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Compression automation of circular stapler for preventing compression injury on gastrointestinal anastomosis

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Abstract

Background: Conventional manual compression relies on the surgeon's subjective sensations, so excessive compression can cause tissue injury to the stapling line of the intestinal anastomosis.

Methods: Automatic compression monitoring and compression control system was developed for circular stapler. The tissue injury related compression variables were evaluated and accommodated by compression control device. The compression injury-reducing performance was verified on collagen sheets of in vitro experiments.

Results: Excessive pressure and tissue deformation were associated with compression-induced tissue damages. The safe pressure range was very narrow in weaker tissue than normal collagen. The automatic system performed proper compression within a safe pressure range without tissue injury.

Conclusions: Manual compression of circular stapler could cause tissue injuries by excessive pressure and tissue deformation. Our automatic compression system is designed to control peak pressure to prevent the compressive tissue injury.

KEYWORDS
actuators, colorectal, computer assisted surgery, gastrointestinal, minimal invasive surgery, reconstruction, sensors

1 | INTRODUCTION

The development of circular stapling techniques has resulted in a reduction in anastomosis operation time, and has also reduced complications such as anastomotic leakages and strictures.[1] Despite the continuous development in stapling techniques, complications such as anastomosis leakages and strictures continue to occur.[2,3] One of the causes of anastomotic complications is improper compression during the anastomosis process of the circular stapler.[4] During anastomosis using a circular stapler, tissue compression is necessary to form a B-shaped staple when the stapler fires, that is, by securing the gap distance between the anvil and staple housing.[5,6] The use of a proper staple height through compression is known to reduce the occurrence of anastomotic strictures.[7] Tissue compression is performed for several purposes in the anastomosis process of a circular stapler. For a safe anastomosis, a proper tissue approximation and haemostasis of the anastomosis must be provided, without ischaemic

or mechanical failure owing to excessive compression while securing the gap distance.[8] However, chemoradiation therapy and cancer obstructions can make tissue oedematous. Oedematous tissue is thicker than normal tissue, and as the elastic modulus increases, a large pressure is applied to the tissue (relative to normal tissue) even in a small compressive deformation, making it more vulnerable to compression.[9] Such characteristics can cause mechanical and ischaemic failures of the staple line, and are factors in the occurrence of complications. Recognising these problems, the US Food and Drug Administration has recommended in a letter that if it is difficult to squeeze the handle of the stapler, a staple size of a different size should be chosen; moreover, for sensitive tissues, applying compression before firing may cause injury.[10] Therefore, the point of this letter was to control the pressure on the tissue from the stapler. In contrast, in the conventional manual compression method, the control of compression is left entirely to the surgeon's judgement. It is recommended that the surgeon should turn a rotary knob of the circular stapler to compress the tissue to a point of the proper pressure, but most surgeon customarily compress to the maximal level. The process to sense the optimal compression pressure depends entirely on the surgeon's tactile feedback transferred through the rotary knob of the circular stapler, and the selection of the compression end point also depends on the surgeon's subjective judgement. However, the threshold value for tactile feedback is different for each operator and for each operation on the different patients; thus, this approach can cause unexpected tissue injuries during compression process. In this context, the anastomotic leak rate is also related to the location of the anastomosis, but it is known that there can be difference of 0.5%–30% depending on the surgeon.[11] One reason for this difference is owing to a deviation in the compression process. Therefore, it is necessary to investigate the deviation in the conventional manual compression process, and to develop an automated device for reducing the compression deviation. Therefore, in this study, we conducted an in vitro compression experiment to evaluate the factors affecting compression injuries and verify that deviations from operators in manual compression can cause unexpected injuries. Moreover, we verified that the automatic compression device can effectively reduce the damage by controlling the compression pressure.

2 | MATERIALS AND METHODS

2.1 | Study design

In this study, the design and operation of an automatic compression device and effect in reducing compression injuries relative to manual compression were verified. The compression variables were evaluated to find the risk factors for tissue injuries. The four compression variables were defined: the compression variable, that is, the compression time (the total time taken for compression during anastomosis), peak pressure (the maximum pressure applied

to the tissue), tissue deformation (the amount of change in the tissue thickness change owing to compression), and gap distance (the distance between the stapler body and anvil after tissue compression). The compression variable measurement was conducted by designing a compression monitoring system as described in Section 2.2. The relationships between the compression variables and tissue injuries were analysed and the risk factors were used to compare automatic and manual compression deviations. Afterwards, as an in vitro experiment, a compression test was performed on collagen sheets in two states, that is, dry (normal) and wet (weakened). Automatic and manual compression was performed by using a circular stapler on the two types of collagen sheets, and the compression injury reduction performance was described in Section 2.4 of the automatic compression device. The verification process consisted of three parts. First, we verified the factors causing compression injuries through the relationships between the measured compression variables and an injury score obtained through an injury assessment (described in Section 2.3). Second, the deviations of the compression variables in manual compression were investigated, and their associations with compression injuries were verified. Finally, it was confirmed that the use of the automatic compression device is effective in reducing unexpected compression injuries compared to manual compression, because the deviation of the compression variable affecting the injury is small.

