New Dressing Technique using Chitosan Gauze to Decrease Pain and Bleeding in Fingertip Injuries: a Randomized Trial

Visit Rungsinaporn MD*, Parunyu Vilai MD*,
Channarong Kasemkijwattana MD*, Thitinut Dilokhuttakarn MD*, Kittipong Kongsomboon MD, MBA, PhD**

** Department of Orthopaedics, Faculty of Medicine, Srinakharinwirot University, HRH Princess Maha Chakri Sirindhorn Medical Center, Nakhon Nayok, Thailand*
*** Department of Preventive and Social Medicine, Faculty of Medicine, Srinakharinwirot University, HRH Princess Maha Chakri Sirindhorn Medical Center, Nakhon Nayok, Thailand*

Background: *In fingertip injuries, dressing material often adheres to the wound because of bleeding, causing pain when removed. Chitosan is a new local hemostatic dressing certified for external use. It can enhance platelet adhesion, aggregation and accelerated blood coagulation.*
Objective: *We hypothesized that dressing with chitosan gauze would cause less pain and decrease bleeding at dressing changes.*
Material and Method: *In a prospective, randomized, controlled trial, 65 patients were diagnosed with fingertip injury. Eight of them were excluded because of underlying disease. Sixty fingers from 57 patients were randomized into the standard dressing group (30) and the chitosan dressing group (30). Visual analogue scale for pain was recorded after the first and second dressings. Blood volume from the wound was collected from the dressing material at the second dressing. Data from both groups were compared using independent t-test.*
Results: *The result showed significantly less bleeding from the chitosan group compared with the standard group. Pain was not significantly different at the first dressing but the chitosan group was significantly less painful at the second dressing. There were no complications after suture removal.*
Conclusion: *Chitosan gauze can be used as an alternative dressing material to decrease dressing pain and bleeding in fingertip injury. Further studies are needed to expand the application of chitosan in other areas.*

Keywords: *Fingertip injury, Dressing, Chitosan gauze*

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Hemorrhage is common problem treated by emergency doctors and surgeons. A common local hemostatic technique involves pressing plain gauze on the bleeding area to create mechanical pressure and stop blood flow. In addition to plain gauze, other local hemostatic agents like oxidized cellulose, gelatin foams, microfibrillar collagen, fibrin adhesives and zeolite can also be used to shorten the bleeding period[1].

Injury to the fingertip is a common hand trauma, especially in factory workers. The severity ranges from finger laceration to distal phalangeal fracture depending on the mechanism of injury. Finger lacerations and open fractures generally have more bleeding compared with other areas because of the high vascularity of the hand. Normally these patients are commonly treated by debridement, bony fixation and/or wound suturing. The normal practice in our hospital includes Bactrigras (Smith & Nephew Medical Limited, Hull, UK) to cover the wound after complete suturing, covered with a plain gauze dressing. Often the wound continues to bleed and clots adhere to the dressing material. This results in a painful dressing change for the patient, even after soaking the soiled dressing with normal saline.

Chitosan is a new local hemostatic dressing certified for external use[2]. It is a biodegradable, non-toxic, complex carbohydrate derivative extracted from the chitin found in the shells of crustaceous animals like lobsters and crabs. It is produced by deacetylation of the chitin, resulting in poly-N-acetyl glucosamine.

Correspondence to:
Rungsinaporn V, Department of Orthopedics, Faculty of Medicine, Srinakharinwirot University, HRH Princess Maha Chakri Sirindhorn Medical Center, 62 Moo 7, Rangsit-Nakhon Nayok Road, Ongkarak, Nakhon Nayok 26120, Thailand.
Phone: +66-37-395085-6, Fax: +66-37-395087,
Mobile: +66-81-6285362
E-mail: moo779@hotmail.com

The main roles of chitosan are enhancing platelet adhesion and aggregation, increasing the production of erythrocytes and blood clots, and initiating blood coagulation[3]. Chitosan also has some antimicrobial activity and improves wound healing. According to laboratory and animal testing, chitosan can help to stop arterial and venous bleeding in the presence of coagulopathy. Chitosan has shown to promote rapid healing, prevention of dehydration, and does not adhere to wounds, while acting as a barrier to bacterial invasion[4]. Safety profile of chitosan usage was shown by Waibel et al[5]. Chitosan bandages showed no reaction in shellfish and shrimp allergic patients while use[5].

