Design of a wire-type stirrer for thrombolysis using opposite-phase vibration

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Abstract: Currently, large hematomas in the brain are removed through craniotomy. However, some patients cannot undergo this procedure due to the significant physical burden it imposes. For these patients, minimally invasive surgical devices exist, but current devices lack the capability to directly agitate the clot. To enhance the vibrational energy at the tip, the application of combined vibrations has been explored, with opposite-phase(OP) vibration showing particular promise in achieving stable and high vibrational output. While previous studies suggested the possibility of exciting combined vibrations at the tip of a 1.0 mm diameter wire, stable excitation of OP mode had not been realized. In this study, we propose a new tip structure that enables OP vibration through a simplified fabrication method. We successfully demonstrated the excitation and propagation characteristics of this vibration mode through finite element analysis (FEM) and experimental validation.

Key-Words: *Minimally Invasive Surgery, Vibration Mode, Stirrer, Single-wire*

1. Introduction

In recent years, pulmonary embolism, heart disease, and cerebrovascular diseases have emerged as some of the leading causes of death in Japan, with blood clot formation playing a significant role in their pathogenesis. Rapid clot removal greatly influences patient outcomes, and many intravascular treatment devices have been developed. Devices such as Penumbra, which rely solely on suction, are commonly used but struggle with large or fibrotic clots[1]. To address this, Hēlo introduced a system that combines suction with vibration, effectively agitating and breaking down clots[2]. This allows Hēlo to outperform Penumbra, especially with larger, fibrotic clots, though further improvements in agitation performance are needed. In our research, we aim to enhance clot removal capability by increasing the output of ultrasonic scalpels through a opposite-phase (hereinafter referred to as OP) vibration structure[3-5]. Achieving clot removal through ultrasound requires miniaturization of devices to approximately 1 mm in diameter to be inserted into a catheter. However, miniaturization often leads to reduced output power. By successfully implementing an OP vibration in a smaller device, we hypothesized that it is possible to maintain or even increase the agitation power, thus enabling more efficient clot removal. This study demonstrates that miniaturization has been achieved, paving the way for less invasive and highly effective treatments.

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2. Principle of Opposite-Phase Vibration and New Processing Method

To realize effective OP vibration, it is essential for the device tip to have a split structure, where the tip branches into two branches [3] as shown in Fig.1. This configuration induced bending vibrations at the tip, and the moments generated by each branch cancel each other out, allowing stable excitation of the target vibration mode. However, implementing such structures on thin wires has traditionally required advanced and complex manufacturing techniques. In this study, the central challenge is to realize high-output and stable OP vibration in miniaturized wire structures. To address this, we developed a simplified processing approach that avoids the use of slits, thereby facilitating device fabrication without compromising vibration performance. As illustrated in Fig.2, by shaving 0.2 mm from both sides of the wire tip and attaching two symmetrical beams, we achieved a structure capable of exciting OP vibration mode even in wires with diameters as small as 1 mm. This approach ensures easy fabrication while maintaining a symmetrical design that cancels bending moments, thereby enabling efficient vibration transmission. On the other hand, the natural frequencies of the wire include longitudinal and bending vibration modes, with the latter being more susceptible to external contact. To stably excite target vibration mode, it is crucial to excite longitudinal vibration modes that are independent of bending modes, which requires precise design of both the wire and beam lengths. According to the combined vibration device design method presented in previous studies, the OP vibration mode occurs when the longitudinal vibration mode frequency of the entire structure is independent of its bending mode frequency and when the longitudinal mode frequency aligns with the bending mode frequency of the beams[6-9]. Following this design principle, we set the wire length to 185 mm, which is expected to produce resonance frequencies at 17 kHz for the 2nd longitudinal mode, 33 kHz for the 3rd longitudinal mode, and 54 kHz for the 4th longitudinal mode, enabling the desired vibration mode.

