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〔 **Original Paper** 〕

The surgical assist suit, a newly developed wearable device that does not interfere with surgeons performing laparoscopic surgery

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SUMMARY

With the increasing numbers of laparoscopic procedures performed, some laparoscopic surgeons report physical symptoms such as stiff shoulders and back pain. We developed the surgical assist suit （SAS）, a wearable device that helps to stabilize the upper extremity posture of laparoscopic surgeons. First, to examine SAS function, we checked that the SAS did not interfere with surgical quality. Second, we checked whether the SAS reduced the surgeons' shoulder stress. Animal experiments were approved by the Chiba University ethics review committees. Six 30-kg male swine under general anesthesia were used for simulation laparoscopic gastrectomy between December 2014 and October 2015. Two experienced surgeons consecutively participated in this experiment. Surface electromyograms （EMG） were recorded from both deltoid muscles while the assistant surgeon either wore or did not wear the SAS. Surgery time and blood loss were compared to assess surgical quality, and the percent maximum voluntary contraction （%MVC） and the amplitude probability distribution function （APDF） were compared to assess shoulder stress. Surgery time and blood loss were not statistically different between wearing or not wearing the SAS. %MVC and APDF were not significantly different depending upon SAS usage. The SAS did not interfere with the surgical procedure, nor did it function to reduce deltoid muscle activity. This is the first report on the SAS, which was tested using a task with low physical burden for the upper extremities. In the future, we expect that the SAS will reduce physical effects on the upper extremities when used during tasks with higher physical burden.

***Key words*: Laparoscopic surgery, shoulder, electromyography, physical burden**

Ⅰ. Introduction

The numbers of laparoscopic surgeries with small incisions made on the abdominal wall have been increasing significantly. In Japan, the number of cases increased from 381 in 1990 to 92,177 in 2015 （13th Nationwide Survey of Endoscopic Surgery in Japan, Japan Society for Endoscopic Surgery[1]）. In

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Abbreviations: APDF: amplitude probability distribution function, EMG: electromyography, MVC: maximum voluntary contraction, RMS: root mean square, SAS: surgical assist suit laparoscopic surgery, the surgeons insert cylindrical instruments (trocars, 3 to 12 mm in diameter) through the abdominal wall of the patient. Surgeons inspect the abdominal cavity and organs with the laparoscope inserted through the trocar. Laparoscopic surgeons use specially designed surgical instruments (such as forceps, coagulation systems with different energies, and staplers), and the quality of laparoscopic surgery is equivalent to that of conventional open surgery.

The merits of laparoscopic surgery for the patient are decreased blood loss during surgery and reduced postoperative pain[2,3]. Early recovery and early discharge are generally recognized after laparoscopic surgery. The physical burden on the patients with laparoscopic surgery is favorable, and laparoscopic surgery is also worth performing for surgeons[4].

However, some laparoscopic surgeons report physical symptoms including fatigue and musculoskeletal system symptoms such as stiff shoulders and back pain[5]. The reasons are that laparoscopic surgeons operate in an unusual posture for prolonged periods due to the increased surgical difficulty, and the conventional operating room environment is not ergonomically appropriate for laparoscopic surgery[6,7]. We therefore developed the surgical assist suit (SAS), a wearable device that helps to stabilize the posture of the upper extremities of laparoscopic surgeons. The prototype SAS is shown in Fig. 1. In this study, we confirmed how the SAS functioned for laparoscopic surgeons in an animal laparoscopic surgical study.

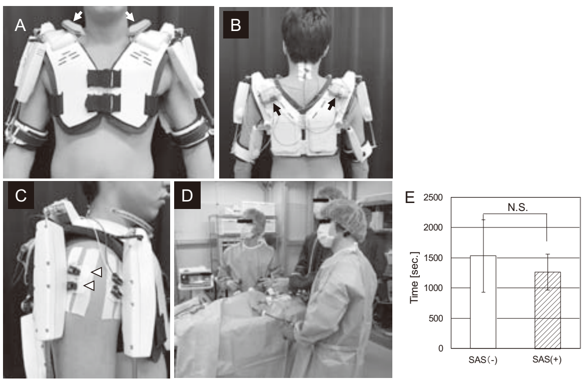

Fig. 1 Overview of the surgical assist suit (SAS). A: Front view of the SAS. White arrows: operation switches for each upper arm. The switches control each side independently. B: Back view of the SAS. Black arrows: wireless electromyography (EMG) sensors. C: Side view of the SAS. White arrowheads: EMG electrodes. D: Animal experiment. E: Results of lymphadenectomy times. White bar: control group; hatched bar: SAS group; error bar: S.D.; N.S.: not significant (paired *t*-test).

