An Easily Movable Hand Support Device Improves the Accuracy and Speed of Suturing Procedures: Concept and First Feasibility Study

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Original

An Easily Movable Hand Support Device Improves the Accuracy and Speed of Suturing Procedures: Concept and First Feasibility Study

Masakazu Taira,[1,2] **Hidetsugu Asano,**[3,4] **Jun Okamoto,**[4] **Tatsuya Ishikawa,**[5] and **Yoshihiro Muragaki**[4,5]

[1]Graduate School of Medicine, Tokyo Women's Medical University, Tokyo, Japan
[2]Taira Denki Co. Ltd., Shizuoka, Japan
[3]Atom Medical Co. Ltd., Tokyo, Japan
[4]Faculty of Advanced Techno-Surgery, Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University, Tokyo, Japan
[5]Department of Neurosurgery, Neurological Institute, Tokyo Women's Medical University, Tokyo, Japan

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Background: Hand tremors during surgery requiring precise techniques increase procedure durations and adversely affect outcomes. Most of the currently available devices used to reduce tremors during surgery are large, heavy, and expensive. This study aimed to develop and evaluate an easily movable hand support device to improve surgical outcomes.
Methods: We designed and developed a new device comprising a hand support bar and foot switch. The utility of the device was experimentally evaluated by 11 neurosurgeons with a mean experience of 6.7 (range: 0-13) years. A patient model simulating puncture techniques of suture needles in superficial and deep cerebral vessels during brain surgery was created, and the accuracy of targeting puncture sites and the time required for puncture were measured.
Results: The use of the newly developed hand support device resulted in a significant improvement in the accuracy of targeting puncture site in both, superficial ($p < 0.0001$) and deep ($p = 0.0041$) surgery conditions and reduced the time required to puncture both, superficial ($p=0.0006$) and deep ($p=0.0527$) targets compared to non-use of the hand support device.
Conclusion: The newly developed hand support device has the potential to improve microsurgery outcomes by stabilizing hand tremors and reducing procedure duration.

Key Words: movable armrest, microsurgery, surgical tremor, hand trembling, support device

Introduction

There have been numerous reports on the adverse impact of surgeons' physiological tremors on surgical results and duration of surgeries requiring precise techniques; these include neurosurgery and plastic surgery, where micron-order accuracy is required.[1,2] In particular, precise techniques are essential in surgery involving cerebral vessels, as minute blood vessels are anastomosed to prevent leakage of blood in this setting.[3,4]

Corresponding Author: Masakazu Taira, Faculty of Advanced Techno-Surgery, Tokyo Women's Medical University, 8-1 Kawada-cho, Shinjuku-ku, Tokyo 162-8666, Japan. taira@taira-denki.com
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Table 1 Comparison of previously developed devices and the target of this research.

Categories	Preriminally fixed armrests	Advanced engineering hand support equipments	Easy movable hand support device (Target of this study)
Degree of freedom of hand support	2-3: horizontal motion (x, y) and vertical motion (y)	3-6: horizontal motion (x, y), vertical motion (y) and rotational movement (θx, θy, θz)	single: vertical motion (y)
Method for alignment of hand support (s)	rotate screw (s) for fixation	- push a button on hand support (s) or footswitch - adjust load (s) onto hand support (s)	operate footswitch
Alignment time of hand support (s) [s]	10 <	< 3	< 2
Energy source	not required	- electricity - compressed air	not required
Dimensions (W, L, H) [cm]	10-30 each	30-120 each	W: <25, L: <10, H: <10
Weight [kg]	< 5	50 <	< 2
Price range [US$]	several thousands to tens of thousands	tens to hundreds of thousands	under several thousands

Several studies demonstrated the utility of hand positioning devices for surgeons' hands and arms to reduce tremors during surgery;[5,6] various devices were developed and are currently used in clinical practice.

