A longitudinal-torsional mode ultrasonic needle for deep penetration into bone

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\textbf{ABSTRACT}

This work presents a longitudinal-torsional (L-T) composite mode ultrasonic needle device for deep bone penetration. The L-T needle is a geometrically modified version of an L-mode needle whose efficacy as a prototype ultrasonic bone biopsy device has been previously demonstrated by the authors. Finite element analysis (FEA) aided in the design of the L-T needle, with the aim of maximising the achievable torsional displacement while matching the longitudinal displacement achieved by the L-mode needle. Experimental modal analysis (EMA) of the fabricated ultrasonic device was used to identify the modal parameters and validate the FEA model. Harmonic analysis then provided an insight into how the inherent nonlinearities of the high-power transducer are affected by incorporating the geometrical features that degenerate the L mode into an L-T mode. High power characterisation shows that the longitudinal displacement amplitude of the L-T mode needle is larger than that of the L-mode needle. Comparative penetration tests in fresh Wistar rat skull were evaluated by investigating cell death and cell survival. The region of statistically significant cell death was small for both devices, with the combined axial and shear motion of the L-T device causing increased osteocyte necrosis within this region. Nevertheless, the results suggest a promising environment for post-operative healing. It is shown how this technology offers a potential technique for a surgical approach to the petrous apex, an application that requires a deep penetration into bone. The benefits of ultrasonic osteotomy are therefore well established, however it is also accepted that current devices are not effective when deep penetrations into bone are required [1,13].

A prototype ultrasonic needle that operates in a longitudinal (L) mode, shown in Fig. 1, has been shown to be capable of excising a core sample of tissue from bone, for example for biopsy. Previous work by the authors [14] demonstrated the ability of the ultrasonic needle to extract a more intact core sample than a standard trephine bone biopsy needle, with less micro-damage to both the recovered sample and the penetration site. Core samples extracted from fresh ovine femur were more cylindrical and exhibited less surface and internal damage. Of importance, the samples were extracted \textit{in-vitro} by applying only sufficient force to the needle to maintain good coupling contact with the bone, whereas trephine needle bone biopsies can require hundreds of Newtons of direct force combined with a twisting action of the needle.

There are other surgical procedures that could benefit from an ultrasonic device capable of deep penetration into bone. One example is...
Access to the petrous apex presents an additional challenge, even for a proven ultrasonic bone biopsy needle, as the temporal bone is particularly dense (reported to reach between 1600 and 2100 Hounsfield units, HU in healthy, mature bone [19]) and consists of 2–3 mm thickness of cortical bone [20]. The vibrational mechanism of bone penetration is therefore important to consider. The presence of a mixture of solid bone (cortex) followed by mastoid bone of different degrees of pneumatisation (depending on each patient’s development) and finally of solid, difficult to penetrate bone towards the petrous apex, presents a major surgical and technical challenge. Given the petrous apex anatomical complexity, being able to penetrate safely towards the petrous apex will additionally create a tool capable of obtaining biopsies from any bony part of the body.

The mode of vibration of an ultrasonic surgical tip affects its interaction with the target tissue and ultrasonic devices are available that exhibit longitudinal, longitudinal-flexural, flexural-flexural, or longitudinal-torsional motion of the tip. For example, longitudinal-torsional mode vibrations have already been incorporated at the tip of some ultrasonic devices for cutting soft tissues [21], for phacoemulsification in the management of cataracts [22] and in sealing larger-sized vessels [23], and flexural-flexural vibration leading to elliptical motion has been incorporated in an ultrasonic aspirator for cartilage removal [24]. However, there are no such devices capable of deep penetration into cortical bone and there is no evidence in the literature that shows whether L-T mode surgical tips could offer measurable benefits over L mode tips for deep penetration. One study that used an L-T mode tip for osteotomy showed it to be highly effective for cutting hard cortical bone, however the geometry of the instrument and tip restricted its use in deep intraoral surgeries [21,26]. L-T mode ultrasonic vibrations have proven beneficial in a number of industrial devices, including in ultrasonically assisted drilling technologies [25,26,27]. For ultrasonic drills, L-T mode vibration has been shown to result in a significant reduction in cutting force [27]. This would clearly be of benefit in bone penetration where a low needle force could enable higher precision and less tissue damage, and hence less risk of morbidity.

