TODAY'S MEDICAL DEVELOPMENTS

Piezo handpieces for ultrasonic surgery

Minimally invasive procedures with gentle instruments.

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Ultrasonic handpieces are being used with growing frequency in medical applications, for example, with minimally invasive surgical procedures and in dentistry. These instruments, which include ultrasonic scalpels, phaco handpieces and scalers, use acoustic waves to facilitate the processing of hard or soft tissue.

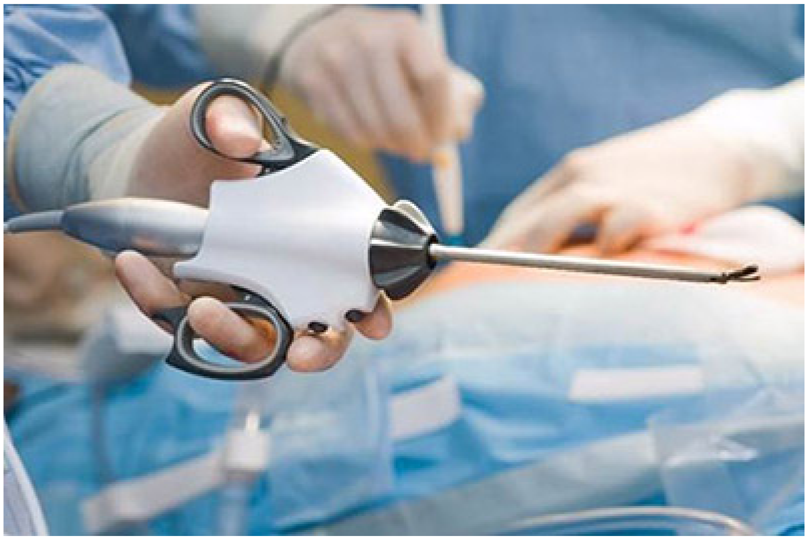


Figure 1: Ultrasonic handpiece for soft tissue dissection and coagulation.

Hard tissue, such as bones or teeth, can be machined with drills or burs, for example, during oral surgery. In this case, ultrasound is used to facilitate the mechanical processing by means of additional shocks or cavitation. Depending on the selected working frequency, tissue can be processed faster, and also more selectively, such as to protect blood vessels in the surrounding area. When working on soft tissue, such as muscles, the targeted generation of ultrasonic waves allows the blades of a scalpel to oscillate in a defined manner at very high frequencies. Targeted heat generation – due to friction between the tissue and the surgical instrument – facilitates rapid cutting of tissue with simultaneous coagulation (Figure 1), which prevents severe bleeding and promotes hemostasis. By applying high energy densities at the surgical instrument's point of contact, cutting processes during surgery or biopsy are significantly easier as lower mechanical forces and pressure are required. As a result, surgical incisions can be made smaller and with less trauma to the surrounding tissue. This results in reduced postoperative pain as well as shorter wound healing and thus improved patient recovery.

Furthermore, ultrasonic instruments can be used to gently break up hard concretions, such as tartar or kidney stones, with the aid of cavitation and the force of acoustic waves. Soft tissue structures can also be liquefied and suctioned in a targeted and minimally invasive manner, like during cataract operations (phacoemulsification) or wound debridement.

Ultrasonic handpieces of this kind, which are based on **piezoceramics**, are generally referred to as scalers. Modern scalers consist of a tool and typically include additional functions, such as a light, cooling water, gas supply and suction, which can be integrated into the handpiece and optionally switched on and off as required. Typical applications for ultrasonic scalers include:

- Ultrasonic scalpels and tissue sealing tools, for example in vascular surgery for coagulation;

- Laparoscopic ultrasonic dissection;
- Bone drills and saws, as used in orthopedics and maxillofacial surgery;
- Tartar removal;
- Intracorporeal stone disruption;
- Ophthalmic phacoemulsification;
- Ultrasound-assisted wound debridement

For medical procedures in which hard tissue is processed on a larger scale, rotary tools (such as spiral drills) are used as an alternative. To enable faster tissue removal and reduce trauma to the surrounding tissue, these tools can also be supported with ultrasound.