The present study was designed to compare efficacy of our standard dressing technique using Bactrigras and a new dressing technique using chitosan, with regard to visual analogue scale (VAS) for pain and bleeding volume at the first dressing change after injury. We hypothesized that the chitosan dressing should cause less bleeding because of its pro-coagulation properties, which along with the non-adherent properties of the chitosan, should result in less wound adhesion and less pain. We also considered secondary outcomes like infection rate and other complications.

Material and Method

This study was approved by the Ethics Committee of the Faculty of Medicine, Srinakharinwirot University (SWUEC/EX 29/2556). All patients who came to HRH Princess Maha Chakri Sirindhorn Medical Center with fingertip injury from September 2012 to July 2014 were included in the study. All patients gave informed consent. Inclusion criteria were distal phalangeal laceration, fingertip injury, nail bed injury and open distal phalangeal fracture if the wound size was less than 2 cm. Exclusion criteria were anticoagulant or aspirin administration, concurrent diseases like diabetes, rheumatoid arthritis and chronic vascular insufficiency, treatment more than 24 hours after injury, being unwilling to consent and being unwilling to return for follow-up.

All patients were asked to give personal information including sex, age and dominant hand preferences, and the appearance of the wound was recorded. All patients were treated with debridement and wound suturing with digital nerve block. Patients were divided into two groups, the standard group and the chitosan group, using randomized sealed envelope. The standard group was treated with a standard dressing of 5x5 cm Bactrigras directly on the wound and two pieces of 3x3 inch plain gauze on top. The chitosan group was treated with a dressing of 5x5 cm Bactrigras covering the wound, covered with a 5x5 cm chitosan gauze (AnsCare, Ben Q Material Corporation, Guishan Township, Taoyuan County, Taiwan, ROC) and two pieces of 3x3 inch plain gauze. VAS for pain was recorded after the first dressing in both groups. The VAS began at 0 for 'no pain' and 10 for 'the worst possible pain'. Every patient was prescribed tramadol (50 mg orally after meals, three times per day) and paracetamol (1,000 mg orally every 4 to 6 hours) as needed for pain control. Patients were scheduled for their second dressing within 24 hours after the first dressing. The old dressing material from both groups was removed and a new dressing was applied. VAS was recorded after finishing the second dressing. All dressing materials removed from the patient at the dressing change were weighed to determine the volume of blood absorbed into them. We used a single operator to weigh the dressings for blood volume. The baseline weights of the dressing materials were 3x3 inch plain gauze (1.1 g), Bactrigras 5x5 cm (0.45 g) and chitosan gauze 5x5 cm (0.28 g). The weight of blood was calculated by subtracting the known dry weight of the dressing materials. Then the weight of blood was calculated using the rate of 1.04 g of blood equal to 1 mL. Blood volume and VAS at the first and second dressings were compared using independent t-test or Mann-Whitney U test depend on data distribution. A *p*-value less than 0.05 was considered statistically significant. A previous study found that chitosan can shorten time to hemostasis by 50% compared with the standard method[6], so we calculated what sample size was needed to have a 50% difference in bleeding amount. This was calculated to be 30 fingers in each group (Fig. 1). Patients were scheduled for follow-up on day 7 and day 14 post-injury. Infection and wound complications were recorded. Sutures were removed at day 14.

Results

There were 65 patients initially considered for the study. Eight patients were excluded because of underlying disease. Six of those patients had diabetes mellitus and two patients were taking aspirin. The remaining 57 patients and 60 fingers were included and randomized into two groups of 30. One patient in the standard group was lost to follow-up at the time of the second dressing. Demographic data from both groups is shown in Table 1.

Data from Table 1 show that there was no difference in sex between both groups. The most common injury in both male and female group was the index finger and the second most common was the middle finger following with ring finger, little finger and thumb, respectively. Ages from both groups were nearly the same. Average age were 33.83 and 32.27 year old in male and female groups, respectively. The dominant hand was the most commonly affected in both groups, which is right hand. Results of blood volume and VAS for both groups are shown in Table 2.

Data from both groups were compared using independent t-test and Mann-Whitney U test. There was significantly less bleeding in the chitosan group compared with the standard group (p<0.001). There was no significant difference in VAS at the first dressing (p = 0.244), but at the second dressing, the chitosan group had less pain than the standard group (p = 0.010) (Fig. 2).

