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An ultrasonic orthopaedic surgical device based on a cymbal transducer

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ABSTRACT

An ultrasonic orthopaedic surgical device is presented, where the ultrasonic actuation relies on a modification of the classical cymbal transducer. All current devices consist of a Langevin ultrasonic transducer with a tuned cutting blade attached, where resonance is required to provide sufficient vibrational amplitude to cut bone. However, this requirement restricts the geometry and offers little opportunity to propose miniaturised devices or complex blades. The class V flextensional cymbal transducer is proposed here as the basis for a new design, where the cymbal delivers the required vibrational amplitude, and the design of the attached cutting insert can be tailored for the required cut. Consequently, the device can be optimised to deliver an accurate and precise cutting capability. A prototype device is presented, based on the cymbal configuration and designed to operate at 25.5 kHz with a displacement amplitude of 30 μm at 300 V. Measurements of vibrational and impedance responses elucidate the mechanical and electrical characteristics of the device. Subsequent cutting tests on rat femur demonstrate device performance consistent with a commercial Langevin-based ultrasonic device and show that cutting is achieved using less electrical power and a lower piezoceramic volume. Histological analysis exhibits a higher proportion of live cells in the region around the cut site for the cymbal device than for a powered sagittal or a manual saw, demonstrating the potential for the ultrasonic device to result in faster healing.

1. Introduction

Ultrasonic cutting devices have been developed for use in a number of orthodontic and surgical procedures, for example in oral prophylaxis [1], periodontics [2], and soft [3] and hard [4] tissue dissections. The increasing number of surgeons adopting ultrasonic devices has increased the demand for devices capable of procedures where delicate tissue structures must be protected, and at surgical sites that are difficult to access. This presents challenges in design for miniaturisation and for the incorporation of more complex geometries. Currently, ultrasonic surgical devices most commonly consist of a Langevin piezoelectric transducer with an insert, such as a cutting blade, attached, where both the transducer and cutting insert are tuned to resonate in a longitudinal mode at a low ultrasonic frequency, usually in the 20–60 kHz range. Langevin transducers incorporate a stack of piezoceramic discs or rings, and a Langevin-type device must be in resonance to achieve sufficient ultrasonic displacement amplitude at the cutting tip, usually in the order of several tens of microns. The requirement for resonance places design constraints on the geometry of ultrasonic devices. For longitudinal-mode resonance, the device geometry must be a multiple of a half-wavelength at the operating frequency. If required, combined longitudinal-flexural [5] or longitudinal-torsional [6] motions of the cutting tip can be introduced through features such as slits in the transducer and/or cutting insert and curved cutting inserts, and this motion can be further controlled by the proximity of features to nodal locations. The cutting insert itself must incorporate amplitude gain, usually achieved through increasing the slenderness of the device towards the cutting tip, but this can result in stress concentrations, causing failure of the insert, and motion consisting of multiple modes of vibration through the excitation of nonlinear responses [7]. There is hence an opportunity to design ultrasonic orthopaedic devices for a much wider range of bone cutting procedures, if the actuation of the transducer alone can excite sufficient ultrasonic amplitude, for example in the order of tens of microns, such that there is no need for the cutting insert to be in resonance. One such potential transducer is the class V flextensional transducer, known as a cymbal. This study reports on the adaptations of the cymbal transducer in the design of an ultrasonic orthopaedic surgical device (UOSD) and on the subsequent characterisation of its performance in comparison with more conventional bone cutting devices. The motivation for the development of the UOSD is to demonstrate that an

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ultrasonic device for orthopaedic surgery based on a cymbal transducer can deliver comparable or improved cutting in bone at low electrical power and with lower volume of piezoelectric material than a device based on a Langevin transducer, and that the device can cut successfully without tuning the cutting insert.

1.1. Ultrasonics in bone surgery

The first attempt to introduce ultrasonic technology into bone cutting procedures was a drilling device for dentistry [8]. However, subsequent applications of ultrasonics in dentistry have principally concentrated on dental scaling. A number of inventions by Balamuth formed the foundation for developments in this field. The first of these inventions was a cutting device which incorporated an abrasive slurry [9]. The original device comprised an outer casing with an enclosed magnetostrictive transducer which was connected to a mechanical amplifier, known as a horn. The horn was secured at one end of the laminated stack of magnetostrictive material, and a threaded end-section allowed for connection of a cutting insert to the horn. During cutting, the abrasive slurry was applied directly to the bone surface. The device possessed an external flexible sheath, which contained capillary tubing for abrasive slurry delivery to the cut site and also provided cooling for the transducer.