General structure

A scaler is a handheld, modular ultrasonic transducer. Scalers usually consist of a driver, a booster, and a sonotrode (Figure 2). The driver, also called the converter, generates ultrasonic waves, and usually consists of two or four piezoceramic rings that are screwed together. To prevent overheating during operation of the handpiece, low-loss piezoelectric materials with a high mechanical grade are used, e.g., PIC144, PIC184 or PIC181. These constitute the group of "hard" piezoceramics that are particularly suitable for high-power ultrasonic applications.

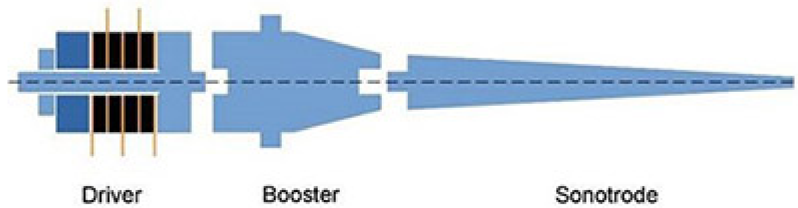
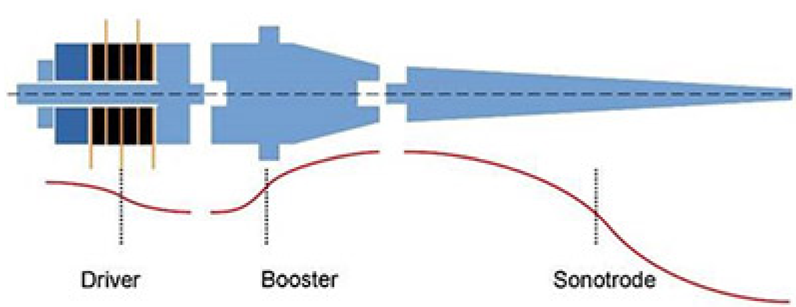


Figure 2: Structure of a scaler, consisting of the three components – piezoelectric driver, booster and sonotrode.

The booster serves both as a mechanical amplifier and as a suspension mounting. The gain value results from the volume ratio of the booster sections on both sides of the suspension mounting. The position of the suspension mounting is determined by the neutral level of the vibration in the booster.

The sonotrode (horn) of the handpiece transmits the ultrasound to the tool at the tip, whereby the contact surface of the tool must be at the maximum of the vibration amplitude. The sonotrode also acts as a mechanical amplifier for the amplitude (Figure 3). The gain value is calculated on the basis of the



ratio of the cross-sectional areas at both ends of the sonotrode. In medical technology, working frequencies of 20kHz to 100kHz are used and the geometry of the entire scaler is designed accordingly in multiples of half of the wavelength.

Figure 3: Position of nodes and amplitudes of ultrasonic waves in a scaler.

This guarantees the maximum amplitude at the tool. The choice of frequency depends on the tissue to be treated: For example, bones can be optimally processed at 20kHz to 25kHz, whereas soft tissue is easiest to process at around 60kHz.

Extremely high-grade alloys are used for the metallic components to keep the mechanical losses to a minimum. Typical materials are titanium, aluminum, or steel alloys. The actual choice of material depends on the requirements for the application, such as the desired weight of the scaler and the permissible costs. In addition, various coatings, such as TiN, are used to prevent corrosion or allergic reactions.

Design variants

For applications in which no variation of the scaler's gain value or operating frequency is necessary, the driver and booster are combined in a single component. Commercial scalers offer the possibility to freely exchange tools – one scaler can be used for different applications. It should be noted that the tools must be precisely matched to the operating frequency of the respective scalers to ensure optimum operation.

