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The effect of driving conditions on the performance of an ultrasonic bone biopsy needle

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Ultrasonic surgical devices are currently used in various soft and hard tissue surgeries. This study focuses on investigating how modifications of the device driving signal can affect the needle penetration speed. The penetration speed, and therefore time for extraction of a biopsy, should be comparable with a conventional trephine biopsy needle. The ultrasonic bone biopsy device was designed using finite element analysis (FEA) and tuned to operate in a longitudinal mode at 25 kHz. The device was manufactured and experimental modal analysis (EMA) was used to validate the FEA model and measure the modal parameters. A series of tests were carried out, based on the time to perform a 5mm penetration of the needle into a polyurethane foam which acts as a substitute trabecular bone material. During each penetration the temperature and time were recorded. Following this, the study focused on investigating power modulation techniques, as have been widely adopted for phacoemulsification where power modulation in cataract surgery delivers less ultrasound energy to the eye and hence improves visual rehabilitation. It is shown how modifications to the signal shape and power modulation techniques when driving the ultrasonic bone biopsy device effect the penetration speed of an ultrasonic needle device.



1. INTRODUCTION

Ultrasonic surgical devices are currently used in a number of soft and hard tissue surgical procedures, where they offer precision cutting and tissue selectivity. Ultrasonic cutting of bone allows cutting with low force, while reducing the risk of damage to surrounding soft tissues compared with manual instruments.¹

An ultrasonic bone biopsy needle device, reported previously, is developed in this current study.² Ideally, the penetration speed, and therefore time for extraction of a biopsy, should be comparable with a conventional trephine biopsy needle. Towards this aim, the new prototype incorporates a redesigned and sharper tip, and this current study focuses on how modifications of the device driving signal can affect the needle penetration speed. A resonant tracking system drives the ultrasonic needle device at resonance and enables an investigation of power modulation techniques. Sawbone, a polyurethane foam trabecular bone mimic, is chosen as the sample material as its consistent properties make it suitable for evaluating the penetration speed. While Sawbone is not suitable for evaluating temperature in bone directly, as it does not exhibit comparable thermal properties to bone, it does provide some insight as to whether power modulation can affect the temperature at the needle penetration site. A 5 mm insertion is recorded in each test using a thermal camera to record temperature at the site and penetration speed.

2. DESIGN

An ultrasonic bone biopsy needle was designed and tuned using Abaqus finite element analysis (FEA), (Simulia, Dassault Systemes). The design is in the form of a Langevin transducer with two PZT-26 (Ferroperm) piezoceramic rings sandwiched between two Ti6Al4V end-masses which are held under compression by a class 12.9 M6 caphead screw. The Ti6Al4V needle with a sharpened tip connects to the transducer via an M6 threaded joint. The dimensions of the needle were adjusted in the FEA model to ensure that neighboring mode frequencies were sufficiently spaced to minimize the likelihood of modal coupling. For the final design, the tuned mode was the second longitudinal mode, L2, and the closest neighboring mode was the seventh bending mode, B7. The device was tuned for L2 at 25.7 kHz as shown in Fig. 1(a), with mode B7 predicted at 21.5 kHz, providing an adequate frequency spacing of 16%.

Experimental modal analysis (EMA) was performed on the fabricated device to validate the FEA results. The device was excited with a random excitation over a frequency range of 0-80 kHz and the velocity responses were measured across a grid of points on the surface of the device using a 3D laser Doppler vibrometer (Polytec CLV-3D). The results in Fig. 1(b) show the longitudinal mode at 24.9 kHz. The bending mode B7 was identified at 20.8 kHz producing a final frequency spacing of 16.5%.