2.2 | Compression monitoring system

The variables judged as influencing the compression when using a circular anastomosis and tissue injury were called the compression variables. They included the peak pressure, that is, the maximum pressure applied during the compression process, tissue thickness, gap distance, that is, the tissue thickness at the end of compression, and tissue deformation, that is, the ratio of the final deformation of the tissue after compression to the initial thickness. To measure this, a compression-monitoring system was designed. The system measured the pressure, gap distance, and time taken from the start of compression to the firing, and recorded it on the user's PC. Figure 1A shows the compression monitoring system configured as with an automatic compression device. The pressure measurement was realised by combining a BF350-3AA strain gauge (AGS-TECH Inc.) with the shaft of a commercial stapler, and the pressure sensing principle was as follows. The compression force of the stapler was transmitted to the anvil of the tip through the central axis. At this time, the force caused displacement of the central axis, and thus, the force applied in the axial direction could be measured. The strain gauge showed the difference in the electrical resistance according to the displacement of the shaft. A reference weight was applied to the shaft, and a regression formula for the force applied to the shaft and electrical resistance was established. Through this process, the pressure applied to the tissue
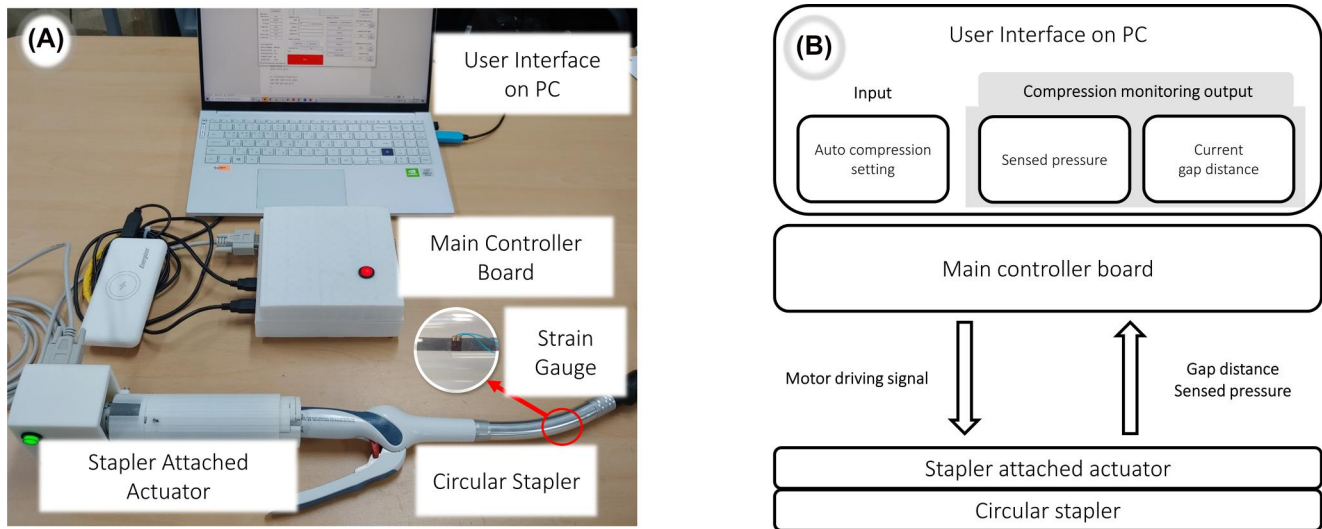
FIGURE 1 Designed system: (A) compression monitoring system and automatic compression device, (B) system block diagram of compression monitoring system and automatic compression device

was calculated using the force obtained through the strain gauge electrical resistance measurement and the anvil area of the tip. Next, a rotary encoder was used to measure the gap distance. This generated a pulse according to the rotation of the circular stapler rotary knob, and the movement distance of the stapler anvil could be determined according to this value. As the rotary encoder had only incremental distance information, it went through a calibration process to find the end point of the stapler shaft, and the zero point was set when the system started to match it with the gap distance. The information sensed through this system was processed and transmitted by a microprocessor (STM32103ZET6, STMicroelectronics) at a sampling rate of 1 ms, and was stored in the user's PC.

2.3 | Compression injury assessment

The compression injuries were evaluated by assigning an injury score through image processing on a collagen sheet. This method is illustrated in Figure 2. Figure 2A shows a damaged collagen sheet sample. The surface of the stapler anvil in contact with the collagen sheet was cracked by the pressure, and there was a difference in the pixel brightness between the cracked and non-cracked parts. Using this point, the damage score was calculated by separately classifying the colour of the crack in the hue, saturation, value(HSV) colour space, and measuring the classified area. However, owing to the nature of classifying the cracks through the colour space, the brightness of the image itself changed, so the calculation results could vary. Therefore, images were acquired using a transilluminator (BIO-HELIX - BP001CU) to create a constant lighting environment, and contrast enhancement was performed, as shown in Figure 2B. Figure 2C shows the section determined as the crack area through this process. At this

time, because the tissue inside the anvil of the circular stapler was cut off when the stapler fired, the area of compression damage was calculated by setting the region of interest only for the contact part of the anvil, as shown in Figure 2D. The injury score was calculated by the ratio of the damaged pixel area in the collagen sheet image of 720 pixels horizontally and vertically. Injury score result was 10 points in the case of 1% damage in the entire image. In addition, pixel segmentation criterion was calibrated during colour space segmentation to exceed half of the collagen thickness, which is the criterion for unacceptable injury suggested in the previous study.[12] And this sheet was defined as an injured sample. Figure 2E–H show the respective shapes of the collagen sheet according to the injury score, and it could be confirmed that more than half the thickness of the collagen sheet was penetrated when the injury score is greater than 10.