In this study we evaluate an L-T mode ultrasonic bone penetrating needle by comparing with one based on L mode vibration of the needle tip. The aim is to demonstrate the L-T needle as a suitable candidate for deep bone penetration, including direct access to the petrous apex, and to draw general conclusions regarding the influence of the vibration mode on the effectiveness of bone penetration, relevant to this and other ultrasonic bone surgery devices.

2. Design and characterisation of the L mode and L-T mode ultrasonic needles

The ultrasonic needles are driven by a Langevin transducer with two piezoceramic rings (PZT-26, Meggitt), copper electrodes and Ti6Al4V end-masses held under compression by an A2 steel bolt (Figs. 1 and 3). The hollow Ti6Al4V needle is connected to the transducer via an M6 threaded stud. The ultrasonic needle devices were designed using finite element analysis (FEA) (Abaqus, Dassault Systemes, Simulia), based on a needle and a transducer that were both a half-wavelength of the longitudinal mode at a nominal 24 kHz resonance frequency, hence operating in the second longitudinal mode (L2). The needle geometry (Fig. 1), and therefore final frequency, of the L mode device was selected by

![Fig. 1. The L mode ultrasonic needle.](image1)

![Fig. 2. Anatomical location of the petrous apex [18].](image2)

![Fig. 3. Components of the ultrasonic longitudinal-torsional needle.](image3)
identifying a design where the frequency spacing around the L2 mode ensured avoidance of coupling with parasitic modes.

For the L-T mode device, by introducing helical flutes into the conical sections of the transducer front mass and needle, mode degeneration diverts part of the longitudinal wave such that there is combined longitudinal and torsional motion of the needle tip. FEA was used to optimise the depth and pitch of a quarter-circle helical cut to give a high predicted value of torsionality (defined as the ratio of the tangential to longitudinal components of displacement at the tip), while ensuring sufficient frequency spacing around the composite 2nd longitudinal – 3rd torsional (L2-T3) mode frequency to avoid coupling with parasitic modes.

The helical cut is defined by its depth (Fig. 4), which is the radial distance from the outside circumference to the inside of the cut, and its pitch, which is the length of one complete turn. By altering the pitch, the twist angle of the cuts was varied between 60° and 360°. The frequencies of the L-T mode and neighbouring modes, and the torsionality, were predicted from FEA models (Fig. 5). Torsionality, was highest in the 180°–240° range, reaching 35%.

A 240° helical cut was selected for the final design. This configuration provided the best compromise between the criteria of modal frequency separation between the bending modes and L2-T3, proximity of T3 and L2-T3, and the predicted overall torsionality. As can be seen in the figure, the frequency separation between the bending modes, B7 and B8, and L2-T3 is largely unaffected by twist angle, whereas T3 comes increasingly close to L2-T3 as the twist angle increases. However, it is the shape of the helical cuts as well as these modal frequency separations that determines the torsionality, as can be seen by the maximum torsionality being predicted for a 180° twist angle. From previous research [28], it has been found that torsional modal frequency proximity to the L-T mode in experiments has a dominating beneficial influence on the measured torsionality, hence the selection of 240° rather than 180° for the helical cut twist angle.

Experimental modal analysis (EMA) was used to measure the modal frequencies and mode shapes of the two needle devices (Fig. 6). Frequency response functions (FRFs) were acquired using a 3D laser Doppler vibrometer (3D CLV, Polytec) to measure the vibration response at a grid of measurement points covering the surface of each device. FRF data was curve-fitted, and the extracted normalised amplitude and phase data was applied to a wire-frame geometric model of the measurement grid, allowing a mode shape to be visualised for each modal frequency. The EMA results are shown along with the FEA predictions for the tuned mode in Fig. 7. For the tuned modes of the needle devices, L2 and L2-T3 modes, resonance frequencies were predicted by FEA models to within 0.4% of the measured data.

Curve-fitted frequency response data for the L mode and L-T mode needles are shown in Fig. 8. Because the needle is slender, there are many responsive modes in the frequency range of the measurement, in the bending, longitudinal and torsional mode families. Despite this, sufficient frequency spacing can be confirmed by observing the absence of parasitic vibration mode responses in the measured L and L-T modes in Fig. 7.