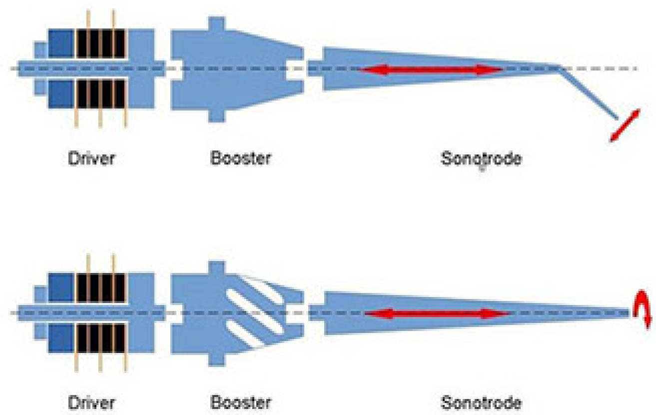


Figure 4: Scaler with angled sonotrode and spiral sonotrode.

For special applications, non-axial vibrations may also be required. To drill into dense bone tissue, additional torsional motion is advantageous; when sawing soft bones, transverse vibration is required (Figure 4). The scaler's functions can thus be optimized and unwanted tissue trauma minimized via relatively simple modifications to the design.

System design

The overall design of a high-power ultrasonic transducer is simulated in advance using FEM (finite element method) models. Several key properties must be considered when designing a new scaler:

- Optimum operating frequency
- Vibration amplitude
- Operating temperature/cooling
- Vibration mode

The working frequency is primarily determined by the mechanical properties of the tissue to be processed, as well as the type of processing (Table 1, below).

Table 1: Typical ultrasonic frequencies for tissue processing.

Tissue treatment	Frequency [kHz]
Hard-tissue processing	25
Cutting soft tissue	60
Sealing soft tissue	30
Phacoemulsification	25
Tartar removal	35

The maximum available power input, the strength of the tool material and the treated tissue limit, the maximum vibration amplitude at the tool tip. It is also determined by active cooling of the handpiece, which is usually necessary to enable the operator to work without interruption.

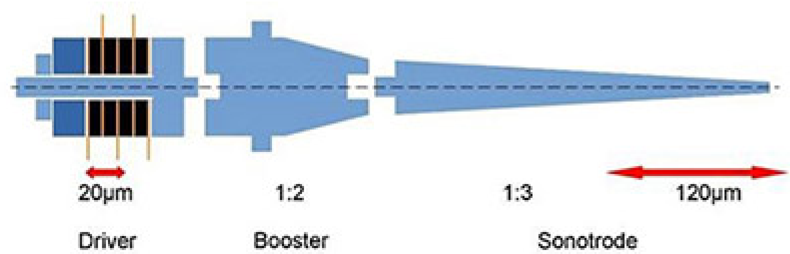


Figure 5: Ultrasonic multipliers in a scaler.

In modular scalers the amplitude at the tool is first approximated on the basis of the resonant amplitude of the driver and the multiplying factors of the booster and sonotrode (Figure 5). However, this is a vast oversimplification, and, for medical applications, should always be verified by means of FEM simulation. Depending on the application, adjusting the vibration mode at the tool tip can lead to significant benefits during treatment. For example, by using a torsional vibration, a bone biopsy can be performed faster and with less damage to the surrounding tissue.

Table 2: Ultrasonic vibration modes for different tissue treatments

Vibration mode	Treatment
Longitudinal	Soft-tissue biopsy
Transversal	Cutting, coagulation

Vibration mode	Treatment
Torsional	Hard-tissue biopsy

Modification of the vibration mode (Table 2, above) is accomplished in the simplest case via modification of the tool tip (e.g., the bend angle) and in the most complex case by adapting the design of the transducer, booster and sonotrode. Critical design factors are the areas of maximum strain, temperature control, and precise positioning of the vibration nodes in the scaler.