All wounds healed normally. No wound infections were noted after suture removal and no other complications occurred.

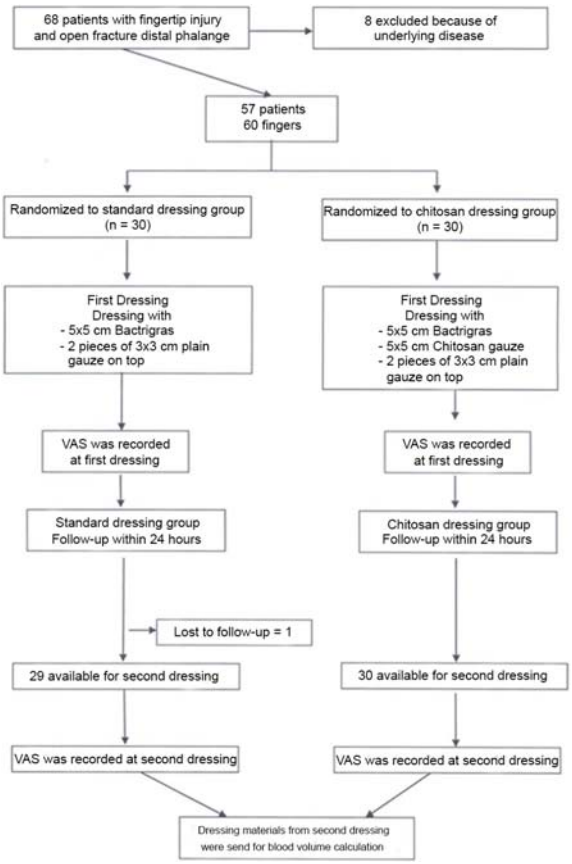

Fig. 1 Patient flowchart and dressing techniques for standard group and chitosan group.

Discussion

Chitosan was first used in humans by the military. It was distributed to medical units during the Iraq and Afghanistan wars. According to the report, there were 69 injured soldiers with heavy bleeding for whom common hemostatic methods were ineffective. The use of chitosan successfully stopped the bleeding of 62 soldiers (97%) before they arrived at the hospital[7]. Brown et al. reported the use of chitosan bandages in an ambulance setting with bleeding traffic accident victims. In those cases, nurses would first

Table 1. Show demographic data from both groups

	Standard dressing (29 finger)	Chitosan dressing (30 finger)	*p*-value
Sex			
Male (%)	16 (55.2)	13 (43.3)	0.363
Female (%)	13 (44.8)	17 (56.7)	
Effected finger (finger)			
Thumb (%)	2 (6.9)	4 (13.3)	0.687
Index (%)	11 (37.9)	9 (30)	
Middle (%)	6 (20.7)	8 (26.7)	
Ring (%)	8 (27.6)	5 (16.7)	
Little (%)	2 (6.9)	4 (13.3)	
Age (year)			
(mean $\pm$ SD)	33.83$\pm$10.77	32.27$\pm$11.79	0.598
Injury in dominant hand (finger)			
Right (%)	25 (86.2)	25 (83.3)	1.000
Left (%)	4 (13.8)	5 (16.7)	

Table 2. Show result from both group regarding to blood volume and VAS for pain

	Standard group	Chitosan group	*p*-value
Blood volume (ml) (mean ± SD)	8.20±3.36	5.34±2.10	<0.001*
VAS for pain first dressing (mean ± SD)	4.48±1.50	5.03±2.04	0.244*
VAS for pain second dressing (median (inter-quartile rang))	4 (3, 5)	2 (1, 3)	<0.010**

