Effects of Frequency on the Cutting Ability of an Ultrasonic Surgical Instrument

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Abstract

This research examines the effects of excursion, frequency, and application force on the cutting rate of an ultrasonic surgical instrument. Devices such as the Harmonic Scalpel, (an ultrasonic surgical instrument from Ethicon Endo-Surgery Inc. (EES) Cincinnati, OH), are gaining popularity in the operating room because of: the control given to the surgeon, reduced tissue damage, decreased operating times, and more rapid healing. The Harmonic Scalpel system consists of a current generator, a hand piece that houses an ultrasonic transducer, and an instrument having an end-effector used to cut tissue. It is a resonant device that operates at a frequency of 55.5 kHz. Surgeons control the Harmonic Scalpel's coagulation rate and cutting speed by the time and force applied to the tissue by the end-effector, and by the selected excursion level of the end-effector. Little attention has been paid to the effects of ultrasonic frequency on cut-rate, and the results from the few published articles found in pertinent literature are inconclusive.

This research compares cutting rate at 27 kHz, 55.5 kHz and 75 kHz, with peak-to-peak tip excursions (end-effector peak-to-peak amplitude) of 80, 120, 160, and 200 microns at 27 kHz, 40, 60, 80, and 100 microns at 55.5 kHz, and 30, 44, 59, and 74 microns at 75 kHz. The end-effector blade shape studied was a 2.2-mm diameter circular cylinder, which is the same as one of popular surgical instruments used with the Harmonic Scalpel. Two materials were selected for study, one tissue (porcine liver) and

one surrogate (machinist's wax). Loads were applied over a cut depth of 4 mm in wax, and 8 mm in liver, resulting in an overall load per unit length of 0.3125, 0.625, and 1.25 N/mm, and 0.156, 0.3125, and 0.625 N/mm respectively. These three forces represent the low, average, and high loads applied by one of EES' veterinary surgeons cutting a variety of tissues.

An Instron test system with MTS software for load-control and rate-control was utilized to perform constant-force and constant-velocity specimen cutting. Cutting speed was determined from average crosshead velocity during a 3-second period that commenced after the start-up transients. An MTS internal rate function was used to calculate cutting rates for each specimen.

Fixed factor Analysis of Variance was used to test significance of independent variables relative to the cutting speed of the ultrasonic surgical system. Results show that end-effector velocity and application force were the primary determinants of cutting speed. Frequency had an insignificant effect on cutting speed at a given tip velocity. This suggests that any frequency may be selected for a surgical cutting device, and the cutting speed of the device due to frequency may be compensated by altering tip excursion.

Background

This research examines the effects of excursion, frequency, and application force on the cutting rate of an ultrasonic surgical instrument. Devices such as the Harmonic Scalpel, (an ultrasonic surgical instrument from Ethicon Endo-Surgery Inc. (EES) Cincinnati, OH), are gaining popularity in the operating room because of: the control given to the surgeon, reduced tissue damage, decreased operating times, and more rapid healing. The Harmonic Scalpel system consists of a current generator, a hand piece that houses an ultrasonic transducer, and an instrument having an end-effector used to cut tissue. This is a high-Q resonant system that operates at a frequency of 55.5 kHz.

Surgeons control the Harmonic Scalpel's coagulation rate and cutting speed by the time and force applied to the tissue by the end-effector, and by the selected excursion level of the end-effector. Little attention has been paid to the effects of ultrasonic frequency on cut-rate, because in part, each frequency used in any study requires a separate generator and trnasducer. The results from the few published articles found in pertinent literature are inconclusive.

At the power levels used in low frequency therapeutic ultrasonics, the ultrasound is generated by transducers that use Langevin sandwich construction. These transducers are mechanically resonant devices with piezoelectric ceramics transforming electrical energy to mechanical vibratory energy. The ceramics are typically formed into circular disks or rings, sandwiched between two metallic cylindrical segments. When alternating electrical energy is applied to the disks, they expand and contract to create mechanical energy. The overall construction of the ceramic disks and metallic segments determine the resonant frequency. In ultrasonic surgical devices, blades or other end-effectors are attached to a transducer and are designed to resonate at the same frequency as the transducer. End-effectors take the form of long rods or tubes that act as waveguides to receive ultrasonic energy from the transducer and deliver it to the end-effector in contact with tissue.