In the 1960s and 1970s, fixed metallic armrests were developed for ophthalmic surgery,[7] microsurgery,[8] and neurosurgery,[9] and surgeons reported them to be efficacious. However, these early hand-positioning devices were fixed; this implies that at every use, they needed to be repositioned. The screws fixing the armrest position had to be loosened and re-tightened for positioning; this interrupted the surgery. Therefore, there was an urgent need for developing an easily usable device to improve clinical outcomes. Ohta et al.[10] and Goto et al.[11] used advanced engineering techniques to develop positioning devices with armrests that could be freely adjusted by simple manipulation during surgery. They conducted studies to evaluate the utility of these devices in bench tests and clinical practice.[3,12,13] However, these devices require numerous expensive engineering components such as pressure drivers, motors, and counterweights, and need placement and/or harnessing of energy supply lines (pneumatic tubes and power cords), making them large and heavy. This causes operational and cost issues, making their use difficult when operating space is limited or the operating room is small; many people are needed for setting up and transporting the instrument, and they require storage space. Inability to introduce the devices due to high costs prevents their widespread use in current clinical practice.

As shown in **Table 1**, in this study, we aimed to design a well-balanced new hand support device equipped with new features; using a prototype, we also evaluated its utility in achieving superior usability and maneuverability for performing precision surgery and in addressing issues related to operation and costs. A bench patient model was developed that simulated the puncture techniques of suture needles for superficial and deep cerebral blood vessels during brain surgery. The accuracy of targeting puncture sites for sutures (error between the target point and actual puncture position) and the time required for puncture were measured using this patient model.

Materials and Methods

1. Design of an easily movable hand support device

The prototype of the hand support device for performing cerebrovascular anastomosis is shown in **Figure 1(a)**. The apparatus consists of 4 main parts: (1) a hand support bar on which surgeons can place their hands or wrists, (2) a slider that allows surgeons to move the hand support bar up and down or fix the height of the bar, (3) a foot switch that allows surgeons to unlock the slider, and (4) an arm that allows surgeons to fix the hand support device on operating tables or chairs.

Surgeons could place the sides of their hands, side of their little fingers, or wrists on the support bar to use the device [**Figure 1(b)**]. The range of motion of the hand support bar of the device is 3 cm up or down in the vertical direction. The up and down motion of the slider and the locking mechanism inside the slider allow the hand

