


Validation of digital tourniquet pressures

An experimental comparison of T-Ring™ and conventional surgical glove in human volunteers

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Abstract

Digital tourniquets are widely used for the management of digital injuries in emergency departments or outpatient clinics. This study is focused on the pressure analysis of digital tourniquets on some points not covered in the existing literature.

A total of thirty volunteers were enrolled in this study. Instantaneous surface pressure was measured at the thumbs, index fingers, and little fingers. We investigated the pressure according to the circumference of digits, tourniquet types, and measurement sites (dorsal and mid lateral volar sides) above the digital vessels. Continuous pressure was measured in artificial silicone models to determine the change of pressure over 2 hours.

The average pressure measured on the mid lateral volar side of volunteers fingers were 154.3 ± 54.9 mm Hg by T-Ring™ and 162.6 ± 61.0 mm Hg by surgical glove. The pressure on the dorsal side were 224.7 ± 57.7 mm Hg by T-Ring™ and 228.8 ± 66.0 mm Hg by surgical glove, each significantly higher than the mid lateral volar side. The circumference of digits did not significantly affect the surface pressure. The pressure pattern did not change significantly over 2 hours in both tourniquet types.

The surface pressure of the mid lateral volar side was significantly lower than that of the dorsal side. However, there was no significant pressure difference according to the circumference of digits. Time dependent pressure change were not significantly different between 2 tourniquets.

Abbreviations: BMI = body mass index, FSR = force sensitive resistor, NPSA = National Patient Safety Agency.

Keywords: digital tourniquet, glove tourniquet, pressure, T-Ring

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BHK and YHJ contributed equally to this study as first authors.

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

The datasets generated during and/or analyzed during the current study are publicly available.

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1. Introduction

Digital tourniquets are commonly used for hemostasis during minor operations involving the finger digits. Rolled surgical gloves have been widely used as traditional digital tourniquets, whereas commercially available tourniquets include T-Ring™ (Precision Medical Devices LLC, San Clemente, CA, USA) and Tournicot™ (Orthotic-Lab Limited, Middlesex, UK).^[1] At our institute, we have used rolled surgical gloves (according to the method of Salem^[2]) and T-Ring.

Excessive pressure on the skin can cause complications such as blistering, skin necrosis, and nerve paresis in case of limb tourniquet.^[3] Most complications by digital tourniquets have been reported to occur due to damaged underlying neurovascular structures from the excessive pressure.^[4-7] The digital tourniquets can cause a greater risk of injury compared with their pneumatic tourniquet counterparts because the pressure is unable to be monitored effectively.^[8,9]

Generally, adding 50 to 75 mm Hg to the systolic blood pressure for 2 hours is considered safe for limb operations.^[10-14] Some previous authors had suggested the use of pneumatic digital tourniquets; however, these are not yet popularly used.^[15,16] Instead, most digital tourniquets are non-pneumatic and do not provide the exact value of pressure when applied on digits. Therefore, it is necessary to evaluate whether digital tourniquets are compressing the underlying soft tissue too much or not enough.

The pressure applied by digital tourniquets on the skin have been evaluated in some previous studies.^[17,18] Lahham et al

measured the amount of pressure applied by different kinds of digital tourniquets in patients of the emergency department.^[19] In their study, the measured pressure of rolled glove was 232 ± 36 mm Hg and that of T-Ring was 157 ± 8 mm Hg. The authors measured the surface pressure applied by tourniquets at the dorsal midline of the digits. However, these measurement points may not represent the pressure exerted on the digital vessels because they are located at the lateral volar side of the digits. Middleton et al suggested that the results of Lahham et al were influenced by patient variabilities; thus, they tested the surface pressures of various tourniquets by using an artificial model.^[20] Their results showed that the pressure of T-Ring was 146 to 427 mm Hg and that of rolled glove was 35 to 439 mm Hg. However, for clinical application, this study is limited because the pressure measurement was conducted not on human digits.

The objective of the present study was to compare the surface pressure applied above the digital vessels with that applied on the dorsal midline in healthy adults, by different kinds of finger tourniquets (commercially available T-Ring vs conventional surgical gloves). Additionally, we investigated the time-dependent pressure changes of finger tourniquets based on the fact that a rubber or silicone (the main component of finger tourniquets) could lose its original elastic property over time.