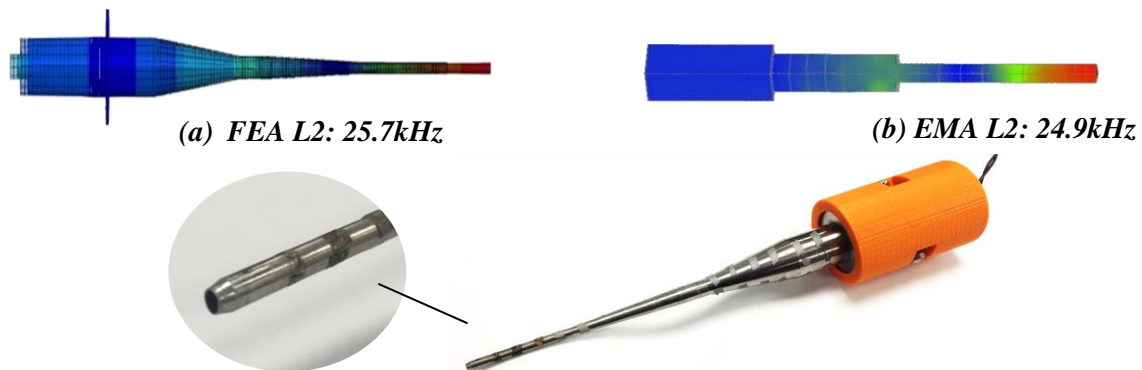


Figure 1(a): L2 FEA (b) L2 EMA (c) Final Design with Sharpened Titanium Needle

3. DRIVING SYSTEM

A LabVIEW-based driving system, for high power low-frequency ultrasonic transducers³ was modified to investigate the excitation signal and power delivery. The LabVIEW system tracks resonance by measuring the voltage and current in real-time to calculate the impedance of the device. The frequency is then tracked to zero-phase. The LabVIEW system is controlled using National Instruments hardware (PXIe 5122 on PXIe-1071). Voltage and current are measured using voltage (P6139A, Tektronix) and current (P6022, Tektronix) probes, while the resonant tracking protocol controls the settings of a function generator (33210A, Agilent Technologies). A power amplifier (240L RF Amp, E&I) amplifies the output signal of the function generator. The LabVIEW program was modified to allow the waveform shape, cycle period, duty cycle and durations of low power to be controlled.

4. TESTING

A. WAVEFORM AND VOLTAGE INVESTIGATION

Initially, a 1D laser vibrometer (CFV 055, Polytec GmbH) was used to measure the displacement amplitude at the needle tip while driving under no load. This established a relationship between displacement amplitude and driving voltage for different waveforms. Generally, the displacement amplitude is related to the penetration speed so this is a useful initial comparison of which waveforms might improve penetration speed. Five waveforms were tested at three different voltage levels, shown in Fig. 2(a). Best fit lines are used to estimate the displacement amplitude at a selected voltage level. In Fig. 2 the displacements are recorded at 60V_{pp}. The square waveform excites the highest displacement amplitude, followed by sinusoidal, ramp-up, triangular and ramp-down. At this point it was decided that ramp up and down waveforms would not be investigated further as they performed poorest over the three voltage levels.

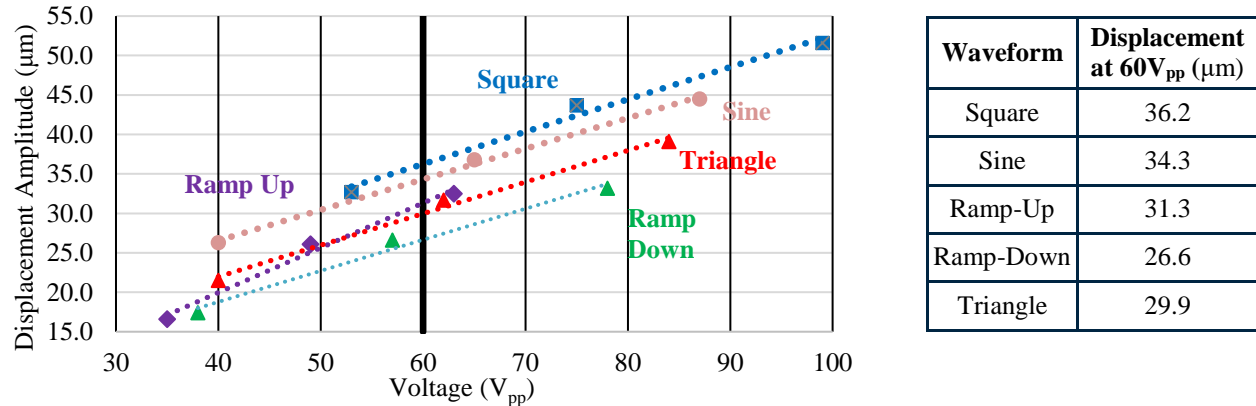


Figure 2 (a): Displacement Amplitude for Different Waveforms (b) Estimated Displacement at 60V

