Short Report

Clinical Use of a Wearable Lower Limb Support Device for Surgeries Involving Long Periods of Standing

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Abstract

In recent years, laparoscopy has become a frequent technique employed in abdominal surgeries. Simultaneously, surgery has become increasingly complex and operating times have lengthened. Surgeons and scrub nurses must more frequently operate in standing position, with increasing physical burden. We assess the effect of the Archelis posture maintenance device, which has been developed for surgeons, in clinical situations. We measure the scopist bilateral iliopsoas muscle surface electromyogram during radical laparoscopic hernia surgery. Muscle potential decreases in the surgery with wearing Archelis. In a subjective assessment, the study participant desired its use during long surgeries. Posture maintenance devices for surgeons and improved surgical environments are important to improving surgery quality and surgeons' work environment.

Key words

wearable device, laparoscopy, robot assisting, assist suit

1. Introduction

In recent years, laparoscopic surgery has become an increasingly frequent approach to abdominal surgery[1]. Compared to a conventional laparotomy, there is less bleeding, and surgery is performed from trocar wounds provided in the body wall, so there is less injury, little postoperative pain, and fewer postoperative hospital days[2]. Surgery is performed based only on monitor images after inserting forceps through the trocar, which raises the difficulty of performing the procedure, lengthens operating time, and intensifies the physical burden placed upon surgeons[3)-5)].

Past surgical practices and the stagnant configurations of medical facilities and operating rooms for laparoscopic and endoscopic surgery have led to frequent cases of surgeons and scrub nurses having to perform surgery in the conventional standing position. That is, surgeons are forced to operate for long hours in a standing position, which reportedly results in musculoskeletal fatigue and stress[6]. Because laparoscopic surgery is performed by inserting forceps through a trocar implanted in the body wall, surgeons must spend long hours in a standing position, and it is believed that this situation requires surgeons to maintain sustained muscle tension, which places a physical burden on them[7]. If surgeons experience increased physical burden, then they may become incapable of delicate forceps manipulation and unable to achieve the intended objectives of surgical treatment.

In addition, fewer younger people are entering the field and the surgeon population is aging. Age may increase surgeon complaints of lower-body stress, such as on the hips and knees[6]. Hence, there has been a focus on arranging the operating environment to reduce surgeons' physical burden, including the use of surgical support chairs, surgical robots, wearable devices, and posture maintenance devices[8)-11)]. We report on developing a device to reduce the burden on surgeons' lower back（iliopsoas muscle） as they perform surgery in a standing position and assessing its effects in clinical settings.

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2. Materials and Methods

a) Archelis

Archelis is a device worn by a physician on the lower half of the body for holding a near-standing posture (https://www.archelis.com, **Fig.1**A). During surgery, a surgeon's knees are gently held in a slightly bent position by a knee-joint locking mechanism (Fig.1B). Fixing and releasing are performed by independent left and right knee-joint locking mechanisms. Archelis's total weight is approximately 3.2 kg per side, it consists of an aluminum plate and plastic cover, and it uses no power source.

b) Study subjects

This clinical study was approved by the ethical review board of Toho University Medical Center Sakura Hospital (Certified number S17023, approved August 25, 2017). The study subjects were 1 male surgeon, aged 33 years, with a height of 178 cm, a body weight 80.0 kg, who was right-handed (and right-footed), who was a scopist for laparoscopic inguinal hernia repair for the right side. Electrocardiograph electrodes were attached 5 cm above the anterior superior iliac spine apart from the supine and 3 cm on either side of the spinal column and surface electromyograms (EMGs) were measured as references for iliopsoas