2. Materials and methods

2.1. Pressure sensor

We used force sensitive resistor (FSR)-QA6P (Marveldex, Bucheon-si, Gyeonggi-do, Korea) as a pressure sensor in this study. FSR-QA6P has a 40 to 32691 mm Hg sensing range, 9.0 mm² sensing area, 1.55 mm thickness, and <5% force repeatability (accuracy) (Fig. 1, Table 4).

2.2. Digital tourniquets

T-Ring and rolled surgical gloves (Cardinal Health, Waukegan, IL) were used in this study. T-Ring is commercially available and has only 1 size; thus, we prepared as many of the same products as needed to obtain data. Further, we used rolled surgical gloves according to the method suggested by Salem.^[21] As we performed in the clinical situations, the glove size was selected according to the hand size of the volunteers - best suited to her or his hands, and the digit of the selected glove corresponding to the finger to be measured was cut and used. The digit of the surgical gloves was cut at the most proximal part. Then the distal tip of the cut glove digit was snipped to make a hole. After placing the cut part of the glove over the volunteers digit, it was rolled down from the distal to the proximal part to exsanguinate blood (Fig. 2).

2.3. Study model

2.3.1. Instantaneous pressure measurement in enrolled volunteers. A total of 30 healthy adult volunteers were enrolled in this study. The number of subjects was determined by statistically calculating the number to draw meaningful conclusions based on the results drawn from our previous pilot study. Those with a history of trauma or operation on the digits, vascular disease including hypertension, or diabetes were excluded. This study was approved by our institutional review board (1803-089-930).

Instantaneous pressure was measured at the thumbs, index fingers, and little fingers of the dominant hand. In each digit, surface pressure was measured at the dorsal midline and lateral volar sides just above the digital vessels. The lateral volar side was determined according to the dominant digital vessels, the ulnar side of the thumb and index finger, and the radial side of the little finger.^[21,22] Once the tourniquets were applied, pressure sensors

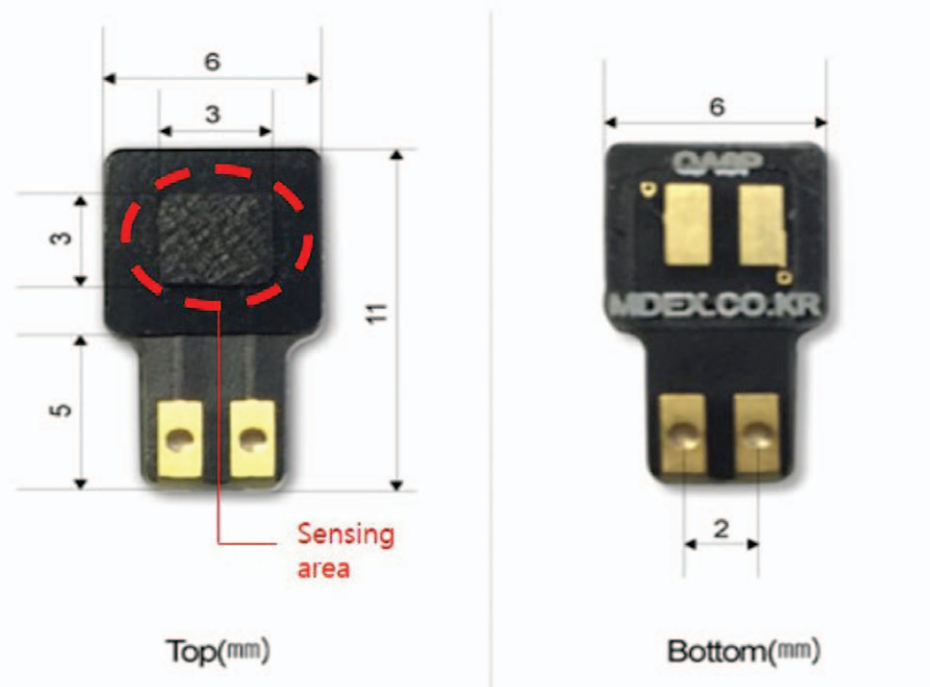


Figure 1. The pressure sensor, FSR-QA6.