The vibration characteristics were also evaluated using harmonic analysis to provide an insight into how the inherent nonlinearities exhibited at increasing excitation levels [29] are comparatively affected by incorporating the helical cut geometrical features that degenerate the L mode into an L-T mode. Harmonic analysis measures the needle tip displacement response in a frequency band around the resonance frequency at increasing excitation levels. Directly comparing measurements of the two needles allows evaluation of the influence of the helical cuts alone, with the effects of the nonlinearities of the piezoelectric properties and device interfaces being assumed consistent for both devices.

The set-up for harmonic analysis is shown in Fig. 9. For each measurement, a burst sine-wave excitation was applied at frequency increments of 5 Hz, from 400 Hz below resonance to 400 Hz above. The measurement was then repeated at increasing excitation levels from 6 Vpp up to 132 Vpp, and the results are shown in Fig. 10. The longitudinal component of the displacement response was captured for both devices using a 1D laser Doppler vibrometer (Polytec, CFV 055) pointing axially and measuring the normal-to-surface response of the needle tip. Additionally, a 3D laser Doppler vibrometer (Polytec, CLV-3D) was used to measure the tangential component of the response of the L-T needle tip so that the torsionality could be derived from the two concurrent measurements.

For all measurements in Fig. 10, a softening nonlinear characteristic is exhibited by a decrease in resonance frequency with increasing excitation level and a bending to the left of the backbone curve of the measurement data. The shifts in the resonance frequency were then plotted from all three of the harmonic analysis experiments and are shown in Fig. 11. The results show that the resonance frequency shifts are remarkably consistent for the L and L-T devices and that, for the L-T device, the frequency shifts are exactly the same for the two components of the vibration response, even though the tangential displacement is much lower. This indicates that the helical cuts geometry does not significantly affect the nonlinear behaviour, compared to a device without the helical cuts, and the nonlinear softening response is predominantly affected by nonlinearities in properties of the piezoelectric material and interfaces. However, at the highest excitation levels the L-mode needle exhibits a more severe left-bending of the backbone curve of the harmonic analysis data and a concomitant higher frequency shift. This is an indication that the L-T mode needle device will be more stable when driven at higher excitation levels [29].

To compare the performance of the two needles during penetration tests, the devices were driven by a commercial ultrasonic generator (PiezoDrive, PDUS210). The driver incorporates impedance matching, generates a pure sine wave to avoid exciting secondary harmonics, and also provides a high speed resonance tracking capability.

The longitudinal displacement amplitude of the two needles was first measured in free vibration using the 1D laser Doppler vibrometer pointing axially and measuring the normal-to-surface response of the needle tip at increasing power settings of the driver, up to 80 W. The results are shown in Fig. 12. The longitudinal displacement amplitude of the L-T mode needle is considerably higher, 1.9 times higher across the range of excitation levels, than the L mode needle. The change in mass and stiffness along the length of the device that incorporates the helical cuts results in higher ultrasonic amplitude at the tip of the device.

The experiments have focused on characterising the two needle devices in air and have shown that an L-T mode needle can be designed to exhibit high torsionality, larger longitudinal displacement amplitude gain in the L-T mode than its comparable L mode needle, higher longitudinal vibrational displacement when driven by an ultrasonic generator, and better stability at higher excitation levels in harmonic analysis measurements.
3. Penetration tests

Penetration tests were carried out to compare the performance of the L mode and L-T mode needle devices. The speed of performing a precise penetration and the cell death or survival around the cut site were evaluated to evidence the potential for the L-T mode needle to result in faster healing.

A. Penetration tests into Sawbones.

Initially, the devices were tested in the bone mimic material Sawbones® with PCF 20 density, a polyurethane foam which offers similar mechanical properties to trabecular bone. Samples of 50 mm width and length, and 5 mm depth were created, as shown in Fig. 13, and all penetration tests were carried out using hand-held prototype ultrasonic needle devices aligned vertically with the axis of the needles.

The L-T mode device penetrated through the sample depth approximately 40% faster than the L mode device for the same applied force. However, the L mode device stalled in the Sawbones sample unless the operator incorporated a slow clockwise and anticlockwise rotation. In this case it was possible to fully breach the back wall of the sample. Some charring around the hole and damage on the rear penetrating wall of the sample could be seen as shown in Fig. 13 (b). The L-T mode needle penetrated without stalling and with no requirement for an additional rotation motion.

