# **Original Article**

# **Superior Effectiveness of a Newly Developed Nonadherent Polyurethane-Coated Surgical Patty for Hemostasis**

#### **Abstract**

Background: Cotton patty is usually used to aspirate blood and cerebrospinal fluid to maintain a dry field. However, the cotton patty easily adheres to the vessels by capillary action, especially in combination with hemostat. Therefore, re-bleeding may be induced by removal of the cotton patty stuck to the vessel despite initial control of the bleeding. Methods: We have developed a new cotton patty (Non-Stina X<sup>®</sup>, Hakujuji, Co., Ltd., Tokyo, Japan) which does not adhere to the vessels. The newly developed cotton patty is made of 100% cotton, with only the contact surface coated with polyurethane film which prevents capillary action. The coated side includes many holes to allow aspiration from both sides. Results: The characteristics of four different surgical patties including our new patty which are available for surgical use in Japan were investigated. Transverse sections of four different surgical patties were investigated by light microscopy (magnification ×150). Our new cotton patty did not show any fluffing on the polyurethane-coated surface. However, other surgical patties showed some fluffing on their surfaces. The friction coefficients of four different surgical patties were investigated. Our new cotton patty had the lowest of the four neurosurgical patties. We confirmed the nonadherent characteristic using with hemostats of gelatinous sponge or fibrin glue-soaked oxidized cellulose cotton during hemostasis in neurosurgical procedures. The polyurethane-coated cotton patty could be removed easily from the hemostats without re-bleeding. Conclusions: The newly developed polyurethane-coated cotton patty is more effective for bleeding control from vessels with several types of hemostat due to the nonadherent characteristics.

**Keywords:** Clipping, hemostasis, microsurgery, polyester-coated surgical patty

## Introduction

Cotton patties are essential materials to control the bleeding from vessels.[1,2] However, cotton patties tend to adhere to vessels through capillary action, especially in combination hemostat.[3] Consequently, despite control of the bleeding, re-bleeding tends to occur after removal of the adhered cotton patty. Polyester film-coated nonwoven fabric has replaced conventional gauze for the protection of burn wounds, because this material has the same capacity to absorb discharges but does not adhere to the wound. We developed a new type of cotton patty using polyester for the coating. Unfortunately, polyester film is a little hard, so may damage the brain in neurosurgery. In contrast, polyurethane has flexible and soft characteristics and is widely used as a material for artificial blood vessels.[4] Both polyurethane and

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polyester repel water. Polyurethane itself has stretching and flexible property as rubber, but polyester does not. According to this, stretching property of polyurethane make feel soft. [5,6] Therefore, we developed another new type of cotton patty using polyurethane for the coating material instead of polyester. The newly developed polyurethane-coated cotton patty and other three types of neurosurgical patty are now commercially available in Japan. The Japan pharmaceuticals and medical devices agency has granted approval for the newly developed polyurethane-coated cotton patty for medical use (registration number is  $13B2 \times 00023000155$ ).

We have evaluated the polyurethane-coated cotton patty for bleeding control with hemostat and for undesirable adherence to the vessels by clinical experience in neurological surgery.

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#### **Methods**

#### **Neurosurgical patties**

The newly developed surgical patty (Non-Stina  $X^{\oplus}$ , Hakujuji, Co., Ltd., Tokyo, Japan) is made of 100% cotton [Figure 1a], with only the contact surface coated with polyurethane [Figure 1b]. The coated side contains many holes [Figure 1c], so aspiration through the surgical patty is possible from both sides.

## Friction coefficient measurement

The friction coefficients of four different types of neurosurgical patties available in Japan including our newly developed polyurethane-coated cotton patty were measured using the friction module test system (Shimadzu Corp., Kyoto, Japan) [Figure 2]. The neurosurgical patties were cut into 3 cm × 5.5 cm pieces, and dipped in saline. A neurosurgical patty was placed on the stainless steel board (SUS304), and one side of the patty connected to the pulling system. A 150 g-3.5 cm diameter weight was placed on the neurosurgical patty. The neurosurgical patty was pulled at 100 mm/min tension speed a length of 150 mm and the friction forces were measured (n = 5). The friction coefficient of the four different types of neurosurgical patties were calculated from the friction forces divided by the applied weight.

# Light microscopy investigation

Transverse sections of the four different types of surgical patties were investigated by light microscopy (magnification ×150).

## Clinical experience

The nonadherent characteristics of the patties were confirmed with the use of hemostat in neurological surgery. The polyurethane-coated cotton patty with gelatinous sponge was applied for bleeding control from the carotid artery, the fibrin glue-soaked oxidized cellulose cotton for bleeding control from the cavernous sinus, and the fibrin glue-soaked oxidized cellulose cotton for bleeding control from the middle cerebral artery.