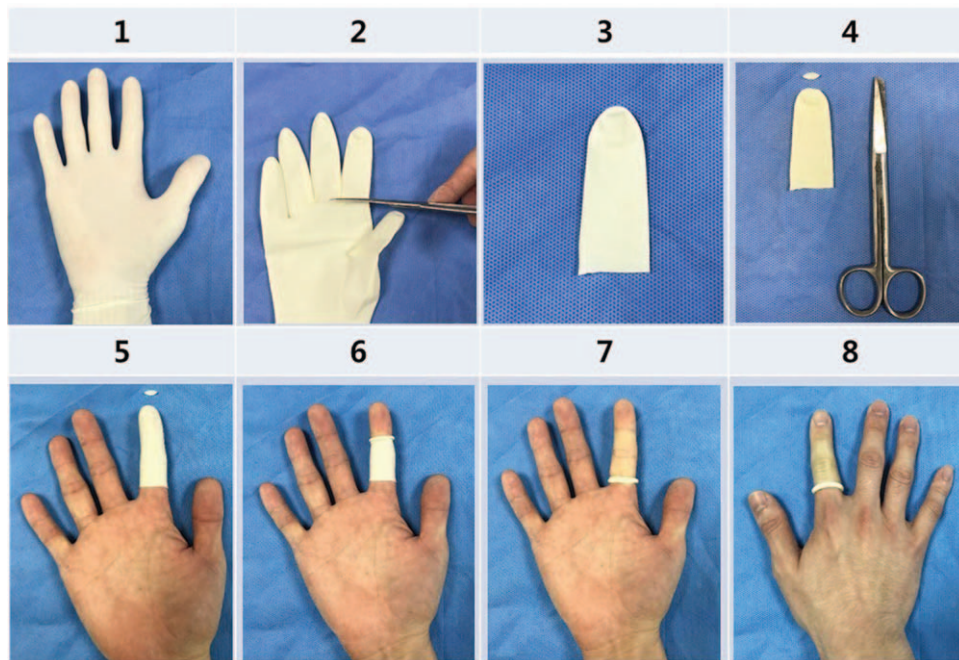


Figure 2. Method of applying rolled surgical glove on the index finger.

were inserted between the tourniquet and the skin (Fig. 3A and B).

2.3.2. Continuous pressure measurement in an artificial finger model. A cylindrical silicone finger model of 15 mm diameter was made with a three-dimensional (3D) printer (FDM; Cubicon, Seoul, South Korea) (Fig. 3C). First, the 3D model was designed using an inventor program (AUTODESK, San Rafael, CA). Second, the molds were printed using the FDM 3D printer. Finally, the silicone was mixed with a hardener, poured it into the molds, and heated in an oven. After 24 hours, the molds were removed from the oven and the replicas were extracted from the molds.

A data acquisition system was designed to measure the pressure applied by the tourniquet to the fingers. The system consisted of FSR-QA6P, Arduino MEGA (Adafruit, New York, NY), power supply, 10 kΩ resistance, a breadboard, a universal serial bus (USB) cable, and a laptop. FSR-QA6P converts physical pressure into voltage. The sensor is connected in one end to a pull-down resistor connected to the ground, and the other end is connected to a power supply. Then, the point between the fixed pull-down resistor and the FSR is connected to the analog input of a controller. The voltage equation is $V_{out} = V_{in} (R_m / (R_m + R_{FSRs}))$, where V_{out} is the voltage indicating the force, V_{in} is the input voltage (5 V), R_m is the resistance of the 10-kΩ resistor, and R_{FSRs} is the resistance of the FSRs. Therefore, the voltage is

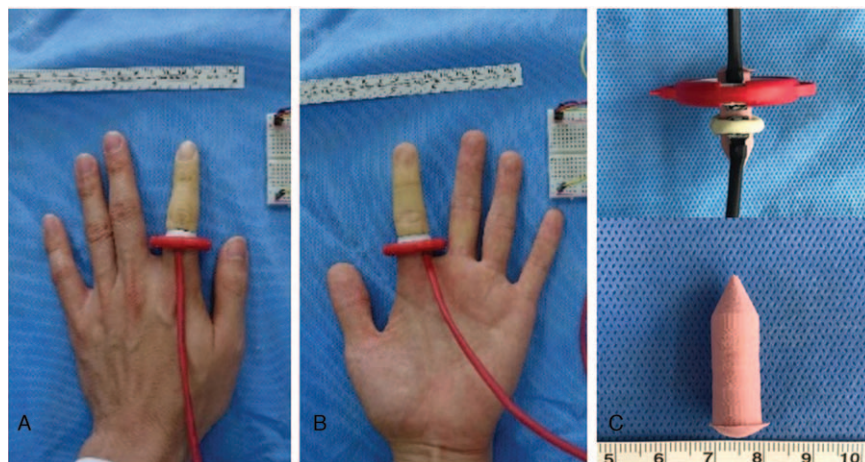


Figure 3. Immediate pressure measurement in enrolled volunteers at (A) dorsal midline, and (B) lateral volar side above dominant digital vessels. (C). Continuous pressure measurement in a silicone finger model.