2.4 | Automatic compression device

The automatic compression device in this study is a system for automatically performing compression by controlling the maximum pressure applied to a tissue during an anastomotic compression process. The pressure control is conducted by torque control of the motor and the linear elastic properties of the tissue. The desired limiting pressure is set through the PC user interface, which drives the pressure control logic of the main controller board, and the actuator attached to the stapler operates accordingly. In addition, in this process, the anastomotic pressure and gap distance are measured by the compression monitoring system discussed in Section 2.2, and the current, which is the driving force of the motor, is also measured in real time and used in the pressure control process. In this process, the pressure control algorithm for the automatic compression device consists of correction and
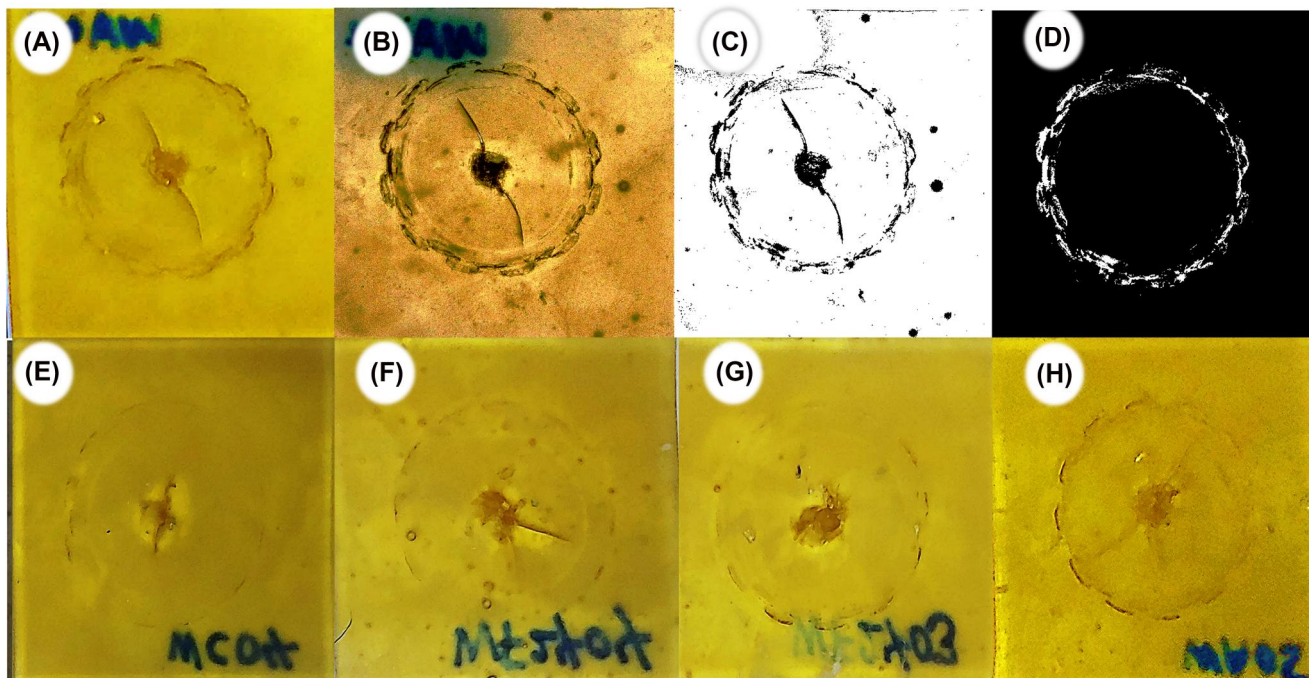
FIGURE 2 Tissue injury analysis and injury score result by hue, saturation, value colour space segmentation: (A) original image (injury score 30 case), (B) contrast enhanced image, (C) binarised image, (D) injured area analysis result, (E) injury score 5 case, (F) injury score 10 case, (G) injury score 15 case, (H) injury score 20 case
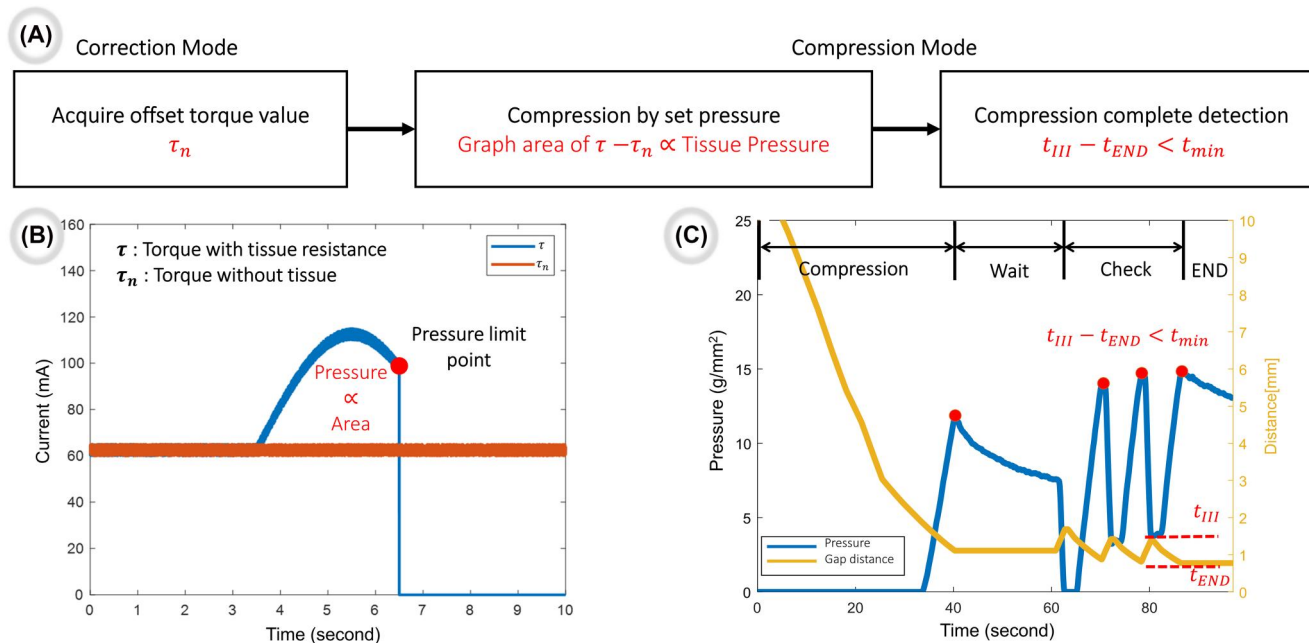

FIGURE 3 Automatic compression step flowchart and operating principle: (A) operating steps of automatic compression device, (B) torque–time plot and pressure control principle, (C) pressure–gap distance–time plot and compression complete detection algorithm

compression modes. The correction mode is a process of measuring the force driven when there is no tissue in the stapler so as to determine the force applied to the tissue, that is, excluding the driving force of the stapler itself. Subsequently, the compression

mode is controlled based on the force value obtained in the correction mode. The operation sequence is shown in Figure 3, and as shown in Figure 3A, the correction mode–compression mode–detection (of the end of compression) is performed according to

the order of detection. Figure 3B shows how to limit the pressure in the compression mode, based on the torque obtained in the correction mode. In this case, τ is the actual torque applied when compressing the tissue, and τ_n is the torque at the corresponding position as obtained in the correction mode. As the torque and current have a linear proportional relationship owing to the characteristics of DC motors, the torque can be adjusted by controlling the current, and the current can be displayed instead of the torque in the graph.

$$\tau = K_t I \tag{1}$$

In Equation (1), the torque τ is expressed as the product of the motor constant K_t and current I. Assuming that the tissue before damage is linearly elastic. The elastic energy of the tissue is as shown in Equation (2), and the elastic repulsive force is as shown in Equation (3).[4,13]

$$E = \frac{1}{2}kx^2 = \tau nx \tag{2}$$

$$F = kx \tag{3}$$

In Equation (2), the elastic energy E is expressed by the elastic modulus k of the tissue and strain x; it can be equivalently expressed as the force and strain x, which represents the product of the torque τ and screw gear ratio n from the viewpoint of the physical work of the stapler.