However, it was not until 2001 that the first ultrasonic device for bone surgery procedures was commercialised, called Piezosurgery® [10,11]. Although there is half a century of research and technological advances between the early invention of Balamuth and the launch of the Piezosurgery® device, the basic design elements have remained largely unchanged, with the exception of the replacement of the magnetostrictive material with piezoelectric ceramics. The Piezosurgery® device comprises a Langevin transducer incorporating a stack of four PZT rings under compression which are coupled to a horn with a threaded end to enable the attachment of different cutting inserts. Inside the transducer body, a tube is introduced, running parallel to the compression bolt, to deliver coolant directly to the cutting tip. The coolant controls the temperature of both the transducer and the cutting site, and also irrigates the cutting site. The Piezosurgery® device operates at a frequency in the range 24–36 kHz. The piezoceramic stack, transducer horn and cutting insert generate micro-vibrations which have a displacement amplitude between 60 μm and 210 μm, depending on which cutting insert is attached, and the designated electrical input power. The device is able to cut mineralised tissue whilst avoiding damage to surrounding neurovascular and other soft tissues, and delicate connective tissue structures, thereby ensuring enhanced precision and visibility and maintaining a blood-free surgical site.

1.2. The cymbal transducer

Although commercial ultrasonic cutting devices have been adopted for a range of surgical procedures, particularly in oral and maxillofacial surgeries, the limitation of the requirement for resonance can restrict the development of new designs. The cymbal transducer is a type of flextensional transducer that was evolved in the 1990s from the moonie transducer [12]. This class V flextensional transducer consists of a piezoceramic disc, poled in the thickness direction, sandwiched between two dome-shaped metal shell end-caps. The resonance frequency of the transducer is dependent on the material properties of the end-caps and their dimensions [13]. Each end-cap possesses a cavity which enables the structure to behave as a mechanical transformer, converting the radial motion of the piezoceramic disc into axial-flexural motion of the end-caps. The mechanical coupling between the piezoceramic disc and the metal end-caps is formed by an epoxy resin. This material acts as a bonding agent, meaning that the conversion of the radial displacement of the piezoceramic to the flexural displacement of the end-caps relies on the formation and strength of this bond.

1.3. Modification of the cymbal for power ultrasonic applications

The mechanical coupling is a limitation for the application of the cymbal transducer in power ultrasonic devices [14–16], where the epoxy resin bond layer is known to fail under ultrasonic vibration. In an attempt to address this, an adaptation of the classical cymbal (CCym) transducer design was fabricated [17], based on the improved cymbal transducer proposed by Lin [16]. This transducer incorporates a piezoceramic disc which is coupled with a metal ring, and fixed with bolts to two end-caps. A high-strength epoxy resin is used to reinforce the mechanical coupling to the piezoceramic disc. This coupling between the end-caps and the piezoceramic disc enables the device to be driven at much higher excitation levels than the CCym transducer. For example, it has been demonstrated that a CCym can be driven at 40 V with a displacement amplitude of approximately 50 μm prior to failure, compared to a displacement amplitude of 90 μm at 100 V for the improved transducer [17]. This displacement amplitude is achievable with the improved transducer, since the mechanical coupling does not rely on the integrity of the epoxy bond layer. Furthermore, the experimental characterisation results of this improved transducer demonstrate that even though the transducer incorporates additional assembly complexity, by the inclusion of threaded bolts and a metal ring, the cavity resonance mode of the transducer matches that of the CCym.

Importantly, for the design of orthopaedic devices, when a metal bar was attached to an end-cap, the displacement amplitude was largely independent of the mass of the bar within the range of masses studied, from 0.39 to 1.48 g, a range that is consistent with small bone cutting blades [18]. Based on the improved transducer, a new configuration was developed for use in power ultrasonic applications [17], referred to as the single output face cymbal transducer (SOFCym), for operation with electrical power of at least 50 W. In this configuration, one of the end-caps is replaced by a supporting back-shell as shown in Fig. 1. A preliminary study of an ultrasonic cutting device based on the SOFCym, which was focussed on transducer design, demonstrated that it could be used to cut bone in ex vivo conditions [19]. This research is extended here to perform design and experimental characterisation of the device and bone-cutting trials. The UOSD under investigation is designed to operate at 25 kHz, which lies within the range of resonance frequencies (typically 20–30 kHz) of commercial ultrasonic surgical devices. By miniaturising the device, there is potential for delicate orthopaedic surgeries to be performed, with less tissue damage, as minimally invasive procedures.

2. Design and fabrication

The schematic of a CCym is shown in Fig. 1(a), where two identical metal end-caps are bonded to a piezoelectric ceramic disc. The SOFCym designed for this study, Fig. 1(b), comprises a single titanium (Ti–6Al–4V) end-cap with a threaded stud for cutting insert attachment, a piezoelectric ceramic disc, and a titanium supporting back-shell. In addition to supporting the end-cap, the back-shell houses the piezoelectric element, in this case a piezoceramic disc (PIC-181, PI Ceramic GmbH), and bonding is achieved with an insulating epoxy resin (Eccobond, Ellsworth Adhesives Ltd) which has a lap shear strength of 17 MPa. The dimensions of the SOFCym components are provided in Table 1.