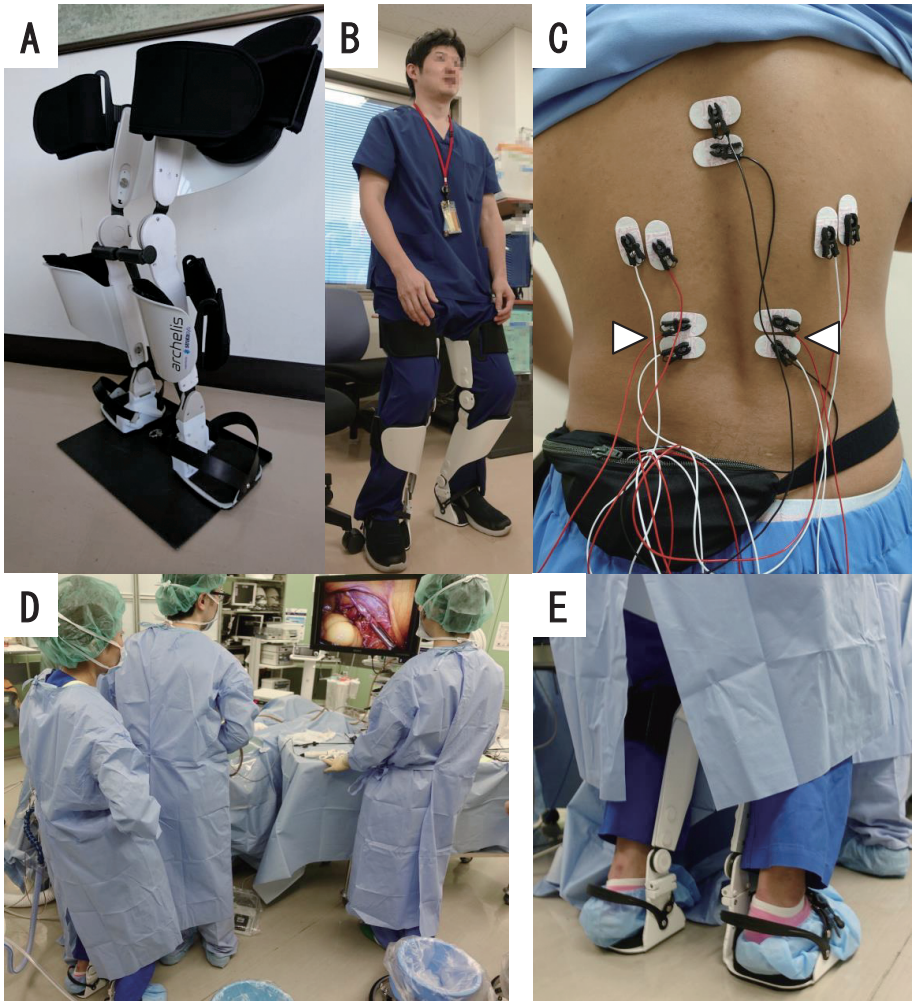

Fig.1 Over view of the clinical trial of Archelis
A : A panoramic view of the Archelis device.
B : A surgeon wearing Archelis.
C : Surface electromyogram measurement site.
D : Performing surgery while wearing Archelis.
E : Enlarged image of the area on which Archelis is worn.

muscles（arrow head, Fig.1C）. The measurements were taken on November 15 and 29, 2017, a during morning surgery. Study subjects' EMG was first measured while not wearing Archelis；then, their EMG was measured while wearing Archelis（Fig.1D, E）. The subject was instructed to not engage in any strenuous exercise the day before EMG measurement.

c） Measurement method

A BIONOMADIX two-channel Wireless EMG Amplifier BN-EMG2（Biopac Systems, Inc., Goleta, CA, USA）consisting of a BIOPAC systems MP150WS®, EMG2-R amplifier, and an attached EMG sensor was used for surface EMG measurement.

d） Data analysis

The EMG results obtained were analyzed using Acknowledge®（version 4.1, ZERO C SEVEN, Inc., Tokyo, Japan）. After removing noise from the muscle potential data, we performed root mean square（RMS）processing on all muscle potential data[12),13)].

e） Subjective assessment

After using Archelis, we distributed a questionnaire to participant to determine whether he had used Archelis, the details of surgery during use, and any comments he might have.

3. Results

Each surgical time was as followes：162 minutes while not wearing Archelis, 200 minutes while wearing Archelis. The bleeding amounts were less than 5grams in both surgeries. Before analysis, we removed noises due to surgeon's body movement or electrocautery from the intraoperative myopotential data. After the noise reduction, the analyzing time after noise removing was 4930 seconds for not wearing Archelis and 4093 seconds for wearing Archelis（**Fig.2**A, B）. The average RMS was 0.09 mV for wearing no Archelis and 0.06 mV for wearing Archelis；0.083 mV for wearing no Archelis and 0.021 mV for wearing Archelis. The Transition of RMS values were lower with wearing Archelis than not wearing Archelis during the surgery（Fig.2C, D）.