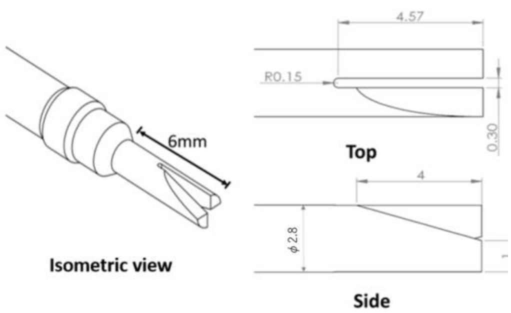


Fig.1 Schematic of the tip structure for inducing opposite-phase vibration in an ultrasonic scalpel.[3]

3. Finite Element Analysis

In this chapter, finite element analysis was conducted to evaluate the superiority of the proposed OP vibration mode. Two models were analyzed: the proposed model with two symmetrical beams at the tip (hereinafter referred to as the "Opposite-Phase (OP model)") and a comparative model with only one beam at the tip (referred to as the "Single-Beam (SB model)"), as illustrated in Fig.3. Previous studies suggested that combined vibration could be excited in a 1 mm diameter wire [6-8], but stable excitation of OP vibration has not been realized due to the difficulty of fabricating precise tip structures. In this study, we propose a simplified design that enables the excitation and propagation of OP vibration. The analysis was performed using ANSYS Workbench (2020 R2), and stainless steel was used as the material for the analysis. The entire structure, including the wire and tip beams, was modeled under cantilever boundary conditions.

Fig.2 Processing the tip of the wire to be fabricated

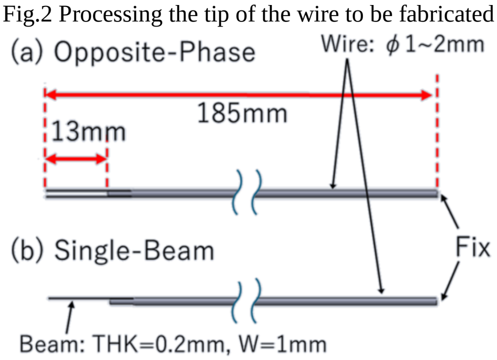
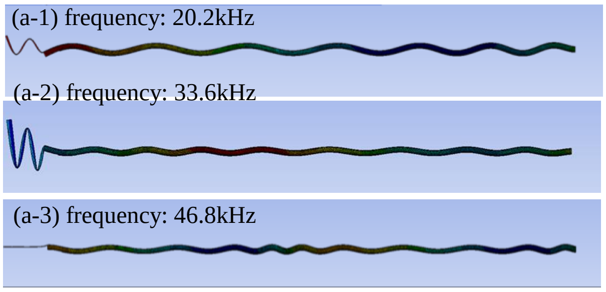
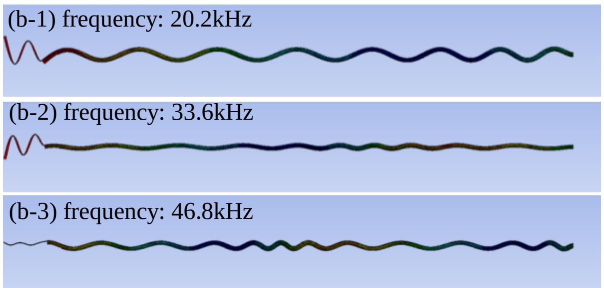


Fig.3 Schematic of beam attachment conditions, wire dimensions, and boundary conditions for analysis.