Table 1
Demographics of enrolled volunteers.

Characteristic	Number
Total	30
Women	13
Men	17
Age	
21–30 years	20
31–40 years	6
41–50 years	3
51–60 years	1
BMI, kg/m ²	
16–20	9
21–25	17
26–30	3
31–35	1
Glove size	
6	17
6.5	8
7	4
7.5	1

BMI = body mass index.

proportional to the inverse of the FSR resistance. Arduino MEGA is used as a controller. It is an open-source electronics platform based on easy-to-use hardware and software. It can sense the environment by receiving inputs from sensors. It measures the voltage indicating the force and sends the measurement data to a laptop through a USB cable. To supply power consistently, the device is connected to a power supply (12 V). In both tourniquet types, the pressure changes were recorded every minute for 2 hours.

2.4. Statistical analysis

The linear mixed model was used to compare the data, considering the significant interactions between the independent variables (different types of tourniquets, different digits, and different sites of simultaneous measurements in each volunteer) and the repetitive measurement in each same volunteer. All data were analyzed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

Table 2
Circumference of digits.

Circumference (mm)	Number
1 st	
51–55	1
56–60	9
61–65	12
66–70	6
71–75	2
2 nd	
51–55	5
56–60	7
61–65	13
66–70	5
5 th	
41–45	1
46–50	10
51–55	13
56–60	6

3. Results

The present study included 13 male and 17 female healthy volunteers. The average age of the volunteers was 30.3 (21–50) years. The body mass index was 22.9 ± 2.8 kg/m² (Table 1). The circumference of the thumb was 63.0 ± 4.6 mm, and that of the index and little fingers was 61.6 ± 5.0 mm and 52.6 ± 3.8 mm, respectively (Table 2).

3.1. Instantaneous pressure measurement in enrolled volunteers

The pressure at the dorsal midline was 224.7 ± 57.7 mm Hg in T-Ring and 228.8 ± 66.0 mm Hg in rolled glove. The pressure measured at the lateral volar side was 154.3 ± 54.9 mm Hg in T-Ring and 162.6 ± 61.0 mm Hg in rolled glove. The instantaneous pressures of both tourniquets at different sites were compared using the linear mixed model (Table 3). There were statistically significant differences in pressure between T-Ring and rolled surgical glove in each digit ($P < .05$). Further, a significant difference existed between the dorsal and lateral volar sides in both T-Ring and surgical glove in each digit ($P < .005$) (Fig. 4). However, circumference was not a significant factor in each digit.

Table 3
Analysis of immediate pressure with linear mixed model.

Finger	Effect	Estimate	Standard Error	P value
Thumb	(Intercept)	311.67	107.25	.0071
	Type	16.99	8.22	.0417
	Position	−53.85	8.22	<.0001
	Circumference	−1.84	1.7	.2829
Index finger	(Intercept)	298.94	104.69	.008
	Type	−13.49	6.53	.0418
	Position	−84.33	6.53	<.0001
	Circumference	−0.62	1.7	.7151
Little finger	(Intercept)	155.34	108.39	.1629
	Type	−21.99	9.55	.0236
	Position	−66.61	9.55	<.0001
	Circumference	1.47	2.06	.4768

ref = reference.

Table 4
Comparison of parameters of commonly used pressure sensors.

	Sensing range (mm Hg)		Sensing area (mm ²)	Thickness (mm)	Force repeatability
	Minimum	Maximum			
FSR-QA6P*	40	32,691	9.00	1.55	<5%
FSR-400†	65	6580	11.40	0.35	±2%
FSR-RA18‡	40	32,691	14.51	0.95	<5%

* Marveldex, Bucheon, South Korea.
 † Interlink electronics, Camarillo, CA.
 ‡ Marveldex, Bucheon, South Korea.
 FSR = force sensitive resistor.

