

The Learning Curve of Robotic-Assisted Pedicle Screw Placements Using the Cumulative Sum Analysis: A Study of the First 50 Cases at a Single Center

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Abstract:

Introduction: The purpose of this study was to clarify how many cases surgeons need to experience to pass the learning phase of robotic-assisted spine surgery using the cumulative sum (CUSUM) analysis.

Methods: A retrospective review was conducted on the initial 50 consecutive patients who underwent robotic-assisted pedicle screw placements with open procedures using a spine robotic system (Mazor X Stealth Edition) at a single center from April 2021 to January 2022. There were 19 male and 31 female patients with a mean age of 58.7 (range, 13-86) years. To split the surgeries into the early and late phases using the CUSUM analysis of screw insertion time, we compared the screw insertion time, the robot setting time, the registration time, and the operation time in the early and late phases.

Results: The screw insertion time, the robot setting time, and the registration time declined as the number of surgical cases increased. The operation time did not decline as the number of surgical cases increased. The learning curve for screw insertion time can be separated into two stages based on the CUSUM analysis. The first 23 cases were in the early phase, and the later 27 cases were in the late phase. The mean screw insertion time was reduced from 3.2 min in the first 23 cases to 2.7 min in the subsequent 27 cases. The robot setting time and registration time in the late phase were also significantly shorter than those in the early phase.

Conclusions: The screw insertion time, robot setting time, and registration time decreased with experience. After 23 cases, surgeons passed the learning phase of robotic-assisted spine surgery and became more proficient.

Keywords:

learning curve, robotic-assisted pedicle screw placement, cumulative sum, spine robotic system

Spine Surg Relat Res 2022; 6(6): 589-595
dx.doi.org/10.22603/ssrr.2022-0049

Introduction

Freehand pedicle screw placement without image guidance has been reported to have a relatively high deviation rate, so many institutions have implemented C-arm image guidance or spinal navigation. To improve the accuracy, the first spine surgical robotic system “SpineAssist” (Mazor Robotics) was developed in Israel in the early 2000s^{1,2)} and approved by the U.S. Food and Drug Administration in 2004³⁾. Consequently, it was improved as Renaissance in 2011 and X in 2016. In 2018, Medtronic developed it as the Mazor X Stealth Edition, which integrates a modern spinal navigation system.

The use of spine robotic systems has been reported to

have a screw accuracy of 85%-100%⁴⁾. Meta-analyses reported that the deviation rate of robotic-assisted pedicle screw placement was low in comparison with the freehand technique^{5,6)}. In comparison with O-arm navigation, it was reported that the deviation rate of robotic-assisted pedicle screw placement tended to be low⁷⁾. Even residents could place the pedicle screw under the guidance of the robotic system with the same accuracy as the attending surgeon⁸⁾. Therefore, spine robotic systems can improve the accuracy of pedicle screw placement.

In addition to screw accuracy, spine robotic systems allow faster screw placement, shorter fluoroscopy time, and shorter hospital stays than the freehand technique⁹⁾. However, spine robotic systems also have drawbacks, such as the need for

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Received: February 19, 2022, Accepted: April 7, 2022, Advance Publication: June 28, 2022

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additional training, learning curves, and the potential for longer surgery times.

Previous reports focused on the operative time from skin incision to closure and the screw insertion time in the learning curves of spine robotic systems⁹⁻¹². Using the spine robotic system required additional time to set up the robot in the operating room before surgery and time to take intraoperative images and register navigation.

The cumulative sum (CUSUM) analysis was first developed in the industrial sector for assessing performance and identifying areas for improvement. Medical doctors began using this analysis to study in the 1970s¹³ and to study the learning curve for surgical procedures¹⁴. CUSUM analysis converts raw data into a running total of data deviations from the group mean, allowing researchers to visually inspect the data for trends that would be difficult to detect using other methods.

The purpose of this study was to clarify how many cases surgeons need to experience to pass the learning phase of robotic-assisted spine surgery. We evaluated the learning curve for screw insertion time using the CUSUM analysis in the first 50 cases after introducing the spine robotic system.

Materials and Methods

1. Study subjects

This study was approved by our Institutional Review Board. A retrospective review was conducted on the initial 50 consecutive patients who underwent robotic-assisted pedicle screw placements with open procedures using a spine robotic system (Mazor X Stealth Edition; Medtronic Inc., Dublin, Ireland) at a single center from April 2021 to January 2022. There were 19 male and 31 female patients with a mean age of 58.7 (range, 13-86) years. Patient diagnoses were lumbar spinal stenosis in 24 patients, adolescent idiopathic scoliosis in 12, vertebral fracture in 5, adult spinal deformity in 3, spondylolysis in 2, and lumbar disc herniation, syndromic scoliosis, metastatic spine tumor, or thoracic myelopathy each in 1. Posterior lumbar interbody fusion was performed in 24 patients, posterior correction and fusion in 15, posterior lateral fusion in 9, and anterior-posterior fusion in 3. Between 2 and 10 segments were fused. Screw placements were performed by five surgeons. Of the 483 placed screws, 33 pedicle screws were placed using a freehand technique or the other imaging guidance, which included one screw that was found to be misplaced during surgery and was reinserted; 10 S2 alar iliac screws were excluded from the analysis. S2 alar iliac screws were excluded because they were not pedicle screws. The 440 pedicle screws that were placed with robotic assistance were evaluated. Six screws were placed at T2, 7 at T3, 5 at T4, 7 at T5, 14 at T6, 11 at T7, 12 at T8, 16 at T9, 25 at T10, 27 at T11, 30 at T12, 23 at L1, 36 at L2, 60 at L3, 67 at L4, 61 at L5, and 33 at S1.

