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ScienceDirect

Physics Procedia 63 (2015) 120 – 126

Physics Procedia

43rd Annual Symposium of the Ultrasonic Industry Association, UIA Symposium 2014

Ultrasonic cutting device for bone surgery based on a cymbal transducer

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Abstract

In this study, we introduce a new prototype ultrasonic cutting device for bone surgery based on a class V flextensional cymbal transducer, configured for use in power ultrasonics applications, which removes many of the geometrical restrictions on the cutting tip of Langevin-based transducers. The benefit of incorporating a cymbal transducer is that since the cutting blade itself does not have to be tuned, blade design can focus more closely on delivering the best interaction with bone to provide a highly accurate cut. Small variations to the geometry of the blade do not affect the final resonance frequency. Also the ultrasonic device can be miniaturised to allow the design of devices for delicate orthopaedic procedures involving minimal-access surgery. The results show how the cymbal transducer, driven by a single piezoceramic disc, can excite sufficiently high vibration displacement amplitudes at lower driving voltages. This is achieved by adapting the configuration of the cymbal to remove the problem of epoxy layer debonding, and by optimising the cymbal end-cap and geometry through finite element modelling supported with experimental vibration characterisation. Preliminary characterisations of the resulting prototype ultrasonic bone cutting device, which operates at around 25 kHz, illustrate the success of this novel device design.

Peer-review under responsibility of the Ultrasonic Industry Association

Keywords: Ultrasonic bone surgery, cymbal transducer, transducer design.

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Peer-review under responsibility of the Ultrasonic Industry Association
doi:10.1016/j.phpro.2015.03.020

1. Introduction

Although the first attempts to introduce ultrasonic technology into bone cutting procedures were reported by Catuna (1952) with his drilling device for dentistry, the main application of this technology was focused on oral prophylaxis procedures or dental scaling. It was not until 2001 that the first ultrasonic device for bone surgery procedures was commercialise, the Piezosurgery® device, which was the result of joint research work between the maxillofacial surgeon Vercellotti and the Italian company Mectron S.p.A. (Vercellotti, 2004; Leclercq et al., 2008). Despite the fact that there is a difference of nearly 50 years between Catuna's experiments and the emergence of the Piezosurgery® device, the basic structure of the design has remained largely unchanged.

Commercial ultrasonic cutting devices have been adopted in a wide variety of surgical procedures, ranging from oral surgeries to maxillofacial surgeries, however there is an important drawback that is inherent to the type of transducer used. Langevin transducers incorporate a piezoceramic stack capable of delivering a few microns of vibration amplitude, and therefore the transducer and the cutting insert as a whole must be resonant to achieve the required ultrasonic displacement amplitude at the cutting tip. The cutting blade itself incorporates high amplitude gain, which can lead to very high stresses, and the design of the blade geometry is somewhat restricted by the requirement for resonance.

Cymbal transducers are a variation of the flextensional moonie transducer design, developed in the early 1990s at the Pennsylvania State University Materials Research Laboratory (Dogan et al., 1997). This class V flextensional transducer consists of a piezoceramic driver (poled in the thickness direction) sandwiched between two shallow shell metal caps. These metal caps have a shallow cavity on their inner surface and they serve as mechanical transformers for converting the high impedance, low displacement radial motion of the ceramic driver into low impedance, large axial-flexural motion of the metal end-caps. The mechanical coupling between the piezoceramic disc and the end-caps is by means of a high strength epoxy, acting as a bonding agent, therefore the conversion of the radial displacement of the piezoceramic to the flexural displacement of the end-caps relies solely on mechanical coupling via this bond. The cymbal transducer benefits from high piezoelectric coefficients and exhibits high vibrational displacement at low frequencies, and has proved to be an excellent transducer for low power applications. However, characterisation of the cymbal transducer as an actuator for an ultrasonic cutting device shows promising behaviour. When different masses are attached to the end-caps, slight variations in the geometry of the added mass do not introduce a significant variation in the resonance frequency of the device. Also, the displacement achieved remains constant, independent of the size of the mass connected. If the mass is a cutting insert, then the cutting insert behaves almost like a rigid body and there is therefore no longer a requirement for a tuned insert.

In previously reported research (Bejarano et al., 2014), a variation of the original cymbal transducer (OC) design was developed for use in high power ultrasonic applications. The new design (NC) incorporates a combination of a piezoceramic disc coupled with a metal ring as the driver. The end-cap is attached to the metal ring through a few bolts and to the piezoceramic disc through an epoxy layer. The mechanical coupling of the end-caps with the piezoceramic enables the device to be driven at higher excitation levels and therefore higher displacements. A difference of more than 30 μm was observed when comparing the operational limit between the OC and the NC for different end-cap materials.