In addition, this device was designed to be compressed at a constant speed within a specified gap distance. Therefore, the work, that is, the product of the force and distance, has a proportional relationship with the product of the force and time.

$$E = \tau nt \tag{4}$$

In Equation (3), the elastic energy E is expressed as the product of torque τ, screw gear ratio n, and time t. In Figure 3B, τ means the torque currently output by the motor. τ_n is the torque obtained in the correction mode; thus, the torque is used only for driving the stapler when there is no tissue. In this case, $\tau - \tau_n$ can be considered as the additional torque generated by the repulsive force of the tissue, and Equation (3) can be applied. That is, $\tau - \tau_n$ is the amount of instantaneous energy change in the organisation. Therefore, the total pressure applied to the tissue is given by Equation (4), and the total pressure p on the tissue is given by Equation (5).

$$p = \frac{\int (\tau - \tau_n)ndt}{A} \tag{5}$$

The pressure is obtained by dividing the time integral of $(\tau - \tau_n)$ by the contact area A of the stapler, and the pressure is controlled by limiting the integral value of $(\tau - \tau_n)$ with respect to time. Finally, the process of determining the compression end time proceeds as shown in Figure 3C. This compression method consists of multiple compression cycles.

In the case of a commercial stapler, the operator compresses to the desired pressure, waits for 15 s for the intercellular fluid to move, and then performs compression again[14]; this process is automatically controlled in this study. This process consists of three parts: compression-wait-check. First, the compression cycle is the process of compression, from the start of compression to the set pressure. Next, in the wait cycle, there is a wait of 15 s to allow the intercellular fluid to move. Subsequently, compression is performed again in the check cycle, and the gap distance when starting the compression again is designated as t_{III}. Even if compression is performed up to the set pressure again, if the additional compressed thickness is compressed to less than t_{min}, the compression is terminated, and the thickness and gap distance of the final tissue become t_{end}. Through this process, the maximum compression distance is drawn to reach the gap distance within the 2.5 mm required for stapler firing within the limited pressure range.

2.5 | In vitro experiment

The physical properties of the collagen plate used as the experimental material were similar to those of a fresh porcine colon, as investigated in a previous study.[12] The collagen plate was a 3 cm^2, 2–3 mm thick transparent plate composed of 80% porcine collagen and 20% glycerin (Collagen plate; SINI Inc.). The collagen sheets were prepared with two types of samples, that is, wet collagen and dry collagen, and were soaked in water at room temperature for 2 min to weaken the strength for the simulation of oedematous tissue. The stapler used in the experiment was a circular CDH29 stapler (Ethicon Inc.), and the compression monitoring system (Section 2.2) and automatic compression device (Section 2.3) were combined with the circular stapler. The experimental protocol was as follows. In the case of manual compression, wet collagen compression was performed five times and dry collagen compression was performed five times for a total of five operators. For automatic compression, the automatic compression device (Section 2.4) was used; wet collagen compression was performed five times and dry collagen compression was performed five times for three set pressures of 8, 16, and 32 g/mm^2. Immediately after the experiment was finished, collagen sheet images were acquired through a transilluminator, and the damage was analysed according to the compression injury assessment method described in Section 2.3.

2.6 | Statistical analysis

The described data are presented as means and standard deviations (mean ± SD). The univariate analysis was conducted using the Wilcoxon rank-sum test. The correlation of each variable was obtained using Spearman correlation. The multivariate analysis was conducted using binary logistic regression. These statistical analyses were performed using R software (R Core Team 2020; R: A language and
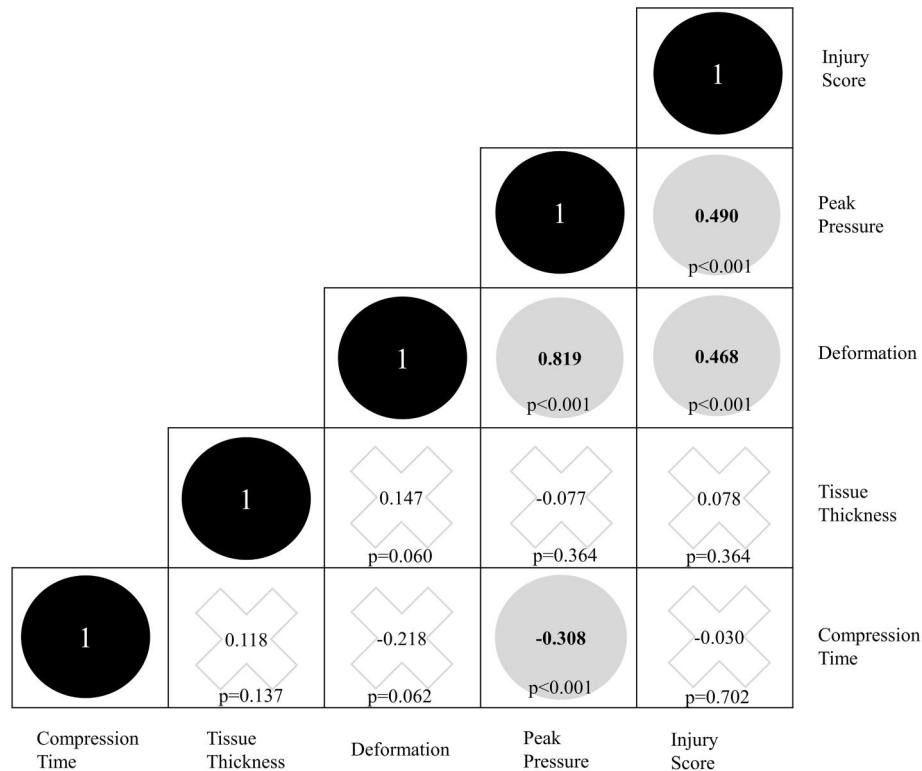
FIGURE 4 Spearman correlation plot between compression variables and injury score

environment for statistical computing, R Foundation for Statistical Computing), and p-value < 0.05 was considered as significant.