Ⅱ. Materials and Methods

To assess the function of the SAS, we first checked to ensure that the SAS did not interfere with surgical quality. Second, we checked whether the SAS reduced stress on the surgeons' shoulders.

Subjects

The animal experiments were approved by the Chiba University ethics review committees (animal experiment authorization number: 26-84, 27-147). Six animal experiments were performed between December 2014 and October 2015. Six 30-kg male swine under general anesthesia were used for this experiment. Two surgeons (Surgeon A, Surgeon B) participated to perform laparoscopic simulation gastrectomy. For the experiments, Surgeon A wore the SAS once and did not wear it once, and Surgeon B wore the SAS twice and did not wear it twice. Data were acquired from all 6 animals.

Instrumentation

The SAS was designed as a wireless, wearable device (Fig. 1A-C). Surgeons control both sides independently with switches located near the neck to lock and release the SAS. The SAS is an exo-skeletal structure that covers both shoulders to the chest. It is controlled with 3 mechanical locks each on both sides. The SAS can be independently controlled to place the right and left arms in appropriate positions. The SAS covers the brachium, thus allowing surgical hand washing. Mechanical locks are controlled by four AA batteries (6V) that allow operation for 8 hours. The total weight of the SAS is 3.2 kg.

Experimental protocol

For the animal experiment, laparoscopic lymph node adenectomy of the greater curvature for gastric carcinoma was performed as a simulation surgery (Fig. 1D). We examined blood loss during the surgical procedure, surgery time, and surface electromyogram (EMG) recordings of the bilateral deltoid muscles of the surgical assistant. Lymph node adenectomy time was the time taken to excise lymph nodes 4sb, 4d, and 6 according to the Japanese Classification of gastric carcinoma[8]. Blood loss during the surgical procedure was judged by review of the surgery video and by the necessity of laparotomy to achieve hemostasis. After the EMG measurements, we examined the value of maximum muscle strength for each surgery. The maximum muscle strength test involved the subject elevating his upper extremity to 90 degrees and then resisting the examiner's downward force. The maximum muscle strength test was performed 3 times for each arm, and the mean value of the three measurements was considered the maximum muscle strength.

Simulation surgery was performed by a pair of surgeons, Surgeon A and Surgeon B. The surgeons operated an ultrasonic coagulation and cutting system (Harmonic, Johnson & Johnson K. K., Tokyo, Japan) with the right hand to dissect tissue and control hemostasis with coagulation. Endoscopic surgical 5-mm grasping forceps (CLICKline; KARL STORZ Endoscopy Japan K. K., Tokyo, Japan) were controlled with the surgeon's left hand and the assistant's hands. During the procedure, EMG of the assistant's deltoid muscle activity was recorded.

EMG measurement

EMG of the deltoid muscle on each side was measured by an MP150WS system with an EMG2-R EMG amplifier and BN-EMG2 wireless EMG sensors (BIOPAC Systems, Inc., Goleta, CA, USA). Electrode patches were placed at 3 cm below the muscular aspects on each side of the acromial process, and a reference electrode was placed on cervical vertebrae C7 (Fig. 1B, C)[9]. The acquired EMG data were analyzed by AcqKnowledge Data Acquisition and Analysis Software (version 4.1, BIOPAC Systems, Inc.).

The recording parameters were amplification × 2000, bandpass filtering of 5-500 Hz, input impedance of 1 GΩ, and a common-mode rejection ratio of 110 dB. The acquired data were A/D converted at 2000 Hz and recorded on a personal computer. The root mean square (RMS) of the myoelectric potential during task execution was calculated offline. For each muscle, the mean RMS of all conditions was divided by the RMS during the maximum voluntary contraction (MVC), referred to as %MVC, to eliminate unexpected individual differences between subjects and muscles. The amplitude probability distribution function (APDF) for the RMS amplitude was assessed every one minute [10]. The 10^{th}, 50^{th}, and 90^{th} percentiles of the APDF were calculated and expressed as %MVC. These percentiles were denoted by APDF10, APDF50, and APDF90.