3.2. Continuous pressure analysis in the artificial finger model

The pressure measurements over 2 hours in the artificial finger model were compared and analyzed using the linear mixed model (Fig. 5). The mean pressures of T-Ring were 253.41 ± 26.24 mm Hg after 5 minutes, 198.01 ± 40.02 mm Hg after 20 minutes, 184.75 ± 46.76 mm Hg after 40 minutes, and 164.76 ± 53.73 mm Hg after 2 hours. The mean pressures of rolled glove were 269.68 ± 32.6 mm Hg after 5 minutes, 235.5 ± 6.45 mm Hg after 20 minutes, 211.93 ± 56.73 mm Hg after 40 minutes, and 192.34 ± 65.8 mm Hg after 2 hours. In each group, there were statistically significant decreases of pressure over time ($P < .05$). However, no difference was found in the serial change pattern between 2 groups ($P = .2573$). The trend lines of pressure change in both tourniquets were obtained with the linear mixed model. Both trend lines showed a plateau shape with decreasing pressure over time. The equation of the trend line of rolled surgical glove was “pressure = 327.52 – 34.3899*log(t) + 0.2745* t ,” and that of T-Ring was “pressure = 325.2791 – 42.3498*log(t) + 0.3713* t .” In both tourniquets, the coefficients of log (t) and t were not significantly different from each other.

4. Discussion

In 1986, Hixson et al measured the pressure applied by digital tourniquets. They used a miniature pressure transducer to assess the surface pressures applied by both a Penrose drain and rubber band, which were measured to be >500 mm Hg.^[17] The pressure measurements in the study of Lahham et al were 157 ± 8 mm Hg for T-Ring and 232 ± 36 mm Hg for rolled glove.^[19] Lahham et al recognized that the limitation of their study was that their patients did not represent the whole population. Therefore, Middleton et al attempted to remove patient variables by using a reproducible laboratory model.^[20] However, the method of Middleton et al was conducted only on the artificial finger model and did not consider the in vivo characteristics.

Although a direct comparison is difficult, our data showed a relatively higher pressure of T-Ring and a lower pressure of rolled glove compared with the study of Lahham et al. These discrepancies may have been influenced by the difference in the pressure sensors used – FlexiForce B201 in the study of Lahham et al and FSR-QA6P in our study.

The commonly used pressure sensors include FSR-QA6P (Marveldex, Bucheon, South Korea), FSRTM-400 (Interlink