3 | RESULTS

3.1 | Factors of compression injury

The correlations between tissue injury score and compression variables are shown in Figure 4. The peak pressure and the tissue deformation have the greatest correlation with the injury score. The peak pressure and compression time have a significant correlation owing to the difference in the compression time between automatic and manual compression. The univariate analysis of compression variables shows that the peak pressure, deformation, and gap distance were significant factors for the injury existence (Table 1).

Table 2 shows that the Odds ratio for the injury score is higher when the tissue condition is wet, the peak pressure exceeds 24 g/mm^2, and the tissue deformation exceeds 35%. The safe pressure ranges without tissue injury were derived from gap distance to injury score graphs in the dry and wet collagen plates (Figure 5). The safe pressure range is indicated a range where a gap is secured within 2.5 mm and compression injury does not occur; in the case of dry collagen, it is 12–50 g/mm^2, and for wet collagen, it is 12–24 g/mm^2. Thus, it can be confirmed there is a narrow safe pressure range, depending on the tissue conditions.

3.2 | Compression variance on manual compression

The compression variables for each compression type are listed in Table 1. The standard deviations of the peak pressure and deformation in the manual compression are more than twice as large as those in automatic compression. In the time–pressure graphs, the wide deviation of compression pressure occurred during the manual compression by the multiple operators (Figure 6A). This shows the differences in the peak pressure and compression time for each operator. Figure 6C shows that the deviations of the peak pressure, tissue deformation, and compression time are large compared to automatic compression.

3.3 | Automatic compression device performance

The injury score results for each compression type are presented in Table 2. The injury score for each compression type is statistically significant (p-value = 0.0293). In the case of manual compression, the injury score or Odds ratio is significantly higher than that of the automatic compression at set pressures of 8 and 16 g/mm^2. In the case of automatic compression, an injury score occurs only when a set pressure of 32 g/mm^2 is set. Figure 7 shows the distribution of the peak pressure and probability of tissue deformation by compression type from the in vitro test results. In the case of Figure 7A, the dotted line shows the upper limit of the safe pressure range, and in the case of Figure 7B, the minimum value of the tissue deformation in the tissue injury sample is shown. According to these

TABLE 1 Univariate analysis of compression variables ($n = 80$)

Characteristics	n (%)	Peak pressure (g/mm²)	p-value	Deformation (%)	p-value	Gap distance (mm)	p-value	Tissue thickness (mm)	p-value	Time (sec)	p-value
Injury existence											
Not injured	67 (83.7)	21.92 ± 8.48	<0.001	25.74 ± 15.43	<0.001	2.15 ± 0.47	<0.001	2.92 ± 0.34	0.703	80.89 ± 35.71	0.699
Injured	13 (16.3)	32.01 ± 5.47		43.12 ± 7.36		1.69 ± 0.31		2.96 ± 0.34		82.25 ± 31.87	
Tissue condition											
Wet collagen	40 (50.0)	23.15 ± 8.18	0.693	29.31 ± 14.83	0.191	2.06 ± 0.044	0.418	2.92 ± 0.33	0.572	78.46 ± 26.83	0.734
Dry collagen	40 (50.0)	23.97 ± 9.56		27.81 ± 16.73		2.10 ± 0.52		2.92 ± 0.35		83.76 ± 41.66	
Compression type											
Manual compression	50 (62.5)	26.38 ± 8.20		34.82 ± 13.42		1.87 ± 0.37		2.89 ± 0.37		60.58 ± 24.24	
Automatic compression											
Set pressure											
8 g/mm²	10 (12.5)	11.02 ± 2.22	<0.001	6.00 ± 1.59	<0.001	2.86 ± 0.24	<0.001	3.04 ± 0.22	0.058	110.42 ± 18.75	<0.001
16 g/mm²	10 (12.5)	16.75 ± 3.91		13.28 ± 9.36		2.46 ± 0.29		2.85 ± 0.32		117.66 ± 23.89	
32 g/mm²	10 (12.5)	28.80 ± 1.79		35.15 ± 4.59		1.97 ± 0.18		3.04 ± 0.24		117.87 ± 18.20	

Note: The values of injury score are expressed as mean ± standard deviation.

Variable	n (%)	Injury score	p-value	Odds ratio	95% CI
Tissue condition					
Dry collagen	40 (50.0)	0.00 ± 0.00	<0.001	1	
Wet collagen	40 (50.0)	6.01 ± 9.00		409.02	25.18–6644.09
Compression type					
Manual compression	50 (62.5)	3.24 ± 7.56	0.029	1	
Auto compression					
Set pressure					
8 g/mm^2	10 (12.5)	0.00 ± 0.00		0.03	0–4.35
16 g/mm^2	10 (12.5)	0.20 ± 0.64		0.05	0–5.35
32 g/mm^2	10 (12.5)	7.63 ± 8.77		80.61	0.42–15615.23
Peak pressure p					
$p < 24$ g/mm^2	35 (43.7)	0.14 ± 0.92	<0.001	1	
$p > 24$ g/mm^2	45 (56.2)	6.70 ± 9.39		706.59	44.99–11097.10
Tissue deformation d					
$d < 35\%$	26 (32.5)	0.40 ± 1.70	<0.001	1	
$d > 35\%$	54 (67.5)	8.41 ± 10.20		3001.98	186.23–48390.42

Note: The values of injury score are expressed as mean ± standard deviation.