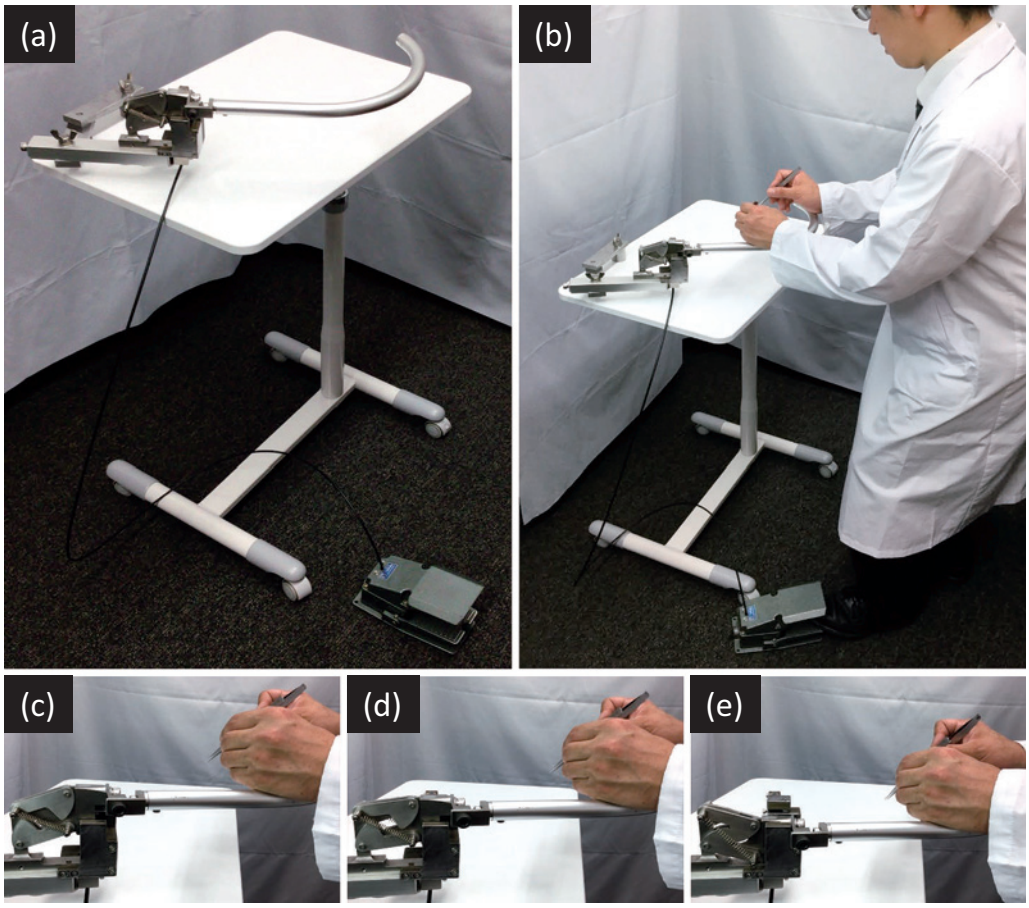

Figure 1 (**a**) The prototype of the easily movable hand support device showing four components: the hand support bar, slider, footswitch, and an arm. (**b**) A surgeon places his hands on the locked support bar that can be moved up and down in the range of 3 cm on pushing the footswitch. (**c**) The hand support bar is pulled upward by the springs in the slider being unlocked by the footswitch. (**d**-**e**) The surgeon can adjust the height of the bar by pushing it downward.

support bar to be fixed at any height within the range of motion during surgery. On stepping on the foot switch and unlocking the slider, the hand support bar automatically moves up due to the contractile force of the spring mounted inside the slider. Surgeons could adjust the height (vertical position) of the hand support bar by adjusting the downward pressure of their hands or wrists (pressing force) on the hand support bar, that would automatically move up [**Figure 1(c-e)**]. The springs mounted inside the slide can be easily replaced with springs of variable contractile forces to alter the force of upward movement of the hand support bar. In addition, the design of the hand support bar allows its easy removal, replacement, and sterilization in an autoclave.

2. Experimental evaluations

To evaluate the newly developed hand support device, we created a system that simulates puncturing sutures into cerebral blood vessels during brain surgery, as for resection of brain tumors and cerebrovascular disorders [**Figure 2(a)**]. Using this evaluation system, the precise puncture position of suture needles and time required for a series of puncture procedures were measured with and without the hand support device. The utility of the hand support device was evaluated by comparing and evaluating the results.

An opening of approximately 4 cm in diameter was created in the temporal region of a full-sized skull model (1688, Guangzhou Blue Butterfly Teaching Model Co., Guangzhou, Guangdong, China), that was placed on the operating table. As shown in **Figure 2(b)**, a piece of paper (the target paper) indicating the targets to be punctured was fixed in the opening at two positions on the paper fixing table. The target paper was an 8 mm wide, 15

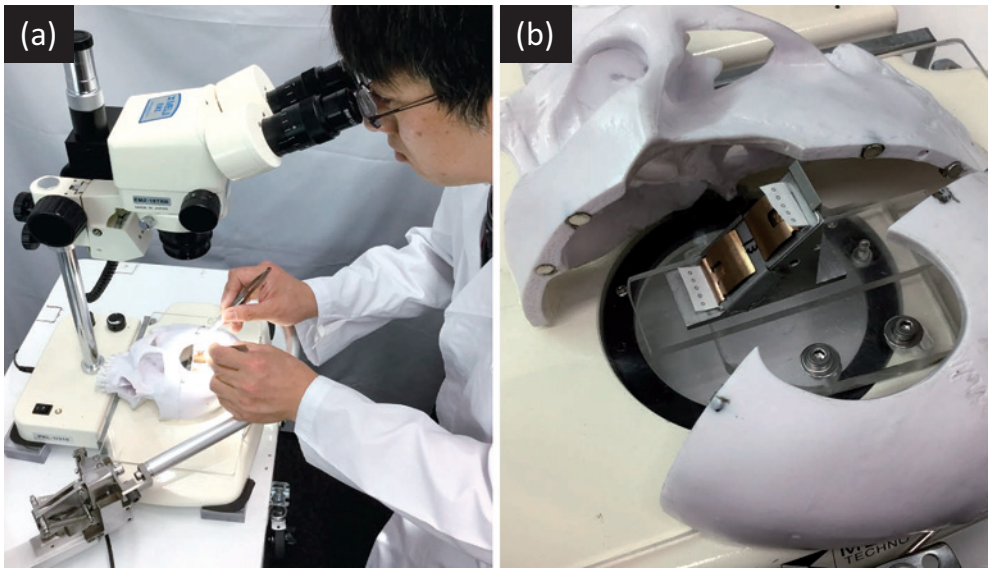

Figure 2 (**a**) The skull model with two target papers, on which 5 circles with a diameter of 1.1 mm were marked at intervals of 2.8 mm at a depth of 1 cm and 4 cm from the skull surface. (**b**) The distances between the center of the target circles and actual puncture positions are shown.

mm long, and 0.13 mm thick general-purpose paper (28906, Boku Undo Co., Nara-shi, Nara, Japan); 5 circles (outer diameter of 1.1 mm and inner diameter of 0.8 mm) representing the targets for puncturing were printed on the paper in a row at 2.8 mm intervals. In accordance with general bypass surgery, the target paper was fixed at a depth of 1 cm (defined as superficial) and 4 cm (defined as deep) from the position of the opening in the skull model.