To characterise the mechanical damage of the penetration sites an x-ray microcomputed tomography (μCT) camera (Bruker, Skyscan 1172 with 11 Mpixels) was used. The μCT reconstruction shows that the resulting hole of the L mode needle is larger than that of L-T mode needle due to the rotational motion performed by the operator. The
incorporation of torsional vibrational motion of the tip of the L-T mode device eliminates the need for rotation of the needle, increasing the precision of the cut and creating a smaller hole.

B. Penetration tests into Wistar rat.

Ex vivo penetration tests were performed with the L mode and L-T mode ultrasonic needles. Biological effects were evaluated by investigating cell death and cell survival. Fresh Wistar rat skull was acquired at the time of sacrifice, Fig. 14. The tissue used was discarded from a non-related study, thus minimising the use of animals for research purposes. Skull penetrations were conducted with the application of saline solution, which is commonly used in surgical practice for irrigation and to limit the temperature rise at the cutting site to avoid tissue necrosis.

Eight skulls were utilised giving \( n = 8 \) penetration tests for each device. The hemisphere penetrated was varied between each skull to produce an even distribution of left and right hemisphere tests of each device. After penetration by both devices, the top of the skull was

![Fig. 8. Curve-fitted frequency response function of the (a) L mode needle and (b) L-T mode needle.](image)

![Fig. 9. Experimental set-up for Harmonic Analysis (HA).](image)

![Fig. 10. Harmonic analysis results in an 800 Hz band, where 0 represents the resonance frequency measured at the lowest excitation level. The longitudinal displacement measured from (a) the L mode needle and (b) the L-T mode needle. (c) The tangential displacement of the L-T needle.](image)

![Fig. 11. Frequency shift of the tuned mode for increasing excitation level.](image)
surgically excised. A gap > 5 mm around each penetration site was maintained and these portions of skull were processed for further analysis using the methods detailed in [30]. Bone sections, cut perpendicular to the penetration direction, were placed in 4% formalin for 48 h before decalcification in 10% ethylenediaminetetraacetic acid (EDTA) for 6 weeks. The specimens were then embedded in wax, sectioned, and stained with haematoxylin and eosin (H&E). The live and dead cells, and their locations were then identified through a histological examination of the scan at 10x magnification. Image analysis software (ImageJ) was used to record the position of the lacunae within the specimen where the cells (osteocytes) are found, as shown in Fig. 15. The presence of the cell nuclei indicated that there were live cells within the lacunae. Absence of nuclei within the lacunae indicated that the cell had died. Some darker pink staining and browning can be seen at the cut site, representing some alteration to the matrix of this part of the bone, with likely change to the collagen area [31]. Although irrigation was used for cooling during penetration, the staining is most likely due to very localised heat damage where the irrigation liquid was not reaching.

The scan was split into 20 µm regions, moving away from the cut site, and within each region the quantity of both live and dead cells was obtained and statistically compared using an analysis of variance (ANOVA) with a level of significance of $p < 0.05$. There were no statistically significant differences in the percentage of cells alive and dead between the two cutting devices across any of the analysis regions. The live cell percentage data for each region are shown in Fig. 16. In a previous study using comparable methods [32], the cell death during ultrasonic cutting of rat bone resulted in less cell death than a manual cutting tool. The result produced in this study, with a higher initial baseline of cell survival, is consistent with these previous findings.

The L-T device penetration resulted in a higher percentage of cell death than the L device. As the penetration tests involved irrigation it is unlikely that this is due to thermal necrosis in the adjacent bone but rather due to mechanical shearing. A zone of osteocyte necrosis is commonly observed at the fracture surface in bone fractures caused by direct mechanical damage and disturbance of the bone matrix causing disconnection of osteocytes from neighbouring cells [33]. The results in Fig. 16 suggest that the combined axial and shear displacement induces increased osteocyte necrosis directly around the penetration holes as compared to the L mode needle. However, the inflated cell death by the L-T device is only apparent within the first 60 µm region of the penetration site. Beyond 60 µm the difference in the cell survival for the two devices is minimal, both > 70%. This small zone of dead cells shows promise in terms of the risk of delayed healing or non-union occurring.

4. Surgery of the petrous apex

This work has demonstrated the potential for an L-T mode ultrasonic needle to achieve penetration of bone with high precision and minimal damage around the cut site. An ultrasonic, navigated biopsy tool can offer the ability to access pathologies of the lateral skull base and the petrous apex through a keyhole, utilising a safe and minimally invasive technique that will reduce morbidity and facilitate accurate diagnosis and tailored treatment.