In this work, a new prototype ultrasonic cutting device for bone surgery based on the NC transducer is introduced. Optimised for use in power ultrasonics applications, it removes many of the geometrical restrictions on the cutting tip of current commercial devices. The benefit of this technology is, therefore, that the cutting blade does not have to be a resonant component and design can focus more closely on delivering the best interaction between the blade and bone to provide a highly accurate cut. Also, due to the high amplification generated by the metal end-cap, it is not necessary to use more than a single piezoceramic element to deliver the desired vibration amplitude. Therefore it can be miniaturised to allow the design of devices for delicate orthopaedic procedures involving minimal-access surgery. Preliminary trials of a prototype ultrasonic bone cutting device, which operates near to 25 kHz, are presented to illustrate the success of this novel device design.

2. Ultrasonic cutting device based on a new cymbal design

Based on the NC configuration, a novel ultrasonic cutting device (UCD) is proposed. Unlike a conventional cymbal, this device has only one end-cap and a back-shell where the piezoceramic disc is placed and bonded with insulating epoxy resin. The metal end-cap is attached directly to the back shell using bolts and to the piezoceramic disc with an epoxy layer. Fig. 1 shows the finite element analysis (FEA) model developed of the UCD, with no cutting insert attached. The end-cap of the cutting device incorporates a threaded stud in the top surface for the connection of the different inserts. The design of the whole transducer is optimised to transfer the radial movement of the piezoelectric disc directly to the metal end-cap, so that at the cavity resonant mode the device exhibits a pure axial movement, consistent with the cavity mode of a conventional symmetric cymbal transducer. The back-shell of the UCD was designed, through FEA, to prevent bending of the piezoceramic and to maximise the conversion of radial movement of the ceramic to axial movement of the end-cap.

The piezoceramic disc is placed in the back-shell and fixed with non-conductive epoxy, to ensure that the electrodes are not in contact with the metallic back-shell. The electrical leads are welded directly to the surfaces of the piezoceramic disc and brought out through a hole placed in the back-shell. When the epoxy that covers the piezoceramic disc is cured, the surface is sanded with a fine grain sand paper to remove any excess epoxy and the end-cap is fixed.

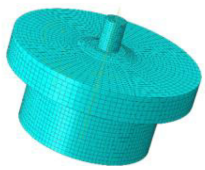


Fig. 1: FE model of the UCD.

3. Fabrication

The UCD was designed to operate at a cavity mode resonance frequency nominally at 25.5 kHz (this frequency can vary slightly depending on the type of insert attached). The end-cap with the threaded stud was made from a solid metal bar using a thread-mill machine. The dimensions for the end-cap are listed in Table 1 and for the back-shell in Fig. 2. The piezoceramic disc used was PIC181 from PI ceramics with a diameter of 27 mm and 3 mm thickness. The end-cap and back-shell were manufactured from Titanium alloy Ti-6-4.

Table 1: End-cap dimensions.

Dimension	**End-cap (mm)**
Total diameter	33 ± 0.01
Base cavity diameter	11 ± 0.01
Apex cavity diameter	6 ± 0.01
Max. cavity depth	1 ± 0.01
Thickness	1.1± 0.01
Threaded part length	5 ± 0.01
Threaded part diameter	3.5 ± 0.01

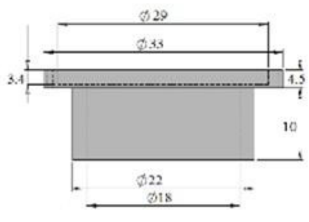


Fig. 2: Geometry of the back-shell of the UCD. Units in mm.

4. Dynamic and modal characterisation

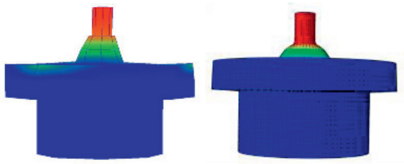
The experimental characterisation of the cutting device consisted of two different procedures. The first procedure was the characterisation of the cutting device under free vibration conditions, where the response of the cutting device with and without out any insert connected was analysed. The second procedure was the characterisation of the cutting device under operational conditions. For these experiments, a commercial insert used for osteotomy was attached. The insert was the OT7 developed by Mectron S.p.A. The fabricated device is shown in Fig. 3.

a) b)

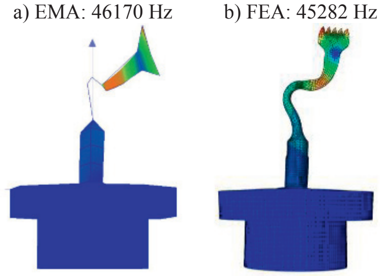
Fig. 3: UCD a) without insert b) with the OT7 insert attached.