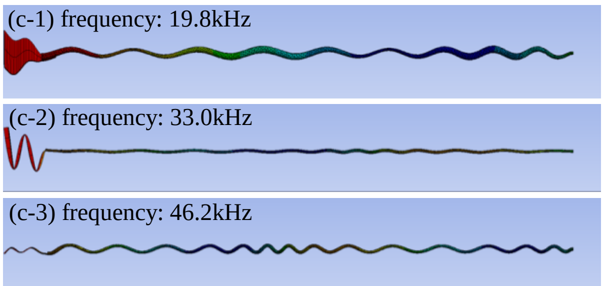
The deformation patterns and natural frequencies for each vibration mode were then calculated. Fig.4 and 5 show the results of composite longitudinal and bending vibration analysis for the SB and OP models, respectively. Each figure presents three dominant vibration modes, labeled as 2L3B, 3L4B, and 4L5B. In the vibration mode notation used in this study, "L" refers to the order of the longitudinal vibration mode of the entire device, including both the wire and the attached beams, while "B" denotes the order of the bending vibration mode of the tip beams. For example, "3L4B" indicates that the third longitudinal mode of the whole structure occurs simultaneously with the fourth bending mode of the tip beams. The FEM analysis successfully confirmed that the designed vibration modes were excited at the intended frequencies of approximately 20 kHz for the 2L3B mode, 33 kHz for the 3L4B mode, and 46 kHz for the 4L5B mode, respectively. These results demonstrate that the OP model, with its symmetrical beam configuration, effectively suppressed bending vibrations in the wire section, achieving stable OP vibrations at the tip. In the SB model, bending vibration in the wire section is observed in almost all vibration modes, due to the structural asymmetry caused. These FEM results suggest that the OP model structurally suppresses wire bending and promotes stable vibration modes. Based on these findings, experimental validation is conducted in Chapter 4 to evaluate the vibration behavior and performance of the proposed model.



(a) Wire diameter: 2.0mm

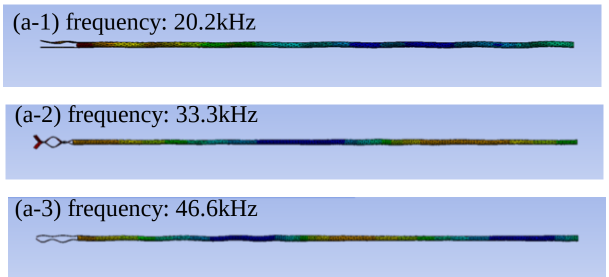


(b) Wire diameter: 1.5mm



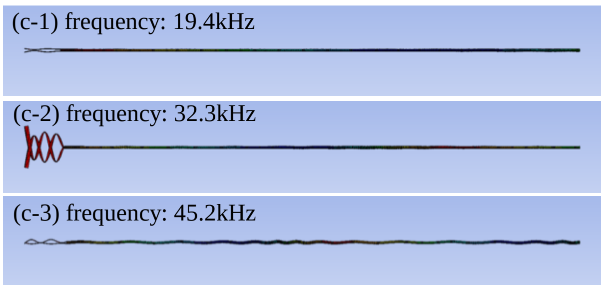
(c) Wire diameter: 1.0mm

Fig. 4 Composite longitudinal and bending vibration analysis results for wire models with a beam attached on one side (SB): (1) 2L3B-mode, (2) 3L4B-mode, (3) 4L5B-mode



(a) Wire diameter: 2.0mm

(b) Wire diameter: 1.5mm



(c) Wire diameter: 1.0mm

Fig. 5 Composite longitudinal and bending vibration analysis results for wire models with a beam attached on both sides (OP): (1) 2L3B-mode, (2) 3L4B-mode, (3) 4L5B-mode

4. Experimental Validation of Opposite-Phase Vibration

4.1 Experimental Setup and Fabrication

To verify the excitation of the desired OP vibration, a displacement measurement experiment was conducted. The aim was to measure the displacement and phase difference of the tip beams. A function generator (Keysight Technologies 33612A) was used to output signals, which were amplified by a power amplifier (NF Electronic Instruments 4010) and transmitted to the wire via an ultrasonic horn to induce vibration. The displacement was measured using a laser Doppler vibrometer (ONO SOKKI LV-1710), and the waveform was observed using an oscilloscope (Keysight MSO-X 6014A). The experimental model used in this study was fabricated by silver brazing the joint between the wire and the jig, and attaching the beams to the tip using an epoxy-based elastic adhesive. Fig.6a shows the image of the jig, while Fig.6 shows the brazed connection and bonded beams, as well as the assembly mounted onto the ultrasonic scalpel transducer (Olympus TD-SB400) and handle.