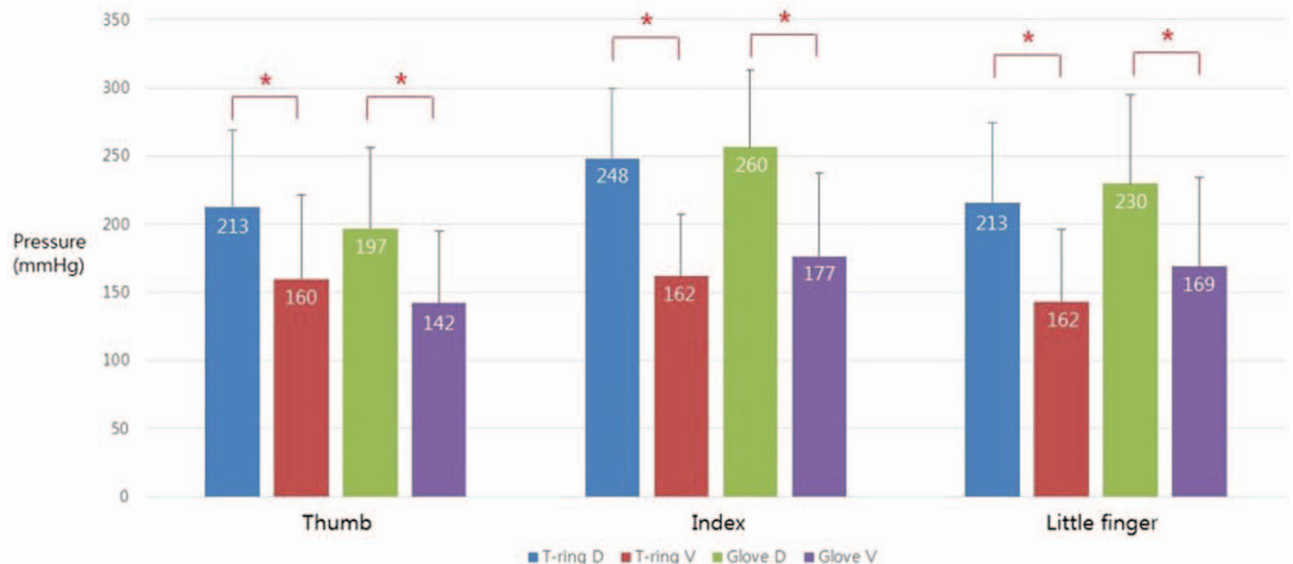


Figure 4. Pressure in each measurement site. D, dorsal midline; V, lateral volar side above digital vessels. Asterisks indicate statistically significant difference between 2 groups.

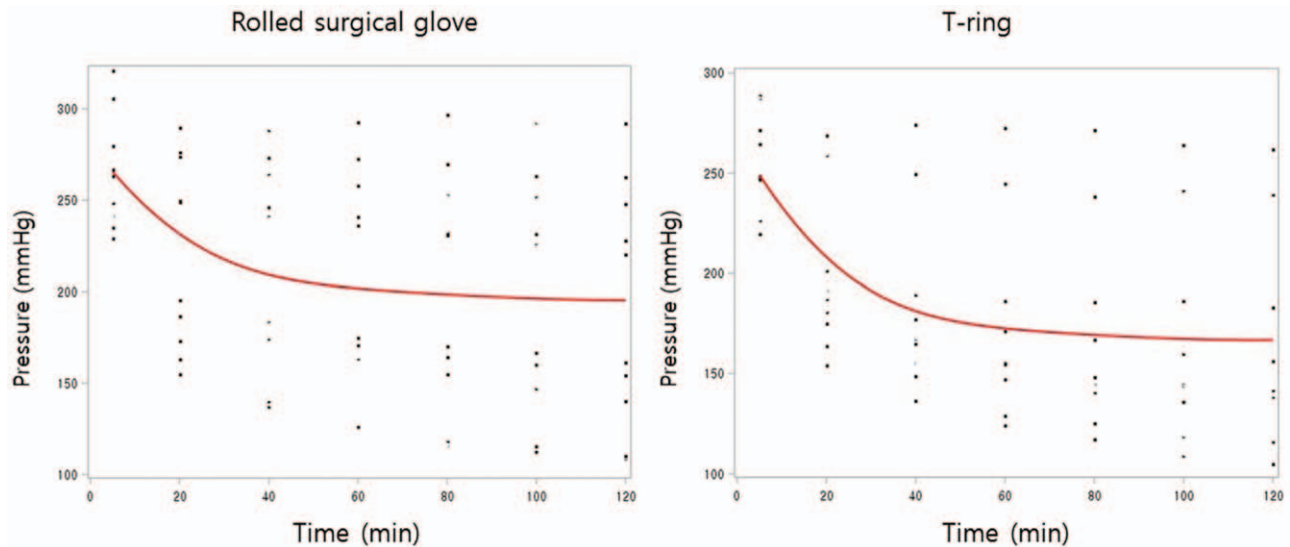


Figure 5. Continuous pressure analysis in artificial finger model in both tourniquet.

Electronics, Camarillo, CA, USA), and FSR-RA18 (Marveldex, Bucheon, South Korea). The parameters of each sensor are summarized in Table 4. Lahham et al used FSR-400 (Interlink Electronics, Camarillo, CA, USA). This sensor has a relatively large sensing area, but digital tourniquets cover a relatively narrow area when applied on the digits. In addition, in FSR-400, the measured data along the location of the tourniquet were highly variable and thus unreliable. Consequently, converting the force to pressure was complicated. Therefore, we selected FSR-QA6P as the pressure sensor in this study, because it has a sensing area small enough (1×1 mm) to be covered by digital tourniquets. The pitfall of FSR-QA6P is that because it is relatively thicker than the other sensor, it can cause a tenting effect that results in surface contour change underneath the digital tourniquet. This effect has the potential to increase the pressure.

The pressure of the dorsal midline was significantly higher than that of the lateral side in this study. This can be due to 2 reasons. First, the axial cut surface of the digit is not an exact spherical shape; instead, the anteroposterior diameter is longer than the radioulnar diameter at mid-proximal phalanx level.^[23] Second, the soft tissues are more distributed at the volar side rather than at the dorsal side. On the dorsal surface, there is a relatively small amount of subcutaneous fat between the skin and bone. Sufficient soft tissue on the volar side could act as a buffer between the pressure sensor and the underlying bone.