Sandwich type transducers are relatively high-Q devicesaand during operation are driven at the resonanct frequency. Because of heating of the transducer materials, the resonant frequency tends to shift slightly lower as activation is maintained. Feedback control is used to track the resonant frequency as it shifts over a relatively narrow frequency range. Because these devices are high-Q in nature, individual devices are tuned both during design and fine-tuned during manufacturing. Therefore, each transducer must be tuned to have the resonance at precisely the desired frequency. Because delivery of ultrasonic energy requires a mechanical resonator, each frequency must have its own transducer and generator. Thus to conduct any study at multiple frequencies, a number of systems are needed that must be characterized by the tip displacement of the end-effector.

At the tip of the end-effector, energy is delivered to tissue where it creates several effects within the tissue. Conversion of mechanical energy to heat from friction at the blade-tissue interface occurs along with bulk heating due to tissue's viscoelastic nature. In addition, there are also ultrasonically induced effects such as: cavitation, microstreaming, jet formation, and sonoluminescence (Ensminger et al., 1988; Young *et al.*, 1989; Christensen *et al.*, 1988; Dyson *et al.*, 1982). These effects can potentially differentiate therapeutic ultrasound from other technologies used to cut and coagulate tissue, such as electrosurgery. For example, the efficacy of shock-wave lithotripsy is achieved by local cavitation at the stones. In some cases, this differentiation may be useful in providing clinical advantages over other energy forms during surgery.

The magnitudes of these effects are known to be frequency dependent. Young *et al.* (1989) presents several definitions of cavitation thresholds, all of which have frequency as a dominant parameter. Both the mechanical index and thermal index used in diagnostic ultrasound dosimetry are frequency dependent (NCRP, 1992). When describing ultrasonic therapeutic devices, frequency and excursion are the two primary reported operational parameters (IEC 61847, 1998). Therefore, the question naturally arises whether there is an optimal or preferred frequency to design and operate an ultrasonic surgical instrument.

Although ultrasonic frequency is always described as a factor in research involving ultrasonics, the frequency's effect on the results has had little attention, with results to date being inconclusive. Unfortunately, quantitative information or analytical models for the cutting mechanism are currently unavailable in the literature. This is at least in part due to the fact that each frequency needs a system and each system must be characterized in terms of tip displacement for any meaningful comparison.

Design of Experiment

Due to the issues described above, the operational frequency of an ultrasonic surgical system is the most difficult parameter to change when developing instruments for surgical applications. This research has therefore been limited to the frequencies of 55.5 kHz, and 75 kHz. The peak-to-peak tip excursions (end-effector peak-to-peak amplitude) for the experiments have been selected based on the maximum tip excursion of a typical instrument for the Harmonic Scalpel, which is 100 microns. Five excursions of 0, 40, 60, 80, and 100 microns have been selected for 55.5 kHz. Excursions of 0 30, 44, 59, and 74 microns have been selcted at 75 kHz. The values where selected so that they have the same tip velocities at the two frequencies. This is because a frictional model would say that that heating is proportional to the product of normal load and velocity independent of frequency.

The vibration excursion of an ultrasonic surgical system is simple to select and set, and depends on the feedback control system utilized during the development of the system being tested. Any amplitude within the allowable stress range of the ultrasonic surgical instruments can be obtained by programming the feedback circuitry of the generator for a corresponding current set point. Current and voltage are related to force and displacement by a full transformation matrix, but in a resonant system excursion is nearly proportional to current.

The end-effector blade shape studied was a 2.2-mm diameter circular cylinder, consistent with the end-effector of a common surgical instrument called the LCS-B5 from EES. Two materials were selected for study, one tissue (porcine liver) and one surrogate (machinist's wax). Loads were applied over a cut depth of 4 mm in wax, and 8 mm in liver, resulting in an overall load per unit length of 0.3125, 0.625, and 1.25 N/mm, and 0.156, 0.3125, and 0.625 N/mm respectively. These three forces represent the low, average, and high loads applied by one of EES' veterinary surgeons cutting a variety of tissues.