This study is approved by the local ethics committee at the National Defense Medical Collage (registration number is 4282).

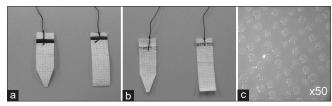


Figure 1: Newly developed surgical patty made of 100% cotton (a), with only the contact surface coated with polyurethane film (b). The coated side has many small holes (c), so aspiration is possible from both sides

#### **Results**

## Light microscopy investigation

Transverse sections of four different surgical patties were investigated by light microscopy. Our newly developed cotton patty did not show any fluffing on the polyurethane-coated surface [Figure 3a]. However, the other three types of surgical patties showed some fluffing on their surfaces [Figure 3b-d].

#### Friction coefficient measurement

The friction coefficient of the polyurethane-coated surgical patty was the lowest compared to other three types of neurosurgical patties [Figure 4].

# Clinical experience

The polyurethane-coated cotton patty was used to achieve hemostasis with hemostat during various neurosurgical procedures. The polyurethane-coated cotton patty was used with gelatinous sponge for bleeding control from the carotid artery in the case of carotid endarterectomy. After finger compression of the polyurethane-coated cotton patty for 3 min [Figure 5a], the patty could be removed easily from the hemostat without re-bleeding [Figure 5b]. The polyurethane-coated cotton patty was also used with fibrin glue-soaked oxidized cellulose cotton for bleeding control from the cavernous sinus [Figure 5c]. After compression and aspiration for 2 min through the polyurethane-coated cotton patty, the patty could be removed easily from the hemostat without re-bleeding [Figure 5d].

A 50-year-old female underwent microsurgery to clip a 5-mm unruptured aneurysm of the left internal carotid-anterior choroidal artery [Figure 6a]. During the operation, the brain retractor was moved more closely than

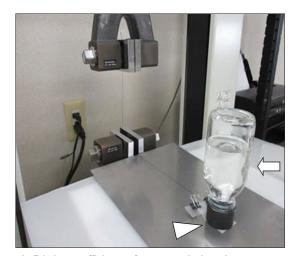


Figure 2: Friction coefficients of neurosurgical patties were measured using the friction module test system (Shimadzu Corp., Kyoto, Japan). The neurosurgical patty (arrowhead) was placed on the stainless steel board (SUS304), and one side of the patty connected to the pulling system. A 150 g-3.5 cm diameter weight (arrow) was placed on the neurosurgical patty. The neurosurgical patty was pulled at 100 mm/min tension speed a length of 150 mm and the friction forces were measured

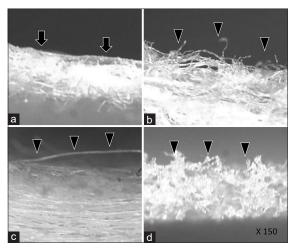


Figure 3: Transverse sections of four different surgical patties were investigated by light microscopy (magnification ×150). Non-Stina X® did not show any fluffing (a, arrow) on the polyurethane-coated surface. However, the other types of surgical patties, (b-d) showed some fluffing on their surfaces

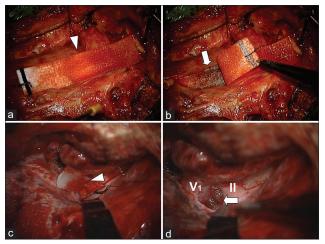


Figure 5: Following suture of the carotid artery, the site was covered with fibrin-soaked polyglycolic acid sheet for control of bleeding. Polyurethane-coated cotton patty was used to cover the fibrin-soaked polyglycolic acid sheet (a), and compressed by the finger for 3 min. The cotton patty could be removed from the hemostat without difficulty and no rebleeding occurred (b). Fibrin glue-soaked oxidized cellulose was also used with polyurethane-coated surgical cotton patty to control bleeding from the cavernous sinus (c). The surgical patty could be removed from the hemostat without difficulty and no rebleeding occurred (d). Arrowhead, polyurethane-coated surgical patty; arrow, fibrin glue, and oxidized cellulose

expected resulting in damage to the M1 portion of the middle cerebral artery. Observation under suction confirmed bleeding from a pinhole injury of the M1. Polyglycolic acid sheet soaked with fibrin glue was applied at the bleeding point of the M1,<sup>[7]</sup> then a polyurethane-coated cotton patty was placed on the hemostat. After compression and aspiration for 3 min through the cotton patty, hemostasis was completed. The polyurethane-coated cotton patty could be removed easily from the hemostat without re-bleeding [Video 1]. No neurological deterioration occurred, and computed tomography angiography and magnetic resonance angiography confirmed no