4.2 Displacement Measurement Results

Displacement measurements were performed by scanning from the tip to 20 mm along the wire at 0.5 mm intervals. Three wire diameters were tested: 2.0, 1.5, and 1.0 mm. The experimental conditions targeted frequencies of approximately 20, 30, and 46 kHz, guided by the modal analysis results.

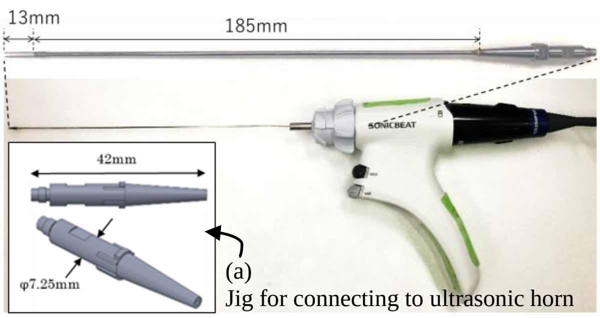


Fig.6 Jig-mounted wire attached to the ultrasonic scalpel handle

At frequencies above 46 kHz, noise interference hindered the precise measurement. In the experiment, the handle of the ultrasonic scalpel was held and fixed perpendicular to the rod, as shown in Fig.7, which illustrates the experimental setup used for the displacement measurement under the contact conditions described in Section 4.3. However, the fixture was not attached, and measurements were performed under non-contact conditions. Fig.8 and 9 show the vibration mode measurement results without the use of the fixture. Compared with the SB model, the OP model effectively suppressed unwanted bending vibrations in the wire section and exhibited more stable vibrational characteristics.

4.3 Contact Experiment Results

To assess the robustness of the device under external contact, a fixture with seismic gel (TF-40K, Kitagawa Industries) was fabricated using a 3D printer , as shown

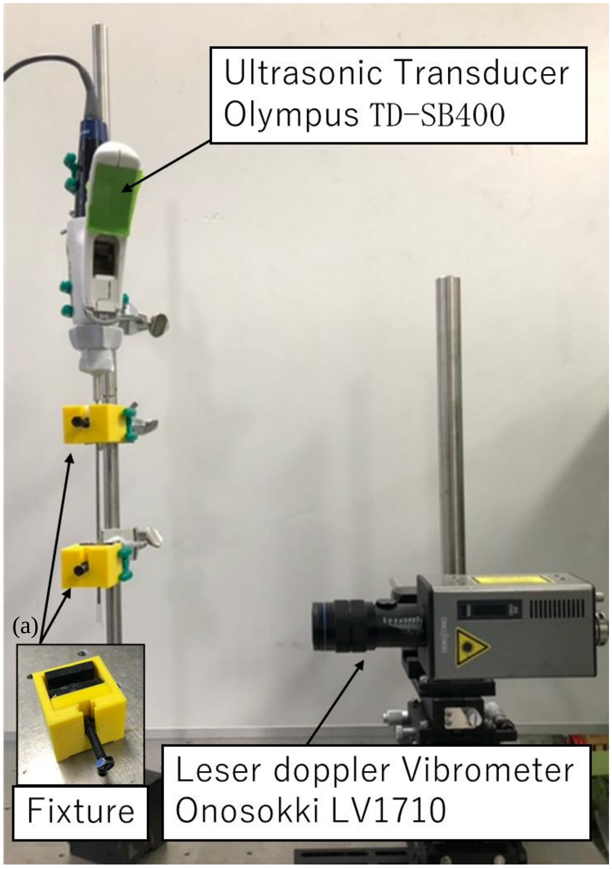
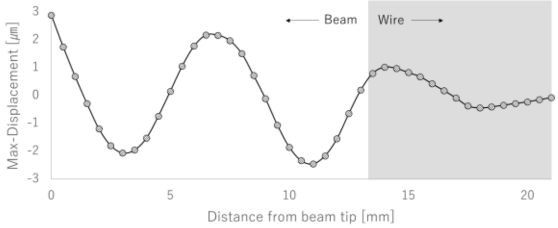
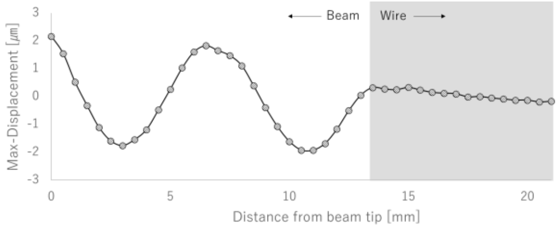