Driver design

In principle, a high-power ultrasonic driver consists of an even number of hard PZT (lead zirconate titanate) rings clamped with a bolt between a base body and an inertial mass (Figure 6). The resonant frequency and the deflection of the driver are determined by the entire structure and not solely by the properties of the assembled PZT components. The choice of **PZT material** is mainly determined by the available electronics and cooling. Materials with high coupling, low internal losses and medium bandwidth, e.g. PIC 181, PIC 184, or PIC 144, are usually available (Table 3, below).

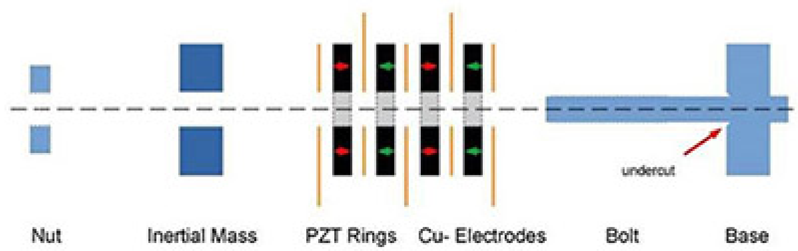


Figure 6: Structure of an ultrasonic driver with positioning of the piezo elements on the base body.

The electrical contact is established by means of intermediate electrodes made of metal foils. Perforated copper-alloy foils are used to carry the high currents in resonance operation and to dissipate the heat from internal losses. The perforation ensures improved force distribution over the surface while maintaining dimensional stability.

Table 3: Properties of hard PZT.

Material	Benefits	Disadvantages
PIC144	Low internal losses	Medium power density
PIC181	High power density	Very narrow bandwidth
PIC184	High bandwidth	Higher internal losses
PIC300	High temperature stability	Less coupling

Care must be taken to ensure that the correct surfaces to be clamped are as parallel as possible. Angular or tapered surfaces usually lead to immediate failure during assembly. Undercutting the inner edges against which the PZT components rest also helps to avoid possible failure due to tilted surfaces. The flatness and roughness of the surfaces affect the reproducibility of the driver's properties. The choice of the electrode for the PZT components has a direct impact here, since the electrode also forms the mechanical contact surface. The electrical insulation is created using epoxy resins, insulating varnishes, or silicone shrink tubing.

The decision as to whether the driver is infiltrated with adhesive (glued stack) or only mechanically preloaded in a dry state (dry stack) depends on the quality of the components used and the area of application. For cost reasons, the glued stack design is often preferred. In this case, the losses due to internal friction are higher and the reproducibility of the operating characteristics lower; however, the structure has a far higher error tolerance than with a dry stack. The adhesive acts as a mechanical mediator for the roughness, flatness, and overall mechanical tolerances.

Resonant drivers must always be mechanically preloaded to avoid tensile stresses during the acceleration phases. The minimum required preload results from the maximum acceleration in free resonant operation and the component masses. The aim is to ensure that no tensile stresses occur, and no separation of the components can take place, even at the maximum free deflection. Since the hard PZT components are particularly sensitive to tensile stress, this can lead to destruction of the driver.

A large number of design variables (mechanical, electrical, thermal, etc.) influence the optimal preload, which is why most manufacturers work with fixed preloads that already includes a high safety factor. Typical preloads are 30MPa to 75MPa (megapascal). To ensure reproducible quality, it is necessary to measure this preload when assembling the scaler. This is achieved either by tightening to a specified torque or by measuring the charge generated by the hard PZT rings during assembly. Since this process is highly dependent on the surface qualities and tolerances of all components, the respective properties may vary widely here. To counteract this, the double-tightening method has become established. In this method the driver is short-circuited, fully preloaded, fully unloaded again and preloaded a second time with a fixed torque or up to a defined load. It is also advantageous if the preloaded components are loosely mounted, i.e. to allow possible deviations in parallelism to be compensated for. This can be achieved, for example, by using loose/tolerant screw threading or floating intermediate rings. In this design, however, a polymer sleeve should be fitted on the clamping bolt to prevent damage caused by dropping.