4.1. Characterisation under free boundary conditions

For the characterisation, an experimental modal analysis (EMA) was conducted using a 3D laser Doppler vibrometer (LDV) with DataPhysics SignalCalc acquisition software. The dynamic behaviour of the two assemblies was studied through a combination of FEA and EMA in order to find the natural frequencies and mode shapes of the cutting device. The experimentally and numerically derived results are shown in Fig. 4. Good correlation can be seen between the mode shapes of the FEA predictions and the EMA results. The percentage differences between the resonance frequencies for the cutting device without insert and the cutting device with the OT7 are 1.92% and 0.44% respectively.



a) EMA: 46170 Hz b) FEA: 45282 Hz



c) EMA: 25842 Hz d) FEA: 25727 Hz

Fig. 4: Mode shapes from (a) EMA and (b) FEA of the cutting device without insert and (c) EMA and (d) FEA for the cutting device with the OT7 insert.

4.2. Characterisation under operational conditions

Bone cutting experiments were conducted using the UCD by the Edinburgh Department of Orthopaedic Surgery The aim of the study was to characterise the extent of cell death around the cut site created by different devices with and without the use of a coolant. Ultrasonic devices used to divide bone have been shown to have advantages such as high precision and to produce less damage to both soft and hard tissues resulting in quicker recovery times than traditional instruments such as bone burrs and bone saws.

For the experiments, six rat femurs were sectioned in two different locations using the ultrasonic cutting device with the OT7 insert. Two different operational conditions were analysed. The first was the cutting action without any coolant and the second incorporated a coolant liquid, Phosphate Buffered Saline (PBS) at physiological concentration, applied directly to the zone of the cut.

After the bones were sectioned with the UCD, they were fixed using 4% formalin for 18 hours before decalcification in EDTA for 6 weeks. The specimens were then embedded in wax and stained with Haematoxylin and Eosin (H&E). Histological examination was carried out to ascertain the cell death in the bone surrounding the cut site. The experiment using the ultrasonic device is shown in Fig. 5 and a H & E stained section showing the sites of live and dead cells can be seen in Fig. 6.

Fig. 5: Image of Novel Ultrasound Cutting Device driven by cymbal transducer.

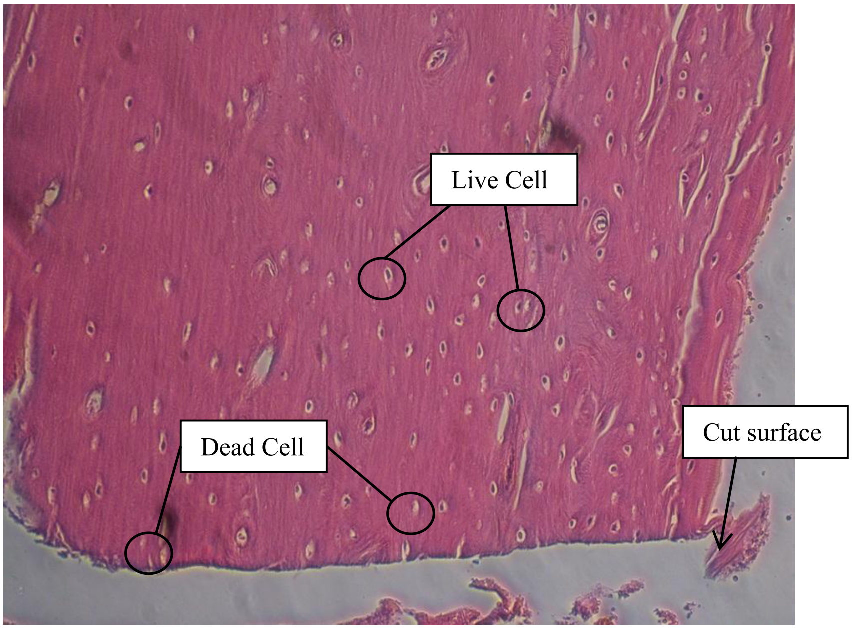


Figure 6: H & E stained section showing sites of live and dead cells

Imaging software (Image J, Co, location) was used to identify and count the lacunae within the bone where the cells (osteocytes) reside. Examination of these for the presence of the cell nuclei determined if the cell was alive or dead.