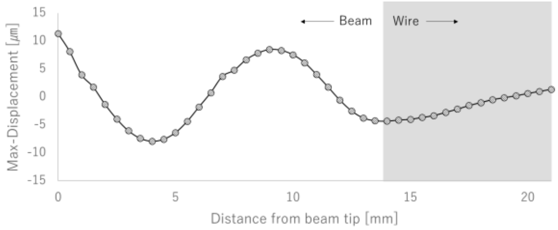
Fig.7 Experimental setup used for contact testing with fixture attached. The fixture was not used during the displacement measurements described in Section 4.2.



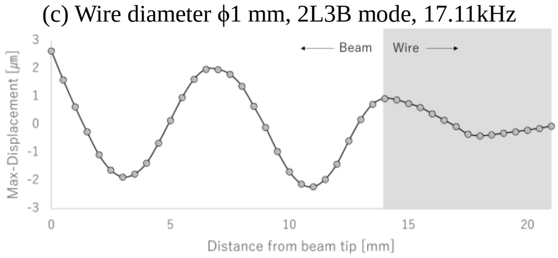
(a) Wire diameter ϕ2 mm, 3L4B mode, 30.52kHz



(b) Wire diameter ϕ1.5 mm, 3L4B mode, 30.36kHz

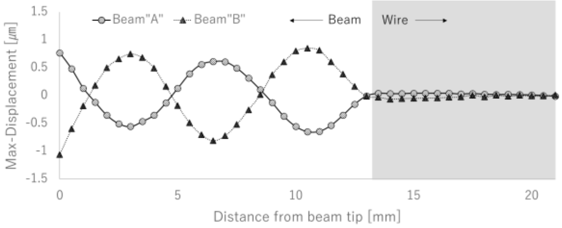


(c) Wire diameter ϕ1 mm, 2L3B mode, 17.11kHz

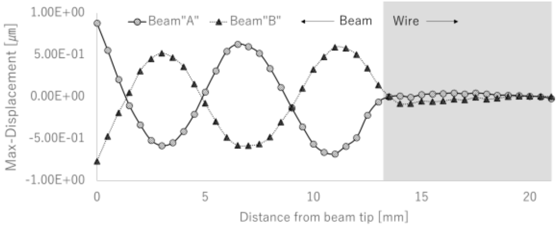


(d) Wire diameter ϕ1 mm, 3L4B mode, 29.43kHz

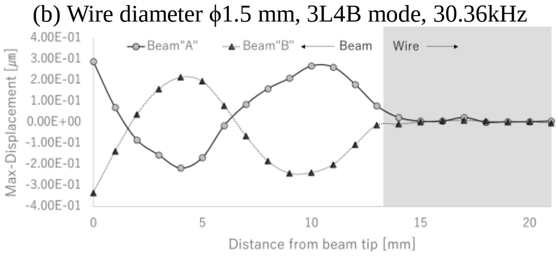
Fig.8 Measured vibration modes of the SB model without fixture