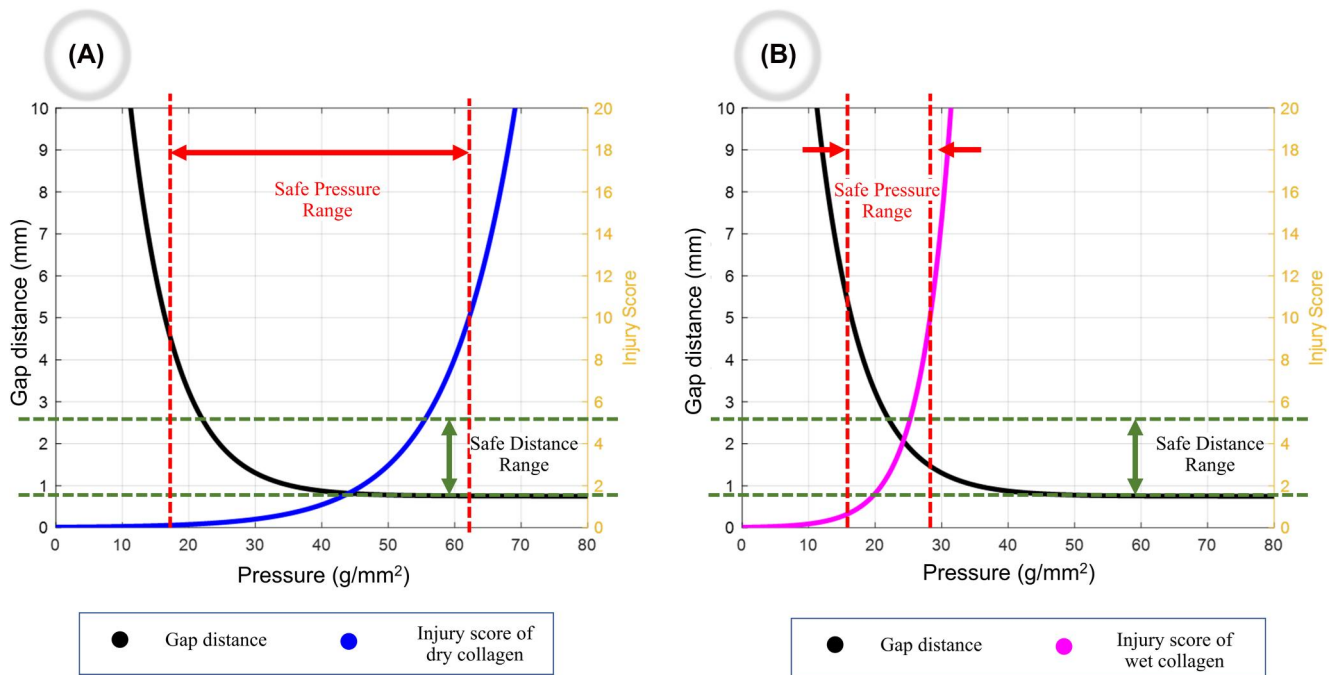Abbreviation: CI, confidence interval.

FIGURE 5 Gap distance–peak pressure–injury score plot and safe pressure range by tissue condition

results, the manual compression has a wide range of deviation in regard to the peak pressure and tissue deformation, that is, the compression variables with the greatest impacts on injury. In many cases, these values exceed the injury threshold, but the automatic compression set pressures of 8 and 16 g/mm^2 show effective control of the two compression variables within the injury threshold.

4 | DISCUSSION

Automatic devices for providing uniform anastomosis by reducing operator dependence are continuously being studied to reduce the anastomotic complications. Representatively, methods using a magnet such as Magnamosis or using a bio fragment ring (BAR) can avoid
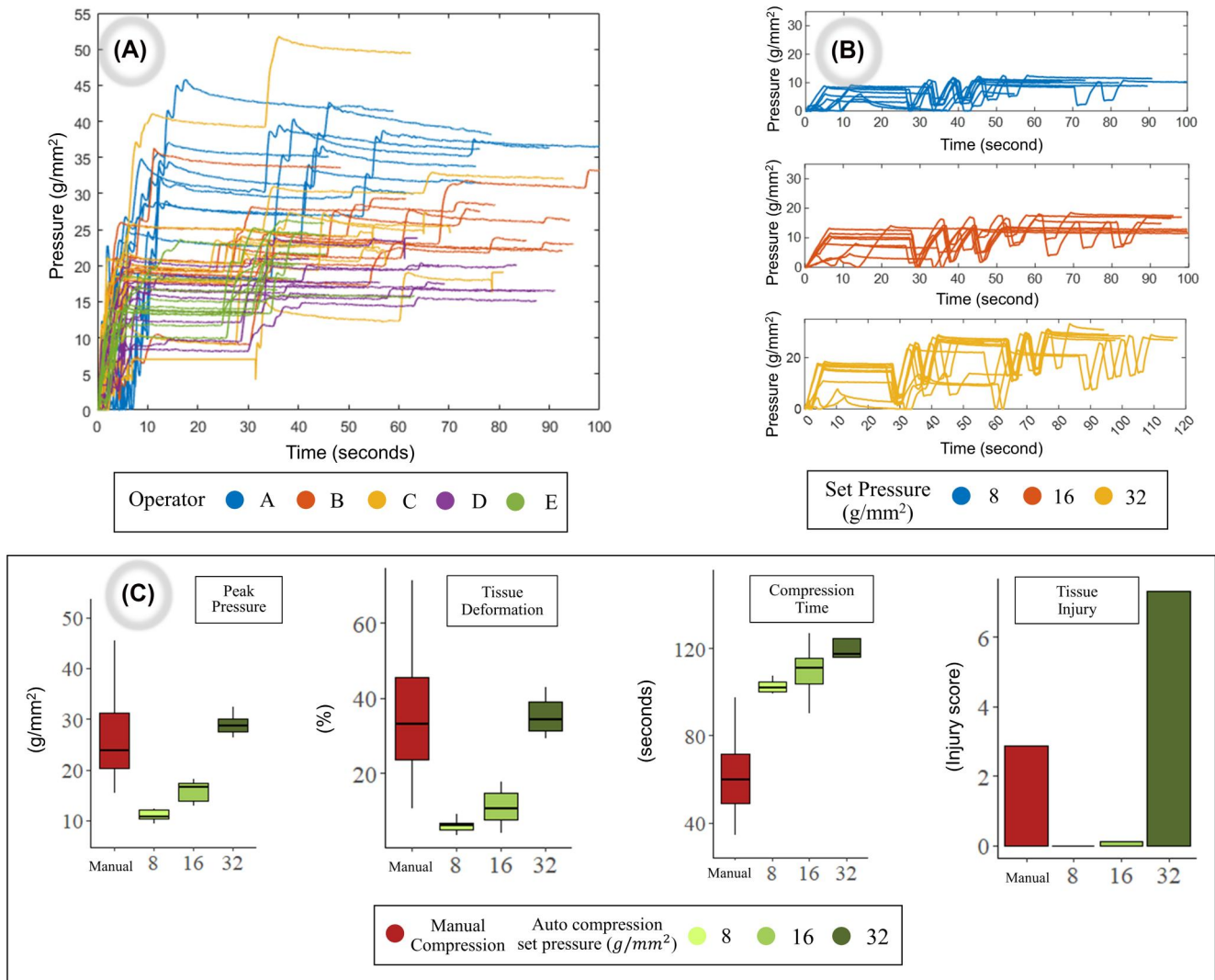
FIGURE 6 Time–pressure graph and compression variables in comparison by compression type: (A) manual compression, (B) automatic compression, (C) compression variables in comparison