* Independent t-test, ** Mann-Whitney U test

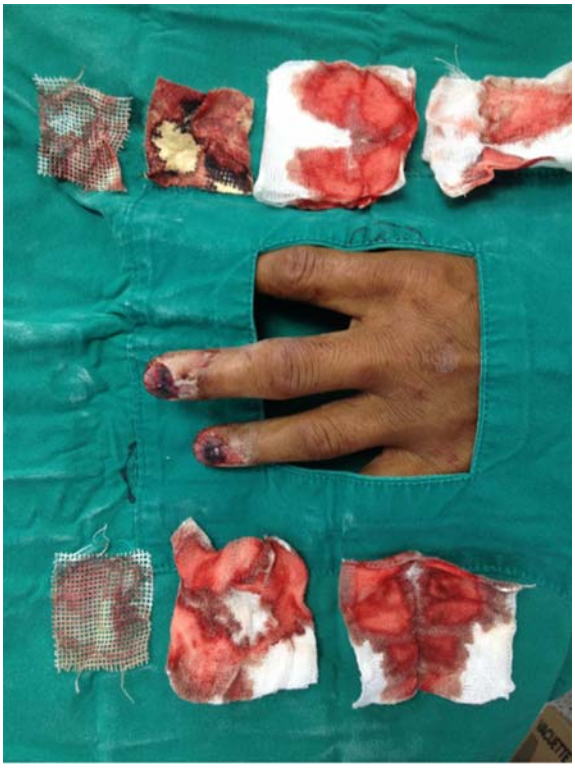

Fig. 2 The standard dressing (ring finger) and chitosan dressing (middle finger). Blood staining on the gauze was slightly less in the chitosan group compared with the standard group.

try hemostasis by applying pressure with plain gauze. If that was not successful, they used the chitosan bandage. They found that the chitosan bandage helped stop the bleeding of 79% (27/34) of the patients whose bleeding could not be stopped by common hemostatic methods. Seventy-four percent of them were stopped completely within 3 minutes. With seven of the patients, the chitosan bandage could not stop the bleeding after 10 minutes because of misuse of the bandage. The researchers concluded that the use of the chitosan gauze was proven effective with people whose bleeding could not be stopped by common hemostatic methods[8].

Arbel et al compared the use of chitosan pads and hand pressure in postoperative hemostasis of femoral artery punctures. The results indicated that the chitosan pad could significantly shorten the bleeding time and lessen the rate of hematoma formation compared with manual pressure on the blood vessel[9]. Kumar et al compared chitosan pads with a mechanical radial compression device in postoperative hemostasis of radial artery puncture. The chitosan pad resulted in less bleeding time and reduced minor bleeding[10]. Yang Jian et al showed the application of chitosan dressings in congenital heart disease intervention can shorten hemostasis time 50% compared with the standard method[6]. Malmquist et al showed clinical effectiveness of HemCon Dental Dressing (made from chitosan) as hemostatic device. It can significantly shorten bleeding time following oral surgery procedures for all patients compare to control group, including those patients taking oral anticoagulation therapy[11].

Huang et al demonstrated the potential application of chitosan sponges to use as absorbable hemostatic dressing in a hepatic hemorrhage model compare to gelation sponge[12]. Chung et al demonstrated effect of newly developed chitosan gel on hemostasis and wound healing after endoscopic sinus surgery. Result showed rapid hemostasis immediately after endoscopic sinus surgery and prevent adhesion formation[13]. Chou et al compared effect of chitosan dressing and gauze on hemorrhage caused by breast biopsy. Chitosan dressing can shorten the bleeding time and significantly reduce the hematoma size during breast biopsy[14]. Hemostatic effect can improve by chitosan even in patients with bleeding tendency such as hemodialysis patients with acquired coagulopathy. Misgav et al demonstrated chitosan pads significantly reduce hemostatic time in patients on chronic hemodialysis compare to gauze[15].

Our study came about based on bad experiences of patients who had pain during dressing material removal from fingertip injuries. When blood clots adhered between the wound and the dressing

material, it becomes sticky and very difficult to remove, even when soaked with normal saline. Chitosan has the ability to accelerate coagulation and should decrease bleeding and blood clot formation. From literature review, there is no literature refer to pain reduction when dressing with chitosan gauze. We hypothesized that if we use chitosan for fingertip injury dressing, it should cause less blood clots and less adhesion between the wound and the dressing material. Patients should therefore have less pain when removing the dressing. The results supported our hypothesis. We found significantly less bleeding and less pain at the second dressing in the chitosan group. VAS score in first dressing is not difference between 2 groups because of we measure VAS score at the time of injury. The result show nearly similar VAS score in both groups.

The strengths of this study were its randomized controlled design, only one patient dropped out and a single operator for blood weighing. The weak point of this study is the variety of wound sizes. Wound size can affect amount of bleeding, making injuries hard to compare. We defined wound size less than 2 cm for all patients to control for this. Even though fingertip injury cause little bleeding compare to other wound, we use fingertip injury wound as model represent new dressing technique to compare difference in VAS score and bleeding from standard wound dressing technique.