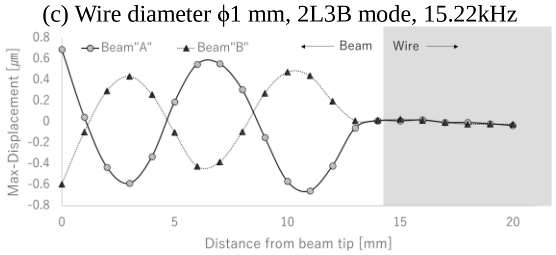
(a) Wire diameter ϕ2 mm, 3L4B mode, 30.24kHz



(b) Wire diameter ϕ1.5 mm, 3L4B mode, 30.36kHz



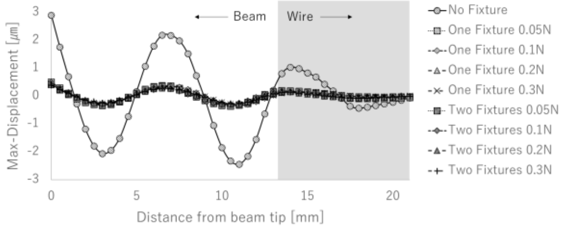
(c) Wire diameter ϕ1 mm, 2L3B mode, 15.22kHz



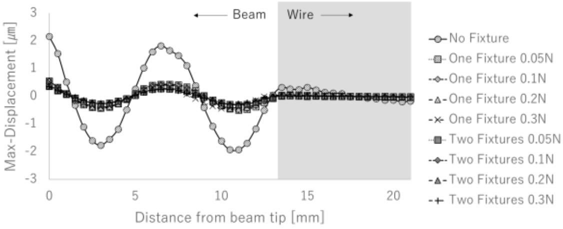
(d) Wire diameter ϕ1 mm, 3L4B mode, 29.80kHz

Fig.9 Measured vibration modes of the OP model without fixture

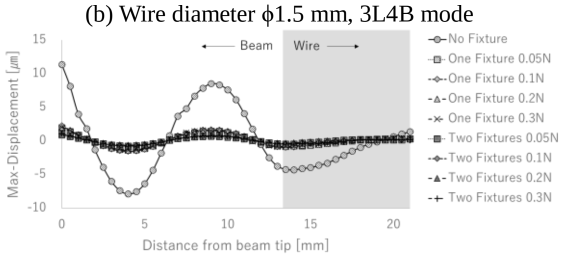
in Fig. 7. The fixture was designed to apply load at specific positions, 40 mm and 130 mm from the tip, based on the bending mode shapes identified in the FEM analysis. In the case of single point fixation, the fixture was applied only at the 40 mm position. Fig. 7a shows an example of the mounted fixture. The fixture was pressed against the wire using an M4 screw with a 0.7 mm pitch to allow precise control of the displacement. Tightening torque was measured using a digital driver (KTC GLK250), and the applied force was estimated from the measured torque. Four torque levels were used: 0.05, 0.1, 0.2, and 0.3 N·m. Each configuration was tested for both the SB and OP models under identical vibration conditions. Results demonstrated that for all wire diameters and frequency modes tested, the OP model showed significantly smaller reduction in tip displacement under contact compared to the SB model. For example, with a 2.0 mm diameter wire at 30.20 kHz, the tip displacement in the OP model retained more than 80% of the initial amplitude with a single contact, whereas that in the SB model dropped below 20%. Similar trends were observed for 1.5 mm and 1.0 mm diameters. The OP structure maintained effective vibration transmission even under contact, supporting its superior robustness for applications involving external contact, such as medical tool operation. These results are summarized in Section 4.4.