Eleven neurosurgeons with a mean experience of 6.7 (range: 0-13) years volunteered to participate in this study. Participating neurosurgeons were instructed to repeatedly puncture and remove suture needles (used for microsurgery training) (suture: 10-0, 15 cm; needle: 3/8, round needle, 4 mm, 0.12 mm thick) (NTDY01V, Kono Seisakusho Co., Ichikawa-shi, Chiba, Japan) into the center of the 5 circles printed on the target paper, with the needles held in their dominant hand, and the surgical forceps in the other. The distance between the center of the target and puncture point, and the time required to puncture the five targets were measured. Experiments were performed using neurosurgical technique-training microscopes (EMZ-TR-250, Meiji Techno Co., Iruma-gun, Saitama, Japan). Participating neurosurgeons punctured three sets of targets, each having 5 circles on the target papers at superficial and deep positions with two patterns (with and without) of using the hand support device (60 in total).

During evaluation, participants performed under 4 experimental conditions. They included surgery with and without the use of the hand support device, and puncturing at superficial and deep positions of the target paper, with the order of the two punctures determined by random chance (draw lots). All participants used the device for the first time after receiving instructions before use.

The distance between the puncture points and the center of the targets was measured using an automated imaging system (VR-3100, Keyence Co., Higashiyodogawa-ku, Osaka, Japan), with an accuracy of 0.003 mm; the time required for puncture was measured using a stop watch (TEV-4013-CL, Crepha Co., Chuo-ku, Tokyo, Japan).

3. Statistical analysis

The data obtained (distance between the puncture point and the center of the target, and time required for puncture) were statistically analyzed and compared using Wilcoxon's rank sum tests. JMP ® 14 (SAS Institute Inc., Cary, NC, USA) statistical software was used for all analyses.

Results

The experiments performed with the support of 11 neuro-

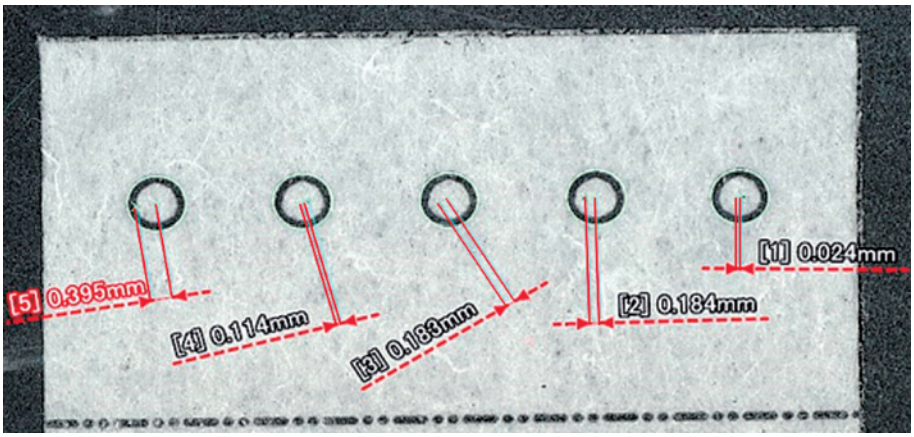

Figure 3 Target paper after the experiment showing the distances between the center of the target circles and actual puncture points, semi-automatically measured using a high-resolution image measurement system.

Table 2 Results of this study.