Subsequently, two constant voltages were established; 85V_{pp} and 125V_{pp}, that are capable of producing a displacement amplitude of the needle tip that can penetrate 5 mm into Sawbone within 20 seconds. This 20 second duration was selected to be consistent with the time to perform the same needle penetration in Sawbone with a trephine needle. The three waveforms (sine, square and triangular), were used to drive the needle device at these two voltage levels. The time to penetrate 5 mm was recorded and the temperature at the penetration site was recorded using a thermal camera (T420, Flir Systems).

| Waveform | Input Voltage (V _{pp}) | Time (s) | Max Temp at Site (°C) |
|------------|----------------------------------|----------|-----------------------|
| Sine | 85 | 17.5 | 145 |
| | 125 | 11.5 | 172 |
| Triangular | 85 | 22.0 | 151 |
| | 125 | 12.0 | 160 |
| Square | 85 | | |
| | 125 | 14.0 | 150 |

Table 1: Time to Penetrate and Maximum Temperature at Site when Penetrating Polyurethane Foam

Table 1 shows that fastest penetration was achieved for a sinusoidal waveform at 125V_{pp}, although this also resulted in the highest temperature. A penetration could not be achieved for a square wave at 85V_{pp}. When driving with a square wave under load, power is reflected back to the power amplifier which resulted in no penetration. Faster penetrations were achieved for the higher voltage level, correlating with the earlier results that larger displacement amplitudes and therefore faster penetrations are achieved with higher input voltages. Temperature at the penetration site is also higher for the higher voltage level and it will be important to consider the implications for cooling the device for achieving fast penetration when moving into animal bone testing.

B. INVESTIGATING POWER MODULATION

The next stage of the investigation involved introducing power modulation techniques, similar to those used in phacoemulsification to reduce temperature. The aim in this study is to investigate the effect of power modulation on penetration speed. A sinusoidal waveform was selected, with a maximum input voltage (MIV) of $125V_{pp}$ and pulse period of 8 seconds. The duty cycle (DC, the percentage of time the signal is maximum) and the low power percentage (LPP, the percentage MIV applied during a rest period) were both varied between 25-100%. Again, penetration time and temperature were monitored using the thermal camera.

Low Power Percentage

| Duty Cycle | Temp (°C) | Low Power Percentage | | | |
|------------|-----------|----------------------|-----|-----|-----|
| | | 0% | 25% | 50% | 75% |
| 25% | Time(s) | 85 | 60 | 28 | 14 |
| | Temp (°C) | 136 | 141 | 156 | 173 |
| 50% | Time(s) | 27 | 24 | 17 | 13 |
| | Temp (°C) | 144 | 150 | 170 | 174 |
| 75% | Time(s) | 14 | 13 | 13 | 13 |
| | Temp (°C) | 165 | 167 | 172 | 171 |
| 100% | Time(s) | 10 | 10 | 10 | 10 |
| | Temp (°C) | 174 | 174 | 174 | 174 |

Table 2: Performance of Needle when Introducing Durations of Low and Off Power

Table 2 shows that extended periods of off-time or low voltage levels result in longer penetration times, for example more than $\times 8$ penetration time when DC is 25% and LPP is 0% (which equates to $125V_{pp}$ for 2 secs and $0V_{pp}$ for 6 secs). Short periods of off-time or low voltage levels marginally increase the penetration time, for example 4 seconds longer when DC is 25% and LPP is 75% (which equates to $125V_{pp}$ for 2 secs and $90V_{pp}$ for 6 secs). It is also noted that low duty cycle and durations of low/zero power do not significantly affect the temperature at the site of Sawbone.

5. CONCLUSION

An investigation into the driving signal of an ultrasonic bone biopsy device has been presented. Following the successful penetration of previous devices into ovine metaphyseal cortical bone, the device was redesigned to incorporate a sharpened titanium tip.

Driving conditions were investigated to record their effects on the displacement amplitude of the needle and the needle penetration speed. A square waveform produced the highest displacement amplitude but proved to be unreliable when driving under load.

The study provided an insight into the performance, in terms of penetration speed, of the needle under different driving signals and power modulations. Long durations of low voltage significantly increased the penetration time while short durations marginally decreased the time. Moving forward, these and further driving signals will be considered to assist in the penetration of bone at a speed comparable with a conventional trephine needle and at a temperature below that of thermal necrosis.

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