Data analysis

• Two-group analysis

This analysis compared lymph node dissection time and %MVC of the deltoid muscle between wearing of the SAS (SAS group) and not wearing the SAS (control group). Blood loss was judged on the basis of whether major bleeding occurred and whether laparotomy was required to achieve hemostasis.

• Three-group analysis

For further analysis, the SAS group was divided into two groups: the SAS- group, in which the surgeon did not use the SAS during surgery, and the SAS + group, in which the surgeon used the SAS during surgery. Because the surgeons who wore SAS controlled SAS in the status of free- or fixed-mode during surgery. SAS-group refers that a surgeon wears SAS, but the status of SAS was in free-mode. SAS + group refers that a surgeon and the SAS was in fixed-mode. The average value of %MVC and the representative value of %MVC for APDF10, APDF50, and APDF90 were validated in the three groups.

Statistical analysis

Analysis of variance was performed between various combinations of the two groups to confirm statistical dispersion, and then parametric or non-parametric analyses were performed. For the analysis of APDF10, APDF50, and APDF90, logarithmic transformations between the three groups were calculated before analysis of variance. The non-parametric Mann-Whitney U test was applied when statistical dispersion between two groups was not confirmed. In all tests, $p<0.05$ was considered to indicate statistical significance. The statistical software R 3.3.2 (The R Project for Statistical Computing, http://www.R-project.org.) was used for all analyses.

Ⅲ. Results

The mean age of the surgeons was 44 years old (SD 5.7 years), and both surgeons were right-hand dominant (Surgeon A: male, age 48 years; 165 cm, 60 kg, with 10 years of laparoscopic surgery experience; Surgeon B: male, age 40 years; 165 cm, 62 kg, with 8 years of laparoscopic surgery experience).

Surgical quality

Between the two groups, lymphadenectomy times (mean ± SD) in the simulated surgery were 1531 ± 601 seconds for the control group and 1269 ± 299 seconds for the SAS group, and the difference between the times was not statistically significant ($p = 0.2987$, paired *t*-test, Fig. 1E). Intraoperative bleeding was not recognized in either of the groups by video review. Hemostasis, such as that requiring the surgeon to perform a laparotomy to control bleeding, was not observed during the experiments.

%MVC and APDF analysis of deltoid muscle activity

%MVC represents muscular strength against maximum muscle strength. Thus, low values indicate low muscle strength and high values indicate high muscle strength. No statistically significant differences were found between the two groups for the mean value of %MVC of the deltoid muscle on both sides (Fig. 2, left: $p = 0.4327$, right: $p = 0.3457$, Mann-Whitney U test). There were no statistically significant differences in the mean values of %MVC between the control, SAS-, and SAS + groups, as shown in Fig. 3 (left:

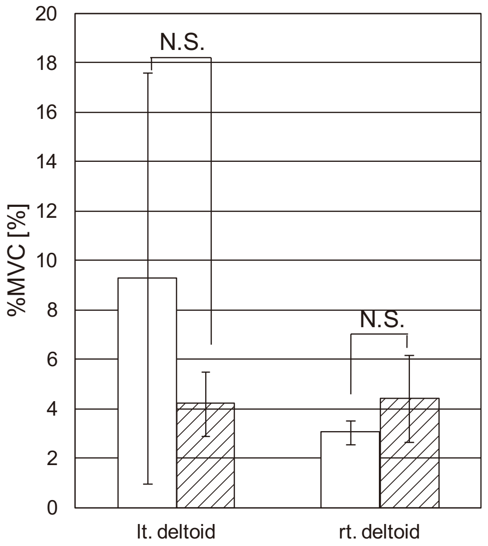

Fig. 2 Results of percent maximum voluntary contraction (%MVC) of the deltoid muscle on each side. White bar: control group; hatched bar: SAS group; lt.: left; rt.: right; error bar: S. D.; N. S.: not significant (Mann-Whitney U test).