Conclusion

Chitosan gauze is a good option to decrease wound bleeding in highly vascular areas. It can be applied to as a dressing material to decrease bleeding and dressing pain in fingertip injuries. More study is needed on other promising applications for chitosan.

What is already known on this topic?

Eventhough chitosan was used to decrease bleeding from wound. From journal review, there is no case control study using chitosan as dressing material to decrease wound bleeding

What this study adds?

This is the first study to apply chitosan to be wound dressing. It may lead to another application of using chitosan in different type of wound to decrease bleeding

Acknowledgements

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Potential conflicts of interest

None.

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การทำแผลวิธีใหม่โดยใช้ไคโตซานในผู้ป่วยที่มีการบาดเจ็บบริเวณปลายนิ้วเพื่อลดการเสียเลือด และลดอาการปวดขณะทำแผล

วิศิษฎ์ รังษิณาภรณ์, ภรัณยู วิไล, ชาญณรงค์ เกษมกิจวัฒนา, ฐิติณัฐ ดิลกหัตถการ, กิตติพงษ์ คงสมบูรณ์

ภูมิหลัง: *การทำแผลในผู้ป่วยที่มีแผลบริเวณปลายนิ้วมักพบว่าวัสดุทำแผลติดแน่นอยู่กับแผลและลอกออกยาก เนื่องจากลิ่มเลือดแข็งตัวยึดติดระหว่างวัสดุทำแผลและแผลทำให้ผู้ป่วยปวดแผลขณะทำแผล ไคโตซานเป็นวัสดุทำแผลชนิดใหม่ที่ช่วยทำให้เลือดหยุดเร็วขึ้น*

วัตถุประสงค์: *ผู้วิจัยมีสมมุติฐานว่าการใช้ไคโตซานทำแผลจะช่วยลดการเสียเลือดและลดการยึดติดระหว่างวัสดุทำแผลและแผล ซึ่งจะทำให้อาการปวดขณะทำแผลลดลงได้*

วัสดุและวิธีการ: *ผู้วิจัยได้ทำการวิจัยแบบ prospective, randomized, controlled trail ในผู้ป่วย 65 คน ที่มีแผลบริเวณปลายนิ้ว ผู้ป่วย 8 คน ถูกคัดออกเนื่องจากโรคประจำตัว มีจำนวนผู้ป่วยทั้งหมด 57 คน รวม 60 นิ้ว เข้าร่วมการวิจัยและได้ถูกแบ่งแบบ randomization เป็น 2 กลุ่ม กลุ่มละ 30 นิ้ว กลุ่มแรกคือ กลุ่มที่ทำแผลแบบมาตรฐาน และกลุ่มที่สอง ใช้ไคโตซานในการแผล ผู้วิจัยวัด visual analogue scale for pain ในผู้ป่วย ขณะทำแผลในวันแรกและวันที่ 2 หลังการบาดเจ็บที่ปลายนิ้ว วัสดุทำแผลที่ใช้ในการทำแผลในวันแรกจะถูกเอาออกจากแผลในวันต่อมาเพื่อเอาไปชั่งวัดน้ำหนักของเลือดที่อยู่ในวัสดุทำแผลเพื่อเปรียบเทียบเลือดที่ออกจากแผลในผู้ป่วยทั้ง 2 กลุ่ม*

ผลการศึกษา: *พบว่าเลือดที่ออกจากแผลในกลุ่มที่ทำแผลด้วยไคโตซานมีจำนวนน้อยกว่ากลุ่มที่ทำแผลแบบมาตรฐานอย่างมีนัยสำคัญทางสถิติ ความปวดในกลุ่มที่ทำแผลด้วยไคโตซานลดลงอย่างมีนัยสำคัญทางสถิติในการทำแผลวันที่ 2 เปรียบเทียบกับกลุ่มที่ทำแผลแบบมาตรฐาน ไม่พบว่ามีภาวะแทรกซ้อนเกิดในผู้ป่วยทุกคน*

สรุป: *การใช้ไคโตซานทำแผลอาจเป็นทางเลือกใหม่ในการลดการเสียเลือดและลดอาการปวดในผู้ป่วยที่มีการบาดเจ็บที่นิ้วจำเป็นต้องมีการศึกษาเพิ่มเติมในอนาคตถึงการใช้งานไคโตซานในแผลลักษณะอื่น*