Outcome	Position of target paper, n	Wilcoxon p value	Use/Non-use of the hand support device	
			with	without
Deviation distance [mean ± SD, mm]	Shallow n = 165	< 0.0001	0.18 ± 0.12	0.24 ± 0.13
	Deep n = 165	< 0.005	0.20 ± 0.12	0.24 ± 0.15
Procedure time [mean ± SD, s]	Shallow n = 33	< 0.001	9.3 ± 2.8	13.2 ± 5.2
	Deep n = 33	> 0.05	11.1 ± 3.4	13.2 ± 4.5

surgeons were successfully completed without protocol deviations. Following a brief description and demonstration of less than 1 minute, all neurosurgeons could understand and master the easy and intuitive procedure for adjusting the position of the hand support bar, and could control the weight load against the hand support bar after pushing the footswitch. A representative target paper after a puncture experiment, and a screen with measurements of the distance between the puncture point and the center of the target are shown in **Figure 3**.

The deviation distance in superficial depth setting ranged from 0.03 to 0.65 mm without the device (mean ± SD: 0.24 ± 0.13 mm), and from 0.02 to 0.92 mm with the device (0.18 ± 0.12 mm). In the deep depth setting it ranged from 0.01 to 1.05 mm without the device (0.24 ± 0.15 mm), and from 0.02 to 0.55 mm with the device (0.20 ± 0.12 mm). The procedure time in superficial depths ranged from 5.7 to 27.0 s without the device (13.2 ± 5.2 s), and from 4.7 to 14.5 s with the device (9.3 ± 2.8 s). In deep depths it ranged from 6.7 to 24.0 s without the device (13.2 ± 4.5 s), and from 6.1 to 20.5 s with the device (11.1 ± 3.4 s).

Statistical analyses of the experimental data are shown in **Table 2**.

Discussion

Compared to non-use of the hand support device, the use of the newly developed hand support device resulted in a significant improvement in the accuracy of targeting puncture sites in both, the superficial ($p < 0.0001$) and deep ($p = 0.0041$) surgery conditions. The differences in mean distance between the puncture point and the center of the target were 0.06 mm (superficial) and 0.04 mm (deep), respectively. During neurosurgery such as in superficial temporal artery to middle cerebral artery by-

passes (STA-MCA bypasses), at least 20 needles may be used with 10-0 sutures to anastomose cerebral vessels that are 1 mm or less in diameter. In the current study, we envisioned of a situation where a blood vessel measuring 1 mm in diameter was sutured using 20 needles. The mean puncture interval for such a procedure would be 0.16 mm (= 1 mm × 3.14/20), and it would be necessary to puncture and evenly suture the surrounding blood vessels at this interval. Less than 50 % accuracy of the puncture needle (0.12 mm thick) is used in this evaluation, implying that control on targeting the puncture position by at least 0.06 mm or less may be required. Based on the difference obtained in the accuracy of targeting puncture sites on using the hand support device (improvement of approximately 0.04-0.06 mm), it is highly likely that the device will be clinically useful.

Use of the current device reduced the mean times required to puncture both superficial ($p = 0.0006$) and deep ($p = 0.0527$) positions of the targets. The difference between the two mean times was approximately 4 s for the superficial and 2 s for the deep positions of the targets. Since these times reflect the duration of performing five punctures, there was an average reduction of 0.4-0.8 seconds per puncture. This reduction in puncture time indicates that puncturing was performed with less hesitation and motion correction owing to the use of the hand support device. Raffaele et al.[14] and Jafri et al.[15] reported that use of an armrest in laparoscopic surgery resulted in improved comfort levels for surgeons and reduced error rates during surgery. These studies experimentally demonstrated that the improved outcomes were attributable to the reduction of physical and psychological stress resulting from the use of the armrest. Elble showed that apart from physical factors, psychological factors may cause tremors in the surgeons' hands, and managing the psychological factors is crucial for reducing tremors.[16, 17] The hand support device in the current study was developed to improve the technical aspects of precise operations by stabilizing the surgeons' hands during surgery; however, the device may effectively reduce their psychological stress. Evaluation of a questionnaire administered to the participating surgeons revealed that the use of the hand support device enabled the surgeons to perform punctures more safely than non-use.

No significant differences in results were found based on depth conditions. This is believed to be attributable to the fact that the target for puncture is placed approximately 3 cm deeper than the superficial target; therefore, the extent of downward movement of the hand (surgical instrument) was larger than that of the superficial target, and it took about 1-2 seconds from initiation to complete the first puncture.

