted teeth and third molars to apicectomies, sinus surgeries, and complex procedures for bone augmentations and reconstructions (vertical bone distractions, sinus lifting and horizontal bone-widening). They also extend to piezoelectric and orthognathic surgery on the maxilla and mandibular, and reductive cosmetic surgery on facial bones, such as rhinoplasties, genioplasties and zygoma-reductions.

In Doctor Troedhan’s case, the operations most frequently requested by his patients involve alveolar bone reconstructions, sinus lifting and cosmetic surgery of facial bones. He performs one or two orthognathic operations every month.

Angelo Troedhan has been using M+ ultrasonic instruments in his operating room for three years now. "I use M+ ultrasounds for ethical and medical reasons. Rotary instruments and chisels in all kinds of CMF surgery should be replaced by ultrasonic surgical devices like M+ because surgery with M+ is more precise, as clinical studies have shown. There is less risk of iatrogenic soft-tissue lesions, and significantly less post-op patient-morbidity, such as pain and swelling. Moreover, and this has also been proven by experimental studies, the use of M+ substantially enhances bone healing. M+ instruments allow for a surgical precision that has never been possible with traditional instruments."

"A patient who consults me for an operation is more often than not very apprehensive. Patients understandably fear the pain they may suffer during an operation, and the pain and swelling that may occur after the operation. They worry that there may be complications, such as heavy bleeding. In a word, they want to know when they will be able to get on with their life again."

"Meanwhile, we surgeons worry about bleeding that may obscure our view while we operate. We are also extremely careful not to accidentally damage the soft tissues and facial nerves. Ultrasounds reduce the risks of complications, sometimes by more than 50%."

M+ is revolutionary

M+ instruments afford unrivalled speed, precision and efficacy in cutting bone. This is made possible by a self-regulatory feedback mechanism during ostetotomies of all kind. The M+ range is currently the finest and most time-efficient ultrasonic surgical device, with the widest range of specialized tips for particular surgical procedures, especially for CMF surgery.

"In 2005, I abandoned all rotary instruments from my operating rooms, and now use Piezotome® M+ and ImplantCenter™ M+, which are as easy to set up as a traditional device for rotary instruments," he explains. And he has never looked back.

PATIENT TESTIMONIAL

Elisabeth N., Vienna, underwent ultrasonic surgery performed by Dr Troedhan

"Some years ago because of a very complicated wisdom tooth I underwent jaw surgery at the University Clinic for Oral-Maxillofacial Surgery in Vienna. The operation and the period following the operation were pure horror for me. I suffered severe pain for 14 days and because of the disfigurement of my face and the bruising right down to my cleavage, I was unable to leave the house for 10 days and the only thing I could eat was liquidised food. Since then I have a huge cavity on the bone of my lower jaw at the site of the operation, in which foods are always getting caught. Therefore, I was terrified by the prospect of the jaw surgery needed for the even worse wisdom tooth on the other side. From information on the Internet I discovered that such operations are much less dreadful with ultrasound. In addition, I had to make my mind up to have the jaw surgery done, since I was suffering constant pain because of the wisdom tooth. The oral surgeon used an ultrasonic operating instrument to carry out the jaw surgery. The contrast with the first operation on the other hand was unbelievable. The operation took less time and was not accompanied by such dreadful noises and after the operation I had hardly any pain and there was very little swelling and absolutely no bruising. Three days later I was able to eat normally again and 5 days after the operation I was able to return to work with no problems. I also do not have a cavity in the bone on this side to annoy me when I am eating. I hope that I will not need any more jaw surgery, but if I do need an operation, I will have it done only by ultrasound surgery."
Facial Plastic Surgeon Milos Kovacevic Advocates COMEG’s Piezotome® Instruments

Milos Kovacevic, MD – Hamburg, GERMANY
Facial Plastic Surgeon, Rhinoplasty specialist

“The main advantage of the Piezotome® ultrasonic instruments used in rhinoplasty surgery is that they enable us, the surgeons, to see what we are doing and actually ‘shape’ the nose. They help us sculpt the nose’s bony vault and perform lateral osteotomies, while reducing the risk for our patients and alleviating their fear of the operation.”

Milos Kovacevic is a facial plastic surgeon, based in Hamburg (Germany), who performs between 280 and 300 rhinoplasty operations a year. Most of these are for cosmetic reasons, and as many as 75% are requested by women, but rhinoplasty operations are also performed to correct breathing issues.

At 52, Dr Kovacevic has been working for 27 years, so he has seen the operative technology evolve. "COMEG’s piezoelectric-powered instruments considerably reduce the risks of complications in plastic surgery, because they give us greater control and prevent us from harming underlying soft tissue – the skin, mucosa and flimsy cartilage – as they act selectively on bones and hard cartilage. Patients are understandably highly sensitive to interventions in the eyes and nose areas, and fear both pain and days or weeks of bruising, and possible complications. The ultrasound technology is very good. The fracture lines created by Piezoelectric instruments are very accurate, and consequently eliminate the risk of the radiating fracture lines we had to deal with when we used traditional instruments. Personally, I use Piezotome® M+.”