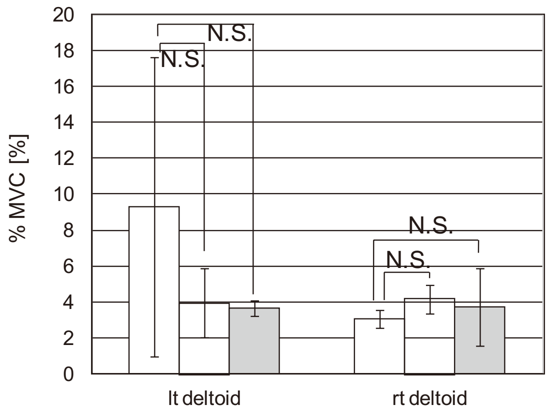

Fig. 3 Comparison of the mean value of %MVC between the three groups during the simulation surgery. White bar: control group; dotted bar: SAS- group; grey bar: SAS + group; lt: left; rt: right. N.S.: not significant (Mann-Whitney U test).

control vs. SAS-, $p = 0.4439$; control vs. SAS +, $p = 0.3654$; right: control vs. SAS-, $p = 0.2187$; control vs. SAS +, $p = 0.7042$; paired *t*-test, Mann-Whitney U test).

APDF represents evaluation of work efficiency. Low% MVC values in each APDF represent muscle strain to low workers. There were also no statistically significant differences in the representative %MVC values of the control vs. SAS- or control vs. SAS + groups at APDF10, APDF50, and APDF90, as shown in Fig. 4 (left deltoid muscle: APDF10 control vs. SAS-,

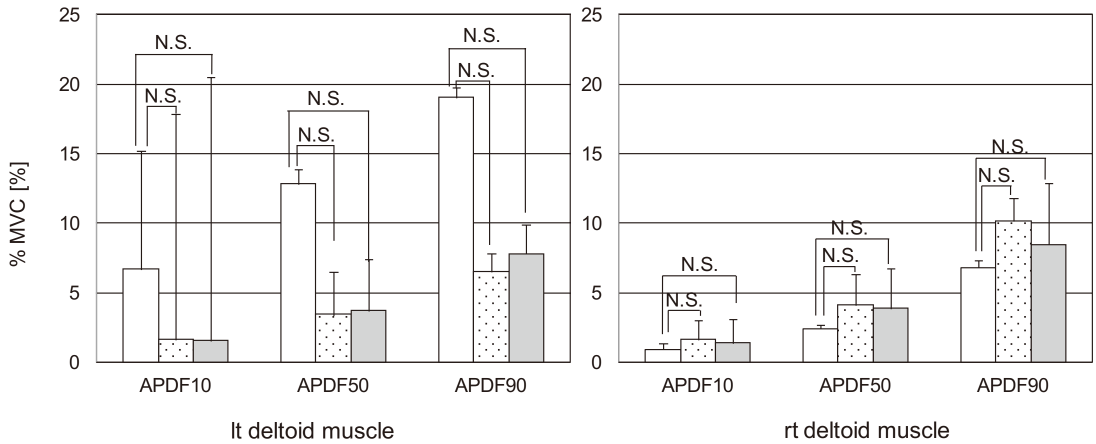

Fig. 4 Summary measurements of shoulder stress for abduction during laparoscopic simulation surgery, represented as the amplitude probability distribution function (APDF) in %MVC. White bar: control group; dotted bar: SAS- group; grey bar: SAS + group; error bar: S. D. No significant differences were found between the SAS- or SAS + vs. control groups (*t*-test, Mann-Whitney U test). N. S.: not significant.

p = 0.4051; control vs. SAS +, p = 0.4025; APDF50 control vs. SAS-, p = 0.4203; control vs. SAS +, p = 0.4335; and APDF90 control vs. SAS-, p = 0.3703; control vs. SAS +, p = 0.4124 and right deltoid muscle: APDF10 control vs. SAS-, p = 0.1009; control vs. SAS +, p = 0.3336; APDF50 control vs. SAS-, p = 0.3365; control vs. SAS +, p = 0.3157; and APDF90 control vs. SAS-, p = 0.1621; control vs. SAS +, p = 0.5730; paired *t*-test, Mann-Whitney U test).