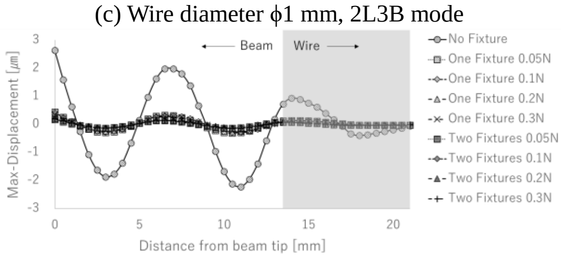
(a) Wire diameter ϕ2 mm, 3L4B mode



(b) Wire diameter ϕ1.5 mm, 3L4B mode

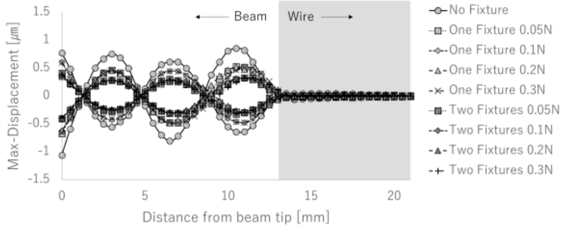


(c) Wire diameter ϕ1 mm, 2L3B mode

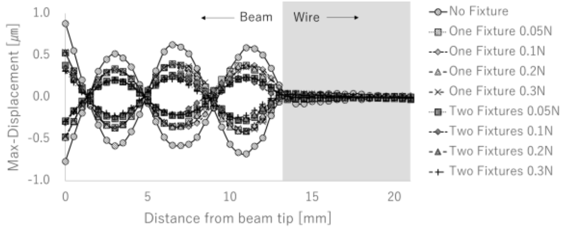


(d) Wire diameter ϕ1 mm, 3L4B mode

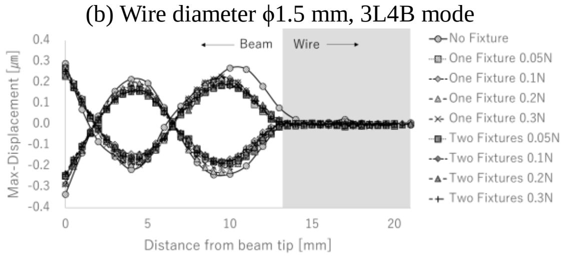
Fig.11 Comparison of tip displacement under contact for SB model