In the post-Archelis questionnaire, the subject responded

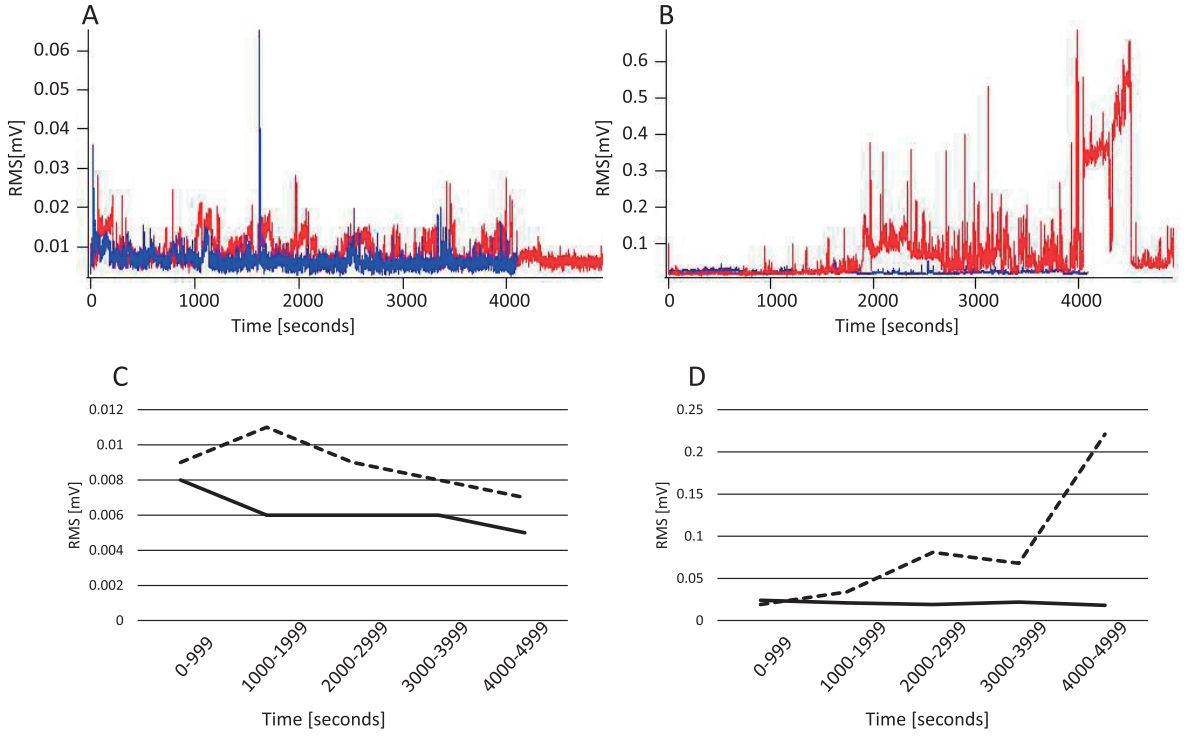

Fig.2 The results of EMG values during laparoscopic iliac hernia repair（$n=1$）. Transition of the EMG with RMS processing. A：left iliopsoas muscle, B：right iliopsoas muscle. Blue line：Wearing Archelis, Red line：Not wearing Archelis. Transition of the mean RMS value. C：left iliopsoas muscle, D：right iliopsoas muscle. Solid line：Wearing Archelis, Broken line：Not wearing Archelis.

that he would use Archelis in the future, wanted to use it during long surgeries, liked the design, and would prefer to be able to walk a little more easily.

4. Discussion

Per convention, surgeons and scrub nurses must typically stand during surgery. Performing surgery for several hours while standing places a physical burden on the lower half of the body[14]. Archelis is a wearable device for reducing the burden on the hips and legs without requiring a power source. The concept behind Archelis' development is that of an effective, simple, and standalone support device that is wearable and does not require cords or other connections. It can be easily introduced into current operating room environments. Surgeons wearing Archelis merely assume a half-sitting posture with their knees gently bent. Potential changes in the iliopsoas muscles of surgeon wearing Archelis dropped slightly. However, per the results of our questionnaire, the subject wanted to try Archelis when performing long surgeries, and he felt that they had achieved a consistent lower body posture.

The da Vinci surgical robot system（Intuitive Surgical Inc., Sunnyvale, CA, USA）was developed in the US in the 1990s and was approved as a medical device in Japan in November 2009. About 237 units have already been introduced to Japan（as of the end of September 2016）. It is a master-slave device supporting endoscopic surgical tool operation by surgeons[15)-18)]. Surgeons operating da Vinci sit at a surgeon console, which is operated with both elbows placed in elbow rests. The physical burden upon surgeons operating while seated is less than when performing regular laparoscopic surgery—in which delicate forceps manipulation is performed for long hours in a standing position. Compared to Da Vinci, which is expensive to introduce and maintain, if objectives are limited to reducing the physical burden upon surgeons, then Archelis may achieve its purpose[19)]. In this study, we did not measure the myoelectric potential in the state of sitting on the chair. In the future, to validate the effectiveness of Archelis, it is necessary to compare the myogenic potential with the condition sitting on the chair.

During laparoscopic surgery performed over long hours in a standing position, a surgeon's lower limbs experience sustained muscle tension and ergonomic improvements have been sought for surgeons in surgical environments[20)]. Static support devices based on a for the purpose of maintaining posture may reduce the physical burden upon surgeons；there is particularly active device development of this field in neurosurgery[21)]. Hybrid assistive limb（HAL）support devices that amplify power using a power source are used in the rehabilitation of patients with reduced limb function[22),23)]. Current HAL devices differ in purpose from that required by surgeons performing laparoscopic surgery because surgeons require static posture support more than dynamic physical function assistance. It is possible that developing a device for maintaining posture in a static position without making any major additional changes to current operating room environments would lessen the burden on surgeons.

5. Conclusion

Archelis is intended to improve surgeons' work environment while keeping costs down；additionally, its introduction into contemporary operating rooms should be seamless. Improving the work environment for surgeons will effectively improve the quality of surgery and benefit patients. In addition, it may help young and female physicians overcome barriers and resolve the problem of the decreasing, aging surgeon population.

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