the user's deviation from the compression pressure.[15,16] However, in cases of Magnamosis using magnets or the BAR, it is difficult to adjust the compression force depending on the tissue condition and expected recovery characteristics; moreover, it is impossible to use such approaches in the low rectum.[17] Heretofore, circular staplers were usually applied for colorectal surgery and that was based on the operator's dependent manual compression. So, the need for research on circular stapler anastomosis remains to achieve automatic control of anastomosis. The introduction of equipment for automating staple firing, such as in the ECHELON CIRCULAR™ Powered Stapler (Ethicon Inc.), has produced encouraging results, such as reducing stapling line leaks by 61%.[18] However, the automation of tissue compression when using a circular stapler before firring is required for additional research.

Therefore, authors designed this noble automatic compression device to prevent compression injuries during circular stapler anastomosis. In this study, we investigated the risk factors of compression injuries using a conventional circular stapler. Then, an automatic

compression device was designed, and the tissue injury reduction performance was verified.

The first step of the verification process was to identify the mechanisms of injury of the collagen sheet through in vitro experiments. Therefore, a compression monitoring device was designed, and was implemented to measure the pressure currently applied to the tissue in the circular stapler and the gap distance between the stapler anvil and stapler body. The principle of the pressure measurement in the compression monitoring device was realised by measuring the displacement of the stapler shaft through a strain gauge, thereby measuring the force acting in the shaft direction, and dividing it by the area of the stapler anvil to convert it into a pressure. The strain gauge represented the physical displacement as a change in the electrical resistance. Compensation was necessary according to the stapler type, owing to differences in the shaft stiffness according to the stapler type and in the force in the shaft direction as divided by the stapler anvil area for obtaining the pressure. In addition, when implementing the gap distance measurement function using the rotary
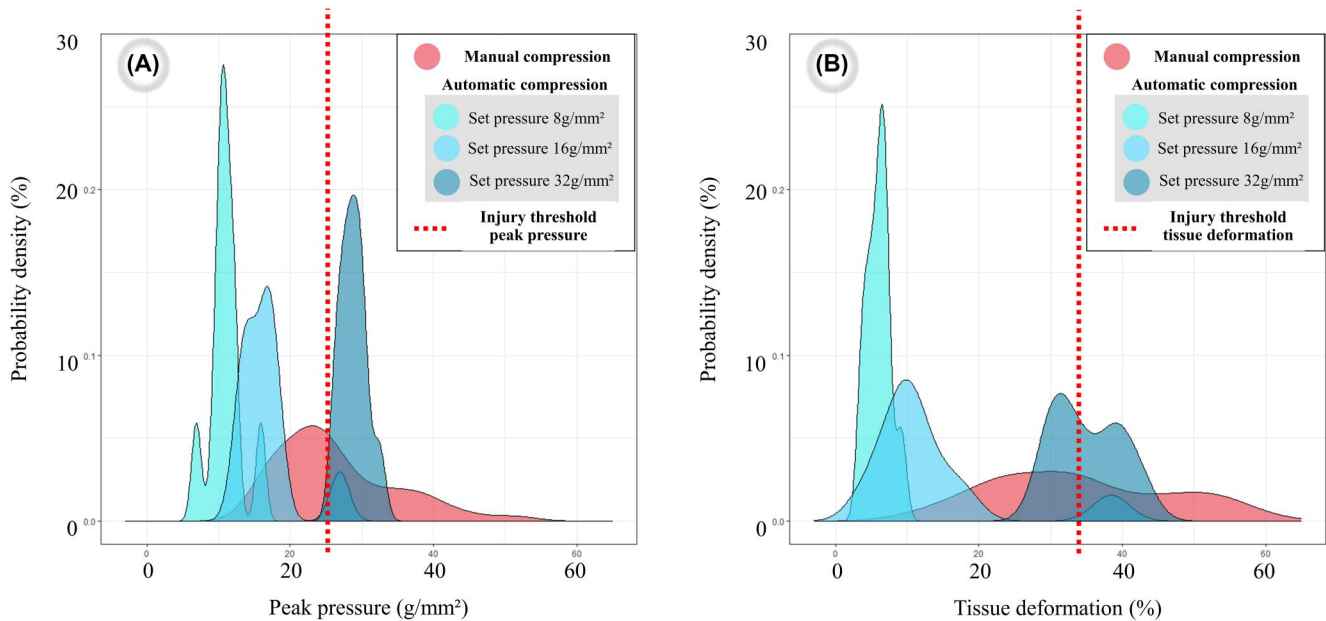
FIGURE 7   Density plot and injury threshold of collagen sheet by compression type: (A) peak pressure, (B) tissue deformation

encoder, the rotary encoder detected the rotation of the rotary knob of the circular stapler, and output the gap distance. At this time, the zero point of the gap distance needed to corrected according to the characteristics of an encoder that output only the incremental position, and the characteristics of the measurement precision could vary according to the gear ratio of the stapler. Therefore, in this study, the compression monitoring device was calibrated according to the specifications of the circular CDH29 stapler (Ethicon Inc.), and the compression variables were measured.

As a result, it was found that the tissue type acts as the largest factor in compression injuries. This is because the tensile strength of wet collagen is half that of dry collagen, as revealed in the physical properties of the collagen sheets from using the rheometer in previous study.[12] However, in general, the tissue conditions cannot be controlled during anastomosis. Therefore, controlling the peak pressure and deformation according to the tissue conditions is effective for reducing compression injury. As a result of the experiment using the collagen sheet, it was possible to confirm the linear proportionality of the pressure and deformation within the deformation range before injury. However, unlike a collagen sheet, actual tissue has a multi-layer structure and a different elastic modulus depending on the tissue condition.[9] However, in view of previous studies, it can be judged that similar injury characteristics will be exhibited.[4,19] This is because a linear proportional relationship can be confirmed to some extent, even though there are variables depending on the tissue state or on the location in the load-strain relationship as obtained from porcine tissue. In addition, prior studies on the physical properties of gastrointestinal tissues, such as the shear force and burst pressure, have been conducted, additional studies are needed to determine a safe pressure range in which a compression injury does not occur during anastomosis using a circular stapler.[13,20] To prevent compression damage and