“There was a tremendous breakthrough two and half years ago, when Olivier Gerbault, a plastic surgeon based in Paris, and I introduced the first full, open approach, which enabled us to see what we were doing when treating the bony part of the nose. It removed the fear of what we used to call “the black box”, working in the dark, as it were, which would make any surgeon apprehensive even after years of experience.”

Testimonial Rhinoplasty
ULTRASONIC RHINOPLASTY

Rhinoplasty: the ultrasonic revolution*
French editorial press - FEMINA - October 31st 2016
Only available in French language

Rhinoplasty is a complex surgery and since now surgeons had to break nose bones to be able to fix them. A new technique called “ultrasonic rhinosculpture” has been introduced during the 1st International Rhinoplasty congress held in Paris in 2016. Bones are sculpt with precision without the need of breaking them thanks to ultrasonic instruments...

*Original Title: Rhinoplastie: la révolution ultrasons

Open ultrasonic rhinoplasty technique: A smooth and less traumatic procedure

Ultrasonic piezoelectric devices open many opportunities in bone reshaping and recently in rhinosplasty. Piezoelectric system paired with ultrasound activated miniaturised instruments increase safety and precision...

The surgeon Pablo Casas, pioneer in performing ultrasonic rhinoplasty*
Spanish newspaper - LA CRONICA DE LEON - July 13, 2017
Only available in Spanish language

Pablo Casas, ENT and Facial Plastic Surgeon is a pioneer in Spain in the use of ultrasonic device for rhinoplasty procedures. Ultrasonic rhinoplasty is the most advanced technique in rhinoplasty and has recently been apporved by the FDA (USA - Food and Drug Administration). With the use of ultrasonic instruments bones are no longer broken and soft tissues are preserved...

*Original Title: El cirujano Pablo Casas, pionero realizar una rinoplastia ultrasonica

Surgical intervention completety new at the San Francisco’s Hospital*
Spanish newspaper - DIARIO DE LEON - July 13, 2017
Only available in Spanish language

Ultrasonic rhinoplasty a atraumatic surgery...

*Original Title: Cirugía pionera en HM San Francisco

The Michel-Ange of the nose*
Spanish magazine - EL MUNDO CASTILLA Y LEON  - Numero 341/July 25, 2017
Only available in Spanish language

Ultrasonic rhinoplasty offers numbers of benefits for the patient such as a faster postoperative recovery and enhanced results as well as for the surgeon who is more precise...

*Original Title: El Miguel Angel de la nariz
Rhinoplasty: a less invasive technique is coming*
French web press - MARIE FRANCE - January 30th 2015
Only available in French language

Rhinoplasty is ranked as the fourth most widely performed surgery among women and men. Request vary from a nose that is too wide to a septal deviation. Ultrasonic rhinoplasty is less traumatic and the recovery is faster...

*NOriginal Title: Rhinoplastie: une technique moins invasive arrive

Rhinoplasty: finally a softer technique*
French web press - FEMME ACTUELLE - May 20th 2015
Only available in French language

Ultrasonic rhinoplasty is more smooth and reduces the post-operative recovery. The patient experiences less bruising and swelling; thus allowing she or he to reintegrate socially about six days after surgery compared to two weeks when performed with conventional instruments...

*NOriginal Title: Rhinoplastie: enfin une technique plus douce

Nose surgery: ultrasounds revolution rhinoplasty*
Only available in French language

Instruments used in rhinoplasty were invented at the begining of the 20 century, in the last century. Medicine is more and more precise it was the time to rethink the nose surgery...

*NOriginal Title: Chirurgie du nez: les ultrasons révolutionnent la rhinoplastie

Rhinoplasty: a new technique could change everything*
Only available in French language

The new approach with ultrasonic instruments allows to shape nose bones without the risk of breaking them resulting in less complications. Instead of blindly breaking bones ultrasonic rhinoplasty allows to shape bone under direct visual control...

*NOriginal Title: Rhinoplastie: un procédé nouveau pourrait tout changer
Ultrasonic piezoelectric rhinoplasty allows for more natural results. Miniaturized instruments adapted to the nose anatomy allow for a tailored remodeling of the nose.

A newly developed "ultrasonic rhinosculpting" promises a less invasive procedure with more precise and natural-looking results. Rhinoplasty, or nose job, as it is commonly known, is the fifth most common cosmetic surgery procedure for women and the second most popular for men.

Alexia, a 29 years old French woman have chosen ultrasonic rhinoplasty as this is "less traumatic for my nose and for me" she says. She is totally satisfied with the result and said that "it is totally possible to go back to work a week after the surgery without no one knowing about it..."

COMEG a French Medtech at the forefront of the innovation seeking to provide minimally invasive surgeries...