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Results

Results show that end-effector velocity and application force were the primary determinants of cutting speed. Frequency had an insignificant effect on cutting speed at a given tip velocity. This suggests that any frequency may be selected for a surgical cutting device, and the cutting speed of the device due to frequency may be compensated by altering tip excursion. Figure 1 is a graph of cut-rate versus load and peak tip velocity of a round blade cutting wax at 55 and 75 kHz. Due to system constraints, the 75 kHz system was only useable in the lower quadrant of the ranges available in the 55 kHz system. However, given the close fit between the 55 kHz and 75 kHz cutting in the lower quadrant, there is no reason to expect that the 75 kHz system would diverge from the fit in the larger ranges, had the ranges been available in the 75 kHz system.

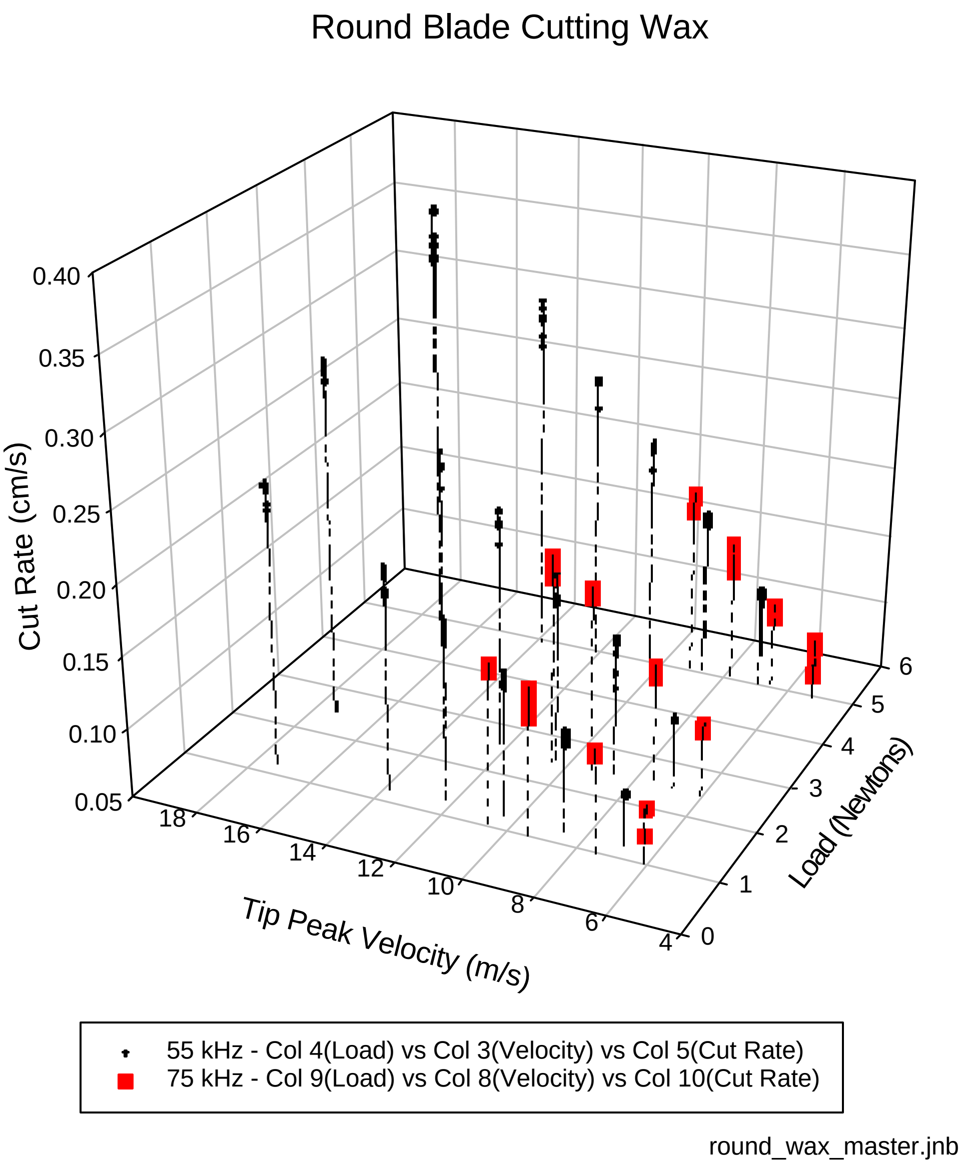