The slide was divided into 50 μm zones from the cut surface to the interior of the bone. In each zone, the number of live and dead cells, were counted and compared for statistical significance by an ANOVA. In Fig. 7 the percentage of live cells for each zone for both operation conditions, using coolant and with the absence of it, are shown. The results particularly show that very close to the cut site, the use of a coolant has no impact on the percentage of live cells, there is then a region up to 250 μm where the use of a coolant is an advantage and then further away from the cut site there is again no advantage. It should be noted that the differences between the cooled and non-cooled devices were not significantly different. The results for the percentage of live cells compared very favourably with similar analyses conducted for other, more traditional bone cutting devices such as saws and burrs. Figure 8 compares the cell death using the UCD with a sagittal saw (Stryker UK, Newbury, UK) and a hand powered steel saw. Statistically significant differences in cell death were seen between the UCD and both the electric sagittal saw and the manual powered saw at 0-50μm from the surface. Between 50 and 200μm the UCD was statistically significantly better than the sagittal saw. At distances greater than 200μm from the surface there were no statistically significant differences.

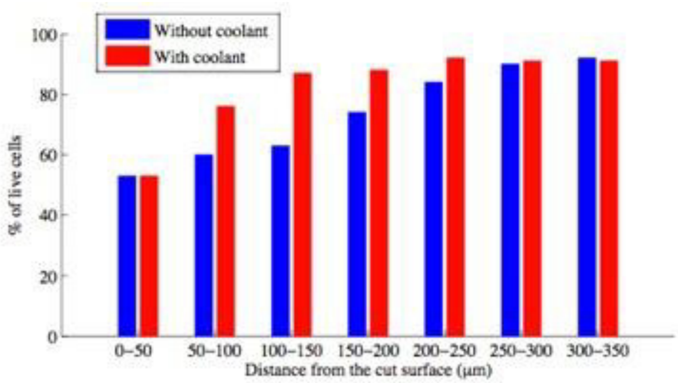


Fig. 7: Histological analysis of the cut bones divided into zones of 50 μm.

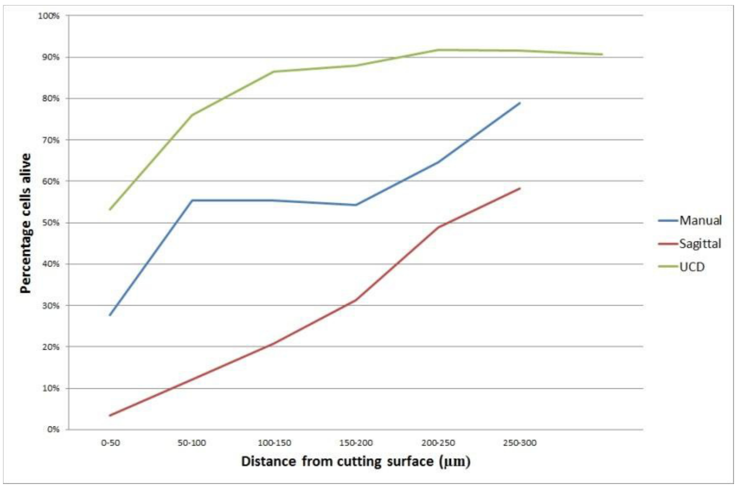


Figure 8: Histological analysis cell death for UCD v sagittal v manual

5. Conclusions

In this paper, a novel ultrasonic cutting device for bone surgery (UCD) based on the new design (NC) has been investigated. The device consists of a single metal end-cap coupled with a back-shell in which the piezoceramic disc is placed. Therefore, the radial motion of the piezoceramic disc is transformed directly to an amplified axial motion of the end-cap, which creates a single radiating face. The design of the back-shell was developed through finite element modelling in order to optimise the transfer of energy from the piezoceramic disc to the end-cap, without introducing additional modes of vibration or bending motion of the disc.

For the design of the cutting device, the metal end-cap incorporates a threaded bar to allow the connection of different cutting tips. The modal and dynamic characterisations of the cutting device have shown a good correlation between the predicted values of frequency, displacement and mode shapes using FEA, and the experimental results. For the characterisation of the device under realistic operational conditions, several cutting experiments were undertaken by the Department of Orthopaedic Surgery of the University of Edinburgh on rat bones. The results obtained have demonstrated promising performance of the device, realising precise cuts in animal bones using a commercial cutting blade designed by Mectron S.p.A.

Acknowledgments

The authors would like to thank EPSRC through an IAA award for funding this research and Mectron S.p.A. for providing the inserts for this study.

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