secure the staple shape, the stapler gap distance is usually required to be 2 mm or less. A shorter staple height is helpful for recovery characteristics and in the prevention of complications, and accordingly, securing an appropriate gap distance is essential.[7] Nevertheless, in the case of patients undergoing anastomosis surgery, when radiotherapy and chemotherapy are performed to further enhance the effects of chemotherapy before anastomosis, the tissue weakness from these processes makes it difficult to reach a gap distance of 2 mm or less.[21] Simultaneously, it may lead to a smaller safe pressure range (or no safe pressure range) for preventing damage. Therefore, to perform an anastomosis without damage under these conditions, a study to determine the safe pressure range according to the tissue state is required. In previous studies, it was found that increasing the peak pressure also improved the maximum intraluminal pressure.[22] However, when this approach is applied to tissues weakened by various factors in consideration of the tissue condition and recovery characteristics, the safe pressure range must be significantly limited.

As discussed in Section 3.2, the compression variance in the manual compression was investigated. Variance was shown in the peak pressure and tissue deformation among the compression variables for each operator and operation. In particular, in the cases of manual compression, several cases exceeding the safe pressure range occurred. In the in vitro experiments, in the case of wet collagen, many injured samples occurred at a peak pressure of 24 g/mm^2 or more, but in another experiment on human colons, wet collagen showed a tensile strength of approximately 90 g/mm^2.[13,23] Therefore, it is difficult to confirm the results from the collagen sheet experiment, presented as an injury criterion in this study, as the mechanical failure of an actual colon. However, in previous studies, factors for complications were analysed as mechanical/tissue causes and ischaemic causes.[8] Previous studies focussed on physical

properties such as the compression force and burst strength, that is, mechanical/tissue causes.[24,25] Other works centred on clinical studies have reported ischaemic causes and recovery characteristics.[26] For clinical application, it is necessary to determine a safe pressure range by additionally considering the occurrence of complications owing to ischaemic causes or tissue recovery characteristics through additional research. Because the tensile strength of the human colon of approximately 90 g/mm^2 indicates the tearing point of the tissue itself, the safe pressure range will comprise a smaller range than this, and a follow-up study to determine the safe pressure range for avoiding ischaemic failure is required.

Finally, as described in Section 3.3, the performance of the designed automatic compression device was compared with that of manual compression. When the set pressure was within the safe pressure range, it was confirmed that the damage was effectively suppressed. However, the device designed in this study also shows a pressure deviation according to the set pressure. This value is smaller than that from manual compression. As one factor in the pressure deviation, curling of the tissue on the stapler shaft was also a factor in the occurrence of the pressure deviation. Owing to the nature of sensing the rotation torque of the rotary knob of the circular stapler in the automatic compression method, there were cases where the compression pressure could not be measured properly, for example, when disturbances occurred such as foreign matter entering the stapler anvil, or tissue being rolled into the shaft. This is because the automatic compression device designed in this study is affected by the geometrical and mechanical characteristics of the stapler, and additional algorithm research is required to detect such disturbances. Moreover, owing to the nature of the operation of controlling the pressure according to the set pressure, if it is set to a value that exceeds the safe pressure range, additional damage results. This means that the user must directly determine and input a set pressure within the safe pressure range.

The safe pressure range defined in this study was determined as a range for avoiding tissue injury, and was based on an appropriate gap distance according to the stapling height. Other studies provide clues regarding the selection criteria for this value. First, in a previous study on the stapling height and suture line blood flow through ultrasound Doppler measurement, although there was a slight difference depending on the stapling type, the suture line blood flow decreased by 50%–70% depending on the stapling height.[27] Therefore, a short stapling height may cause an ischaemic failure. Meanwhile, in previous study, when staple heights of 3.5 and 4.8 mm were compared, it was confirmed that the occurrence of anastomotic stenosis was at less than 3.5 mm.[7] Thus, both results show that there are upper and lower limits for the safe pressure range. Here, the lower limit of the pressure is the point at which the compression is not tight enough and a mechanically leaky state, or the point where the gap distance is obtained but the stapling shape is not formed.[27] The upper limit of pressure is set as the pressure that does not cause mechanical or ischaemic failures. First, in the case of mechanical failure, the movement of extracellular and intercellular fluids through

the introduction of tissue impedance have shown that the cell death by compression is derived through the relationship between tissue pressure and strain rate, and can be observed through changes in the extracellular and intercellular fluid conductance.[28] By observing this, it is expected that it will be possible to determine the upper limit of the pressure for avoiding mechanical failure of the tissue. In the case of ischaemic failure, continuous observation of the tissue perfusion through laser fluorescence angiography has shown that the anastomotic leak rate can be effectively lowered.[29] Finally, manual compression and automatic compression also differ in terms of the compression time. The automatic compression device designed in this study was compressed by fixing the waiting time to 15 s when the target pressure was reached, according to the device manual of the circular stapler manufacturer.[14] In the case of manual compression, compression was performed under an instruction to wait for 15 s when the target pressure was reached. In the case of the manual compression, there were large variations by trial, but in the case of automatic compression, the compression time was determined according to the set pressure, and a constant compression could be performed relative to the manual compression. However, the results of the anastomosis may vary depending on the target pressure and waiting time. According to a previous study investigating compression time and staple formation, the most optimal staple formation was obtained when the precompression time was 5 min.[6] This is owing to the differences in the tissue impedance and physical properties over time, and a method is needed for identifying a variable compression time for each tissue location or condition.[28]

As such, a follow-up study is required to determine the safe pressure range and compression time according to, for example, mechanical failures, ischaemic failures, tissue conditions, and recovery characteristics. Subsequently, it is expected that a safer circular stapler anastomosis can be realised through completely automated compression that automatically selects the set pressure and set time for the automatic compression.

5 | CONCLUSIONS

In this study, the peak pressure and deformation was analysed as the significant factors of compression injury via compression monitoring system. And novel automatic compression device was designed to reduce the deviation of these factors by compression pressure control. The compressive tissue injury could be prevented by compression monitoring and automatic pressure control system.

CONFLICT OF INTEREST

All authors have no conflicts of interest or financial ties to disclose.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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