Figure 1. Cut-rate versus load and peak tip velocity of a round blade cutting wax.

Figure 2 is a graph of cut-rate versus peak tip velocity for 55 kHz and 75 kHz systems. Data displayed in the graph is from a round blade cutting wax, with a constant load of 1.25 N/mm.

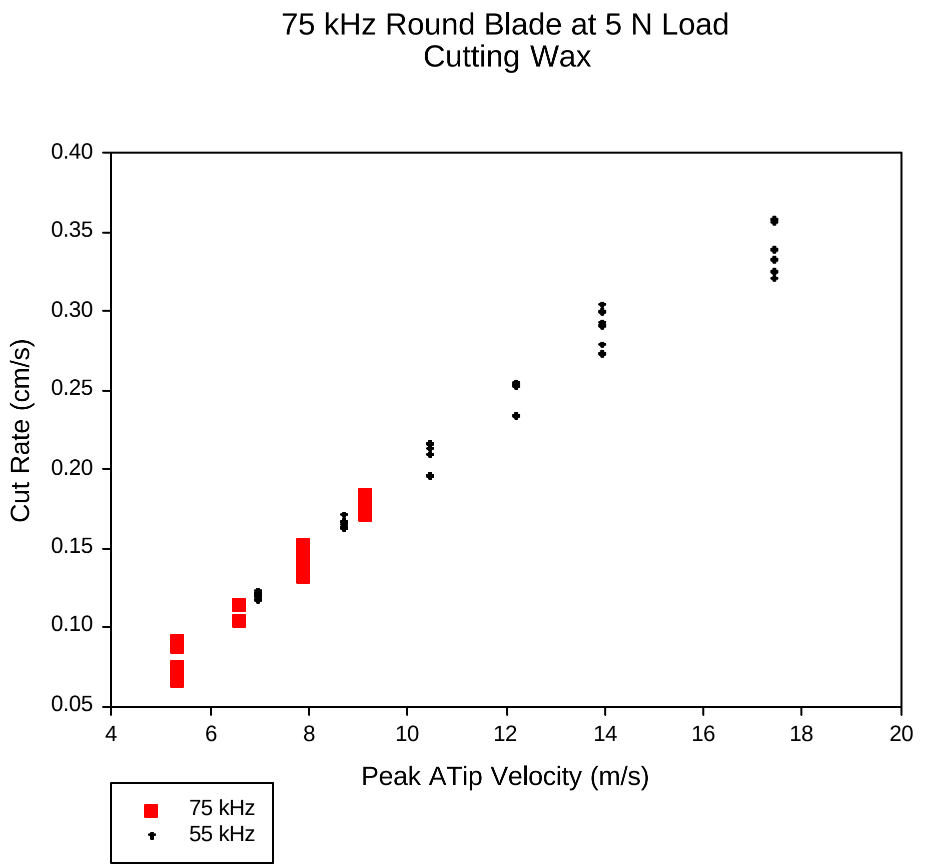

Figure 2. Cut-rate versus peak tip velocity.

Discussion

Fixed factor Analysis of Variance was used to test significance of independent variables relative to the cutting speed of the ultrasonic surgical system. Results show that end-effector velocity and application force were the primary determinants of cutting speed. Frequency had an insignificant effect on cutting speed at a given tip velocity. This suggests that any frequency may be selected for a surgical cutting device, and the cutting speed of the device due to frequency may be compensated by altering tip excursion.

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