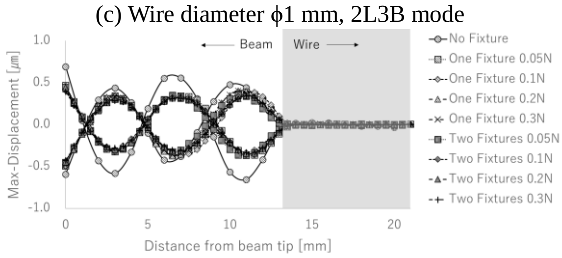
(a) Wire diameter ϕ2 mm, 3L4B mode



(b) Wire diameter ϕ1.5 mm, 3L4B mode



(c) Wire diameter ϕ1 mm, 2L3B mode



(d) Wire diameter ϕ1 mm, 3L4B mode

Fig.12 Comparison of tip displacement under contact for OP model

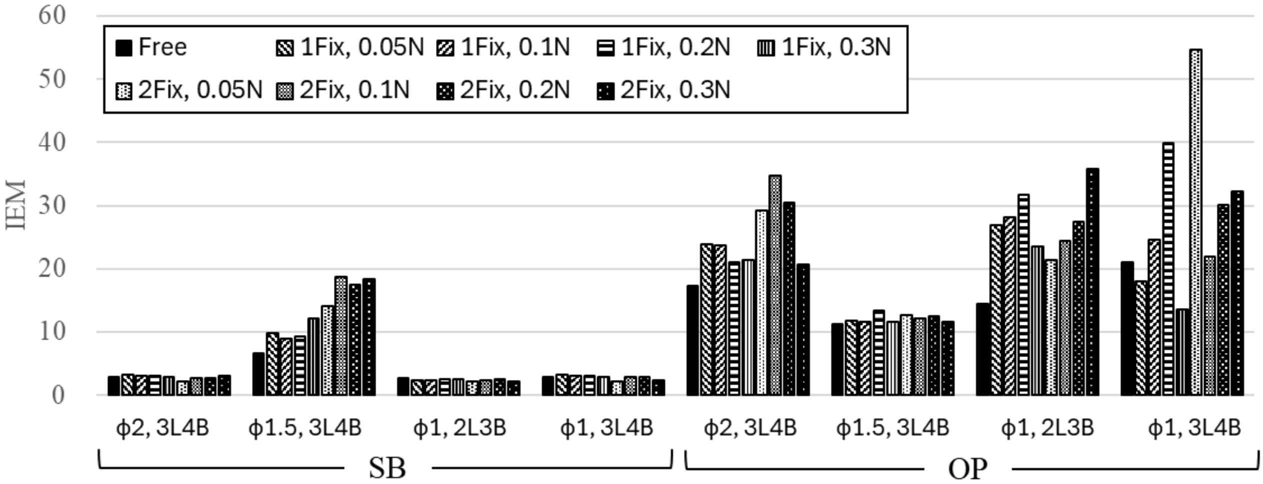


Fig.13 Comparison of the Index of Expected Mode (IEM) under various conditions

4.4 Evaluation Index for Expected Mode Shape

To quantitatively evaluate the excitation of the expected vibration mode, we defined an index called the Index of Expected Mode (IEM), calculated as:

$$IEM = \frac{Maximum\ displacement\ of\ the\ beam}{Maximum\ displacement\ of\ the\ wire\ beyond\ 13\ mm\ from\ the\ tip} \quad \cdots(1)$$

This index quantitatively evaluates the amount of bending vibration energy concentrated in the target beam region. An IEM value of 10 or greater indicates that the bending vibration is effectively concentrated in the tip beams, while unwanted wire bending is minimized[7]. This is considered an ideal vibration condition for effective thrombus agitation, wherein energy is efficiently transmitted to the intended site. To obtain the IEM values, displacement and phase in the bending direction were measured at 0.5 mm intervals from the tip up to 20 mm. Using this data, the vibration mode shape at the moment of maximum tip amplitude was visualized. The region from the tip to 13 mm was defined as the beam, and the section beyond 13 mm was defined as the wire. The maximum displacement values for each region were used in Equation (1), and the results are presented in Fig. 13. The results show that the OP model consistently achieved IEM ≥ 10 under all test conditions, while the SB model failed to meet this criterion in most cases. Although the OP model showed a smaller absolute tip displacement, the suppression of wire bending contributed to higher IEM values, supporting its robustness against contact and stable vibration characteristics. In the φ1.5 mm wire condition, certain SB model configurations under double-point contact exceeded IEM ≥ 10. In these cases, the original bending displacement of the wire was inherently small, producing a vibration mode close to the ideal form. This reduced sensitivity to contact likely contributed to the high IEM value. It is thus inferred that suppressing wire bending widens the displacement contrast between the beam and wire, increasing the likelihood of achieving IEM ≥ 10. Although SB configurations may occasionally reach high IEM values, the fact that the φ1.0 mm and φ2.0 mm SB models failed to meet the criterion suggests that the OP model is structurally more suited for reliably achieving optimal vibration modes.

5. Conclusion

In this study, we proposed a novel design of a wire-type stirrer with OP vibration to improve thrombus agitation performance in ultrasonic scalpel applications. Through finite element modal analysis and experimental validation, we confirmed that the proposed structure effectively suppresses unwanted bending vibrations in the wire section, even when the device is miniaturized to a diameter of 1.0 mm. Displacement measurements and contact experiments demonstrated that the OP model maintained higher robustness under contact conditions compared to the SB model, with superior excitation of the intended vibration mode. The Index of Expected Mode (IEM), used as a quantitative indicator of ideal vibration, exceeded the threshold of 10 in all OP configurations tested, validating the consistency and reliability of the design. Although certain SB configurations temporarily satisfied the IEM criterion under specific conditions, the OP structure was more suitable for stable and reproducible excitation. This finding may facilitate the development of next-generation intravascular surgical devices for effective thrombus removal.

Appendix

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