Ⅳ. Discussion

The SAS is a wearable device for laparoscopic surgeons with the developmental goal of reducing the physical burden on these surgeons. The surgical quality of laparoscopic surgery is as almost the same as that of conventional open surgery with exclusive laparoscopic tools used by the surgical staff, a surgical assistant, and an endoscopist[11].

The surgical assistants need to hold a certain posture when grasping an organ to maintain a secure peritoneal operative field[12]. One stressful posture with high burden is maintaining the upper extremities in an abducted position. Surgical assistants often need to elevate their elbow to the shoulder area and maintain this posture to create surgical space. The laparoscopic surgeons or assistants need to raise their elbow because trocars are inserted in the patients' abdominal wall, and the surgeons' hands are relatively higher than in conventional open surgery. Furthermore, the physical workload can be tougher for laparoscopic surgeons with a smaller physique or for female surgeons[13].

The SAS maintains an elevated position of the upper extremities. It consists of an outer shell construction and mechanical locks. The "lock" and "cancel" operations of the SAS are controlled on each side by independent switches located near the jaw. Automatic control by computer software is presently not enabled. The purpose of the SAS is to maintain the posture of the upper extremities to allow the deltoid muscles to rest. The basic concept is different from that of existing power-assisted suits. The purpose of the SAS is not to move the arms automatically but to manually hold them in one position to reduce fatigue.

The effectiveness of the surgical technique was validated while the surgical assistants wore the SAS and performed simulated laparoscopic distal gastrectomy. In both the %MVC and APDF analyses, the lack of any influence on the effectiveness of surgical technique by the presence or absence of the SAS was proven statistically. The SAS did not cause prolongation of the surgical time or an increase in the amount of bleeding. Therefore, the SAS does not appear to interfere with the surgical procedure. As with conventional laparotomy, laparoscopic surgeons operate in the standing position. Laparoscopic surgery for gastric, colonic, and rectal cancer can take 3 to 5 hours. During surgery, the surgeons often adjust or move their standing positions, and the operating room floor is often crowded with wires for various energy devices and anesthesia monitors. Thus, if possible, stationary-type instruments need to be avoided. Therefore, the need for surgeons to use wearable devices that do not require wires is high.

As a robotic surgical system, da Vinci Surgical System (da Vinci), which was approved for use in Japan in November 2009, allows the surgeon to sit at the "Surgeon Console" and place the elbows comfortably to operate the multiple robotic arms needed for the surgical procedure[14]. Also, robotic arm clamps that function as the surgical assistant are capable of stably securing the surgical field. However, da Vinci is limited to certain surgical operations, and expensive surgery fees are charged for the use of this system[15]. Furthermore, the da Vinci system's initial cost and maintenance fees are also high[16]. Blood loss, postoperative complications, and hospitalization periods are not statistically different between da Vinci surgery and regular laparoscopic surgery[17,18]. Thus, the SAS may help to reduce surgeons' fatigue when performing laparoscopic surgery without relying on da Vinci.

Wang et al. evaluated the value of measuring %MVC of the upper extremities during laparoscopic sigmoidectomy. They reported that the values in laparoscopic surgeons were significantly lower than those in open sigmoidectomy[19]. However, there is no report of EMG measurement in surgical assistants. In laparoscopic surgery, although the priority for comfort is directed at the surgeons, surgical assistants also maintain an uncomfortable position, and their comfort also needs to be addressed.

We analyzed the upper extremities of surgical assistants who perform laparoscopic surgery. During laparoscopic surgery, assistants maintain the surgical field to make the surgery easy. Therefore, they need to keep their elbows elevated to shoulder height. Investigation of significant differences in the EMGs of specific surface muscles was not the goal of our analysis; rather, it was to determine whether use of the SAS had any detrimental effect on the surgery performed in this study.

This is the first report on the SAS, which was tested using a task with low physical burden for the upper extremities. We could not detect any statistically significant differences in the results of the %MVC or APDF analysis. In the future, we expect that the SAS will reduce the effects on the upper extremities when used during tasks with higher physical burden.

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