Laboratory-based evaluation of the L-T mode ultrasonic needle device was performed using a surgical mock-up of the petrous apex.
procedure. A temporal bone trainer was used (Phacon, Temporal Bone Trainer). The Phacon is a benchtop surgical navigation system coupled with advanced and realistic 3D printed skull models. This temporal bone trainer is a modular navigation system for surgical training based on the CT scans of real patients. The system shown in Fig. 17 consists of a navigation camera, instrument tracker, head, bone patient Schmidt and a laptop. The navigation software provides visual and tactile feedback through sensors. The bone insert Schmidt has sensors incorporated so the system can detect if the surgical instrument has contacted a critical anatomical structure such as the dura mater.

The L-T mode needle was used to perform penetration tests on the temporal bone skull model. The tests were performed by an experienced ENT surgeon subspecialised in petrous apex surgery. The location and direction of the penetration through the mastoid bone and angle of attack is shown in Fig. 18 (a). The device successfully penetrated the cortical of the mastoid bone before continuing through the trabeculae as illustrated in Fig. 18 (b).

Penetration of the petrous apex was achieved in minutes, as compared to the 12 h for the surgical intervention normally required by the surgeon to excise a biopsy. To access the petrous apex the surgeon first penetrated through the mimic of the cortical bone of the mastoid, which varies in thickness across its surface. This dense, thick cortical bone proved particularly difficult to penetrate at locations of large thickness, slowing progress. On reaching the cancellous bone mimic, penetration was fast and the petrous apex was easily accessed without the needle coming into contact with any of the models of delicate anatomical features. These initial surgical mock-up tests provided early confidence that the L-T ultrasonic needle was potentially capable of performing this surgical approach and could be a good candidate device for achieving difficult and deep bone penetrations where there is currently no viable alternative.

5. Conclusion

This work focused on investigating the efficacy of an L-T mode resonant ultrasonic biopsy needle for deep penetration of bone. Evaluation of the L-T mode device was achieved through comparisons with an L mode ultrasonic needle, including using finite element analysis, experimental modal analysis, and harmonic analysis to characterise the two prototype devices.

The curve fitted FRFs exhibited dense modal responses due to the slender hollow profile of the needles resulting in close modal frequencies of longitudinal, torsional and bending modes. However, sufficient frequency spacing was confirmed by the absence of parasitic mode coupling. Also, despite the significant geometrical modification of the helical cuts and consequent differences in axial and transverse stiffnesses between the L-T mode needle and L mode needle, the harmonic analysis showed little difference in their softening nonlinear response, apart from at the highest excitation levels where the L mode needle
exhibited a more severe bend in the backbone curve, indicating that the L-T mode needle would be more stable at high excitation levels.

Penetration tests into Sawbones, the L-T mode device was faster and more precise, resulting in a highly circular and less damaged hole surface. Additionally, without the manual rotation required to penetrate using the L mode needle, the L-T mode needle procedure was simplified. For bone penetration tests in Wistar rat skulls, the percentage of live cells close to the penetration site was compared. Penetration with the L-T device resulted in higher cell death up to 60 µm from the penetration site, expected to be due to combined shear and axial deformation. However, the regions of high cell death were small for both ultrasonic needle devices which is known to be conducive for improved post-surgical healing.

The surgical treatment of the petrus apex requires an instrument capable of precise penetration through the mastoid bone. As one of the most inaccessible locations of the skull, the procedure is challenging, often taking up to 12 h. The L-T mode ultrasonic needle was evaluated as a candidate technology for this procedure using the Phaco temporal bone surgical trainer. Successful penetration of this dense and thick bone mimicking 3 mm has provided a strong basis for further investigations of the efficacy of this device for this and other deep bone penetration surgical procedures.

Author contributions
RC contributed to the drafting of the manuscript, the design, fabrication and characterisation of the devices and the data analysis. RW contributed to the penetration experiments, the assessment of cell survival and the data analysis. GK conceived the potential clinical application and characterisation of the devices and the data analysis. ML and HS conceived the study, coordinated the vival and the data analysis. GK conceived the potential clinical application and characterisation of the devices and the data analysis.

Declaration of Competing Interest
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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