It is essential to ensure the sterility of the hand support bar (the region on which the surgeons rested their hands) when developing the hand support device for surgery. In addition, the sterilization method should be simple, fast, and economic. The hand support bar was designed to ensure that it could be easily detached from the hand support device and autoclaved. There was also a provision for using a disposable hand support bar or a sterile cover or drape on the bar to avoid sterilization of the bar itself. However, these proposals were avoided from the standpoint of operational arduousness, preparation time, storage of accessories, and operating costs. The simple detachable mechanism of the hand support bar may have a range of future applications. By developing various bars with different forms depending on the type and site of surgery and preferences of the surgeon, this device would enable selection of the most appropriate bar for each patient or procedure, indicating the prospect of safe and effective clinical use of the device.

Conclusion

In this study, we developed a well-balanced hand support device equipped with new features to improve clinical outcomes of precise operations. Utility of the device was evaluated using a prototype. A bench patient model simulating puncture techniques of suture needles to superficial and deep cerebral vessels during brain surgery was created, and the accuracy of targeting puncture sites and the time required for puncture by 11 neurosurgeons were measured. The results showed that the accuracy of targeting puncture sites and duration of the procedure significantly improved with use of the hand support device, suggesting that it has the potential to improve surgical outcomes by stabilizing surgeons' hands during surgery and reducing the duration of the procedure. Further research will be needed to enable use of the device in regular clinical practice.

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Conflicts of Interest: Masakazu Taira is the owner of Taira Denki Co. Ltd. and receives an allowance from his company. He worked on this research study as a student at the Graduate School of Medicine, Tokyo Women's Medical University, from 2016. All other authors disclose no financial relationships relevant to this article.

References

1. Coulson CJ, Slack PS, Ma X: The effect of supporting a surgeon's wrist on their hand tremor. Microsurgery 30: 565−568, 2010
2. Slack PS, Coulson CJ, Ma X et al: The effect of operating time on surgeon's hand tremor. Eur Arch Otorhinolaryngol 266: 137−141, 2009
3. Ryu J, Choi SK, Chung Y et al: A portable training model for deep bypass surgery. World Neurosurg 107: 263−267, 2017
4. Belykh E, Onaka NR, Abramov IT et al: Systematic review of factors influencing surgical performance: Practical recommendations for microsurgical procedures in neurosurgery. World Neurosurg 112: e182−e207, 2018
5. Hara Y, Goto T, Okamoto J et al: An armrest is effective for reducing hand tremble in neurosurgeons. Neurol Med Chir (Tokyo) 55: 311−316, 2015
6. Yoto T, Goto T, Hongo K: Usefulness and limitation of a freely movable armrest in microneurosurgery. Int J Neuro Neurosurg 1: 185−190, 2009
7. Lehman RN, Mccaslin MF: An arm rest for use in ophthalmic surgery. Am J Ophthalmol 52: 568−569, 1961
8. Duffy MM, Edwards JB, Tumbusch WT: An arm rest for microsurgical procedures. Plast Reconstr Surg 41: 87−88, 1968
9. Sugita K, Hirota T, Mizutani T et al: A newly designed multipurpose microneurosurgical head frame. Technical note. J Neurosurg 48: 656−657, 1978
10. Ohta T, Kuroiwa T: Freely movable armrest for microneurosurgery: technical note. Neurosurgery 46: 1259−1261, 2000
11. Goto T, Hongo K, Yako T et al: The concept and feasibility of EXPERT: intelligent armrest using robotics technology. Neurosurgery 72 (Suppl): 39−42, 2013
12. Ogiwara T, Goto T, Nagm A et al: Endoscopic endonasal transsphenoidal surgery using the iArmS operation support robot: initial experience in 43 patients. Neurosurg Focus 42: E10, 2017
13. Goto T, Hongo K, Ogiwara T et al: Intelligent surgeon's arm supporting system iArmS in microscopic neurosurgery utilizing robotic technology. World Neurosurg 119: e661−e665, 2018
14. Galleano R, Carter F, Brown S et al: Can armrests improve comfort and task performance in laparoscopic surgery? Ann Surg 243: 329−333, 2006
15. Jafri M, Brown S, Arnold G et al: Energy consumption during simulated minimal access surgery with and without using an armrest. Surg Endosc 27: 971−977, 2013
16. Elble RJ, Randall JE: Motor-unit activity responsible for 8- to 12-Hz component of human physiological finger tremor. J Neurophysiol 39: 370−383, 1976
17. Elble RJ: Central mechanisms of tremor. J Clin Neurophysiol 13: 133−144, 1996