Medical scalers are generally designed for routine sterilization in autoclaves. Depending on the required standard, scalers must typically be hermetically sealed and survive up to 1,000 autoclave cycles (RT<>135°C, 85% relative humidity). To ensure consistent performance despite such severe long-term exposure, the fully assembled scalers are pre-aged in a process known as “burn-in”. During this process the scalers are stressed multiple times in an autoclave at temperatures above their usual operating range, whereby the frequency and capacitance changes that would otherwise occur are anticipated (Figure 7). It is important to ensure that the completely assembled and preloaded scaler is pre-aged in the short-circuited state. Pre-aging the PZT rings before installation has no demonstrable effect and is not a substitute for pre-aging of the assembled scaler.

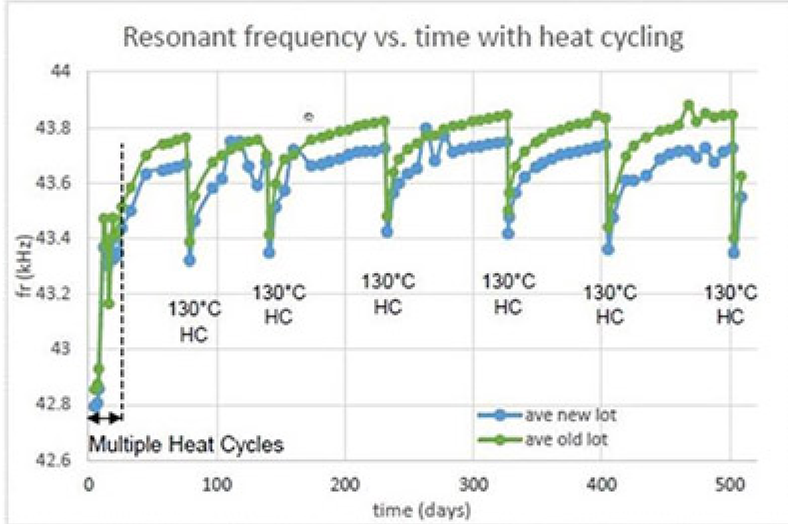


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Figure 7: Frequency drift in a dental scaler during the initial autoclave cycles.

Special applications

A special transducer design is required for use in explosion-proof areas or environments where strong electric fields are not permitted. In such cases the hard PZT rings can be replaced with suitable hard PZT multilayer elements (Figure 8). Although this significantly increases the demands on the power supply and the requirements for active cooling, the operating voltage can be reduced to well below 100V via this approach.

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Figure 8: Hard PZT multilayer ring chips for use inultrasonic handpieces.

Drive electronics

The resonant frequency of power transducers changes depending on the operating status and temperature, whereby the operating frequency and electrical power must be continuously adjusted to ensure optimal operation. The primary task of the drive electronics is to track the resonant frequency of the transducer. In this case, a high-frequency phase-locked loop (PLL) circuit is used to search for the zero crossing of the electrical phase angle and correct the operating frequency accordingly. When designing the electronics, care must also be taken to ensure that the transducer does not run “dry”, i.e. without a load applied, as this could result in damage to the transducer or even injury to the operator. This is achieved by means of active power control using pulse width modulation (PWM). Modern control electronics for high-power ultrasonic transducers combine both control systems (PLL, PWM) with additional overload protection on a single programmable FPGA (field programmable gate array) chip.

Failure mechanisms

The most common cause of failure in high-power ultrasonic drivers is breakage of the PZT components. The main reason for this is a loss of preload, which leads to separation and/or cracking of the components. This does not necessarily lead to a loss of functionality, however, in most cases it is clearly recognizable due to an audible “buzzing” of the scaler. To prevent cracking, the selected mechanical preload when designing the transducer must be high enough that the PZT elements are under compressive stress even in maximum operation. As a first approximation, the preload to be selected is proportional to the mechanical power output.