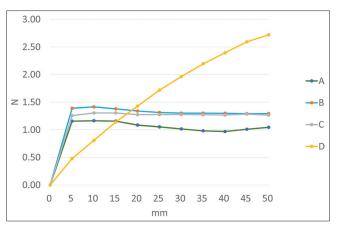


Figure 4: Friction coefficients of neurosurgical patties were measured using the friction modules test system. The friction coefficient of 4 different types of neurosurgical patties were calculated from the friction forces measurement divided by the weight, and plotted in the graph. The friction coefficient of the polyurethane-coated surgical patty (A, orange line) is the lowest compared to other 3 types of neurosurgical patties

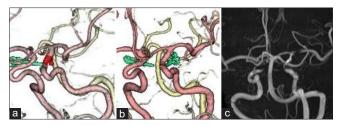


Figure 6: Computed tomography angiography showed a 5-mm unruptured aneurysm of the left internal carotid-anterior choroidal artery (a). During operation, fibrin glue-soaked oxidized cellulose was also used with polyurethane-coated surgical cotton patty to control the bleeding from a pinhole injury of the M1. One week after surgery, computed tomography angiography showed no configuration change of the left M1 (b). One year after surgery, magnetic resonance angiography confirmed no configuration change of the left M1 (c) resonance angiography confirmed no configuration change of the left M1 (c) resonance angiography confirmed no configuration change of the left M1

configuration change of the left M1 at 1 week [Figure 6b] and 1 year after surgery [Figure 6c].

## **Discussion**

Polyester film-coated nonwoven fabric has replaced conventional gauze for the protection of burn wounds in Japan, because this material tends not to adhere to the wound but retains the same capacity to absorb discharges. We developed the polyurethane-coated cotton patty based on this approach. However, polyester film is a little hard, so carries the risk of damage to the brain. Therefore, we identified coating materials softer than polyester film. Both polyester and polyurethane are used to manufacture a wide range of items, including common consumer goods. However, these materials show some distinct differences in chemical compositions.

Polyurethane is a flexible, tough, and resistant elastomer polymer which is widely used in consumer products such as sportswear, the fit-gather function of paper diapers, etc. Polyurethane is also widely used in the medical fields for artificial hearts or vessel catheters due to its high biocompatibility and reliability. The high density alignment of urethane molecules forms a smoother surface and has natural feeling. Polyurethane contains no rubber latex which may cause allergic reactions. The physical properties can be widely adjusted for use in the form of coatings, adhesives, sealants, elastomers, fibers, and foams. Fully reacted polyurethane polymer is chemically inert. No exposure limits have been established in the U. S. by the Occupational Safety and Health Administration (OSHA) or American Conference of Governmental Industrial Hygienists. Polyurethane is not regulated by the OSHA for carcinogenicity. Therefore, we chose polyurethane for the coating material of the newly developed cotton patty instead of polyester.

Adhesion is generally assumed to be the dominant factor in patty friction, [10] so we measured the friction properties of the four types of neurosurgical patty. The friction properties of fabrics depend on the fiber type, yarn count, and yarn density. [11] Consequently, the friction coefficient measurement test is necessary to identify the friction properties. The test data indicated that the polyurethane-coated cotton patty had the lowest coefficient of all 4 neurosurgical patties. Therefore, the polyurethane-coated cotton patty is considered to have the lowest adhesion characteristic.

The polyurethane-coated patty has been approved for medical use by the pharmaceuticals and medical device agency in Japan. Consequently, we could confirm the low adhesion characteristic in clinical use. We evaluated the newly developed polyurethane-coated cotton patty for bleeding control with hemostat and for undesirable adherence to the vessels in neurological surgery. The newly developed patty could be removed from several types of hemostat and vessels without difficulty and re-bleeding was not observed. Our clinical experiences support the nonadherent characteristic of the newly developed polyurethane-coated cotton patty.

Recent research has suggested that, contrary to the intended use, patties adhere to brain tissue and cause damage during removal, despite the claims of "nonadherent" and "atraumatic" of the manufacturer. We have indicated that the physical adhesion mechanism involves protruding patty fibers which may disrupt the tissue surface because of a mismatch in material stiffness. Mechanical adhesion between the patty fibers and tissue can ultimately lead to tissue avulsion when the patty is removed. Light microscopy investigation of transverse sections of newly developed cotton patty did not show any fluffing on the polyurethane-coated surface. This property may also be important in the nonadherent characteristic of the newly developed polyurethane-coated cotton patty.

Our present findings indicate that the newly developed polyurethane-coated cotton patty is more effective for bleeding control from vessels with several types of hemostat due to the nonadherent characteristics, so further experience is required in other neurosurgical procedures.

#### **Ethics**

The procedure was approved by the Institutional Review Board of our institution, and informed consent was obtained from the patient.

#### **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understand that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil

#### **Conflicts of interest**

There are no conflicts of interest.

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