Interestingly, there were no significant pressure differences according to the circumference of the digits in both T-Ring and rolled surgical glove. This was compatible with the result of Lahham et al, who reported that T-Ring and rolled glove did not show an increase in pressure in larger digits.^[19] This result may support the concept that T-Ring is designed as a “one size fits all” device.^[24] In rolled surgical glove, we selected different glove sizes for different volunteers to reflect our clinical situation, and this might explain the similar pressure measurements in digits with different circumferences. Moreover, this result is not consistent with that of Middleton et al, who conducted their experiment in a laboratory setting.^[20] The mean pressure of both T-ring and glove tourniquet were increased with the size of the cylinder.

These different results might be arisen from the difference of characteristics between live human digits and an artificial finger model.

In the case of rolled surgical glove, the pressure measured at the thumb was relatively smaller than that measured at the index and little fingers. This lower pressure might be caused by the anatomical characteristics of the thumb. The thumb has a relatively small length-to-circumference ratio compared with the index and little fingers.^[25] When the glove was rolled from the distal tip to the base of the proximal phalanx, the curled thickness of the glove at the thumb was relatively smaller than at the index and little fingers. Moreover, the thumb has a relatively small circumference at the shaft of the proximal phalanx compared with its whole other part. The design of surgical glove does not fully reflect this characteristic. Therefore, when we applied the rolled surgical glove at the shaft of the proximal phalanx of the thumb, it was looser than when applied on the other fingers.

To the best of our knowledge, no previous studies have measured the pressure changes of digital tourniquets over time. We hypothesized that conventional tourniquets may lose their initial tension as rubber loses its original elasticity under tensile strength over time. We analyzed the pressure change along the time course and obtained results proving our hypothesis. The pressure data of both tourniquets decreased over the time course, and there were no significant differences in the change pattern between T-Ring and rolled surgical glove, which showed similar trend lines. Although the mean pressures were all >160 mm Hg, some individual pressure values in both tourniquets were <120 mm Hg after 80 minutes, which may cause bleeding during the operation. Because this change of pressure is a value measured on the silicone model, so the data can be not applicable to the human digit due to the additional factors such as a tissue swelling. The initial pressure was decreased from 253.41 mm Hg to 164.76 mm Hg (35.0% decrease) in T-Ring, and from 269.68 mm Hg to 192.34 mm Hg (28.7% decrease) in rolled glove, respectively. Our data were compatible with previous study that force degradation was observed approximately 30% at 1 day after mechanical extension of latex or silicone band.^[26] However, elastic property can be influence by various factors such as

material used, degree of extension, temperature, humidity, or pH. Well-designed research should be performed in the future.

Out of 30 volunteers in this study, BMIs were 21–25 in 17 individuals and 16–20 in 9. These relatively thin individuals cannot represent the whole population. We also excluded the individuals with underlying diseases like hypertension and diabetes for the simpler analysis. More heterogenous individuals should be included in the future studies. Although our study also cannot represent the whole population, we attempted to include as many variables of human digits as possible, such as the circumference of digits, measurement sites, and tourniquet types.

Even though our study showed no significant differences between T-Ring and rolled surgical glove in terms of pressure, the National Patient Safety Agency (NPSA) recommends using T-Ring and other CE-approved digital tourniquets instead of the conventional rolled surgical glove.^[27] This NPSA recommendation is based on many reports of cases in which tourniquets were mistakenly left on the digits after the operations.^[28] Because T-Ring has a distinct red color at its rim, it is difficult to mistakenly leave this device on the patient after the operation.^[24] Moreover, T-Ring has a diameter of 36 mm, which creates a space between the digit of interest and the nearby digits.

5. Conclusions

In this study, the surface pressure of the lateral volar side was significantly lower than that of the dorsal side, and there was no significant pressure difference according to the circumference of digits. Time dependent pressure change were also not significantly different between 2 tourniquets.

Author contributions

BJK and STK suggested the idea of the study; JCL and YHJ provided the sensor equipment and collected data; NHY supported the whole process of the experiment; HK analyzed the data and wrote the manuscript.

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