2. Surgical workflow

Preoperative computed tomography (CT) images were obtained and used to plan pedicle screw placements. The spine surgery robotic system worked using the planning data.

The robot arm unit was attached to the operating table. Before the operation, the robot arm unit was equipped with a specific sterile drape, and the robot reference frame and arm guide were attached. A skin incision was made in the posterior midline of the planned fusion area. All surgeries were performed through a posterior approach, which included midline fascial incisions or midline skin and separate fascial Wiltse incisions.

All surgeries were done using “CT to Fluoro” registration. The C-arm (STX-1000A; Toshiba Medical Systems, Ohtawara, Japan or Zenition 70; Philips, Amsterdam, Netherlands) was used to acquire frontal and oblique X-ray images during surgery, which were matched with the planning data. Without Kirschner-wire guidance, pedicle screws were inserted under the robotic arm guide.

3. Time definition

Screw insertion time

The insertion time was recorded for each pedicle screw. The insertion time was defined as the period between making a pilot hole and completing pedicle screw placement (Fig. 1A). In each case, the mean insertion time was defined as the screw insertion time.

Robot setting time

Before the skin incision, the time from the installation of the specific sterile drape for the robot arm unit to the installation of the robot reference frame and the arm guide was defined as the robot setting time (Fig. 1B).

Registration time

During the surgery, the time from the installation of the bone mount platform to the completion of registration by C-arm imaging was defined as the registration time (Fig. 1C). This step included the “3Define” time to scan the three-dimensional surface shape of the surgical field and the time to register and verify all required surgical instruments. In most cases, registration was performed once. If all planned segments were not fully seen in a single fluoroscopy frame, for instance in longer fusion areas, two separate registrations were necessary. The average of the two registration times was used in these cases. If the registration was performed again due to the loss of accuracy of the robotic system during the surgery, the time for re-registration was added to the initial registration time. It was considered as the registration time in one area.

Operation time

The time from skin incision to closure was defined as the operation time. This included all procedures such as ap-



Figure 1. A: The insertion time was recorded for each pedicle screw. The insertion time was defined as the period between making a pilot hole and completing pedicle screw placement. B: Before the skin incision, the time from the installation of the specific sterile drape for the robot arm unit to the installation of the robot reference frame and the arm guide was defined as the robot setting time. C: During the surgery, the time from the installation of the bone mount platform to the completion of registration by C-arm imaging was defined as the registration time.

proach, registration time, implant placement, decompression if needed, and correction if needed.

4. Evaluation of screw accuracy and screw-related complications

CT images obtained 1 week after surgery were used to evaluate the screw positions. Gertzbein-Robbins (GR) grades were used to assess the deviation of 440 pedicle screws in the postoperative CT images: Grade A: no deviation; Grade B: deviation less than 2 mm; Grade C: deviation of 2 mm or more but less than 4 mm; Grade D: deviation of 4 mm or more but less than 6 mm; and Grade E: deviation of 6 mm or more¹⁵. The placement of pedicle screws was evaluated by one of the study's authors (J.U.) who was blinded to the clinical symptoms. Grade A was considered accurate, and Grades B, C, D, and E were considered to have significant deviations. The screw accuracy was calculated as the number of Grade A screws divided by the total number of screws.

Screw-related complications, including neurological deterioration, vascular injury, visceral injury, and reoperation, were also investigated.

5. CUSUM analysis

The CUSUM value for the first case was the screw insertion time minus the mean screw insertion time; the second case's CUSUM value was the second case's screw insertion time minus the mean screw insertion time plus the first case's CUSUM value. The CUSUM value was 0 at the end of the recursive process, which lasted until the final case. CUSUM was used to calculate the model's fit using polynomial curve fitting.

When the fitted curve's form changes from rising to dropping, the learning curve has been successfully crossed. To split the surgeries into the early and late phases, we used this time point. In the early and late phases, we compared screw insertion time, robot setting time, registration time, operation time, screw accuracy, and screw-related complications.

6. Statistical analysis

Normally distributed continuous variables were expressed as mean±standard deviation. A Student's t-test was used to compare the screw insertion time, the robot setting time, the registration time, and the operation time between the two phases. The Fisher's exact test with chi-square was used to compare the screw accuracy rate and the number of pedicle screws at each vertebral body between the two phases. Significant differences were defined as $p < 0.05$.

Results

In all 50 cases, the mean screw insertion time was 3.0 ± 1.1 min, the robot setting time was 2.9 ± 1.1 min, and the registration time was 18.8 ± 6.8 min. All of these times declined as the number of surgical cases increased (Fig. 2A-

C). The operation time was 297.4 ± 112.32 min but did not decline as the number of surgical cases increased (Fig. 2D).

Of the 440 screws, the GR grades were: Grade A for 403 screws, Grade B for 29, Grade C for 7, Grade D for 1, and 0 for Grade E. In total, the screw accuracy was 91.6%.

The learning curve's fitting model formula was $CUSUM = -0.0103x^2 + 0.4742x + 2.4649$ (x represents the case order; $R^2 = 0.8343$). The learning curve for screw insertion time can be separated into two stages based on the shape of the learning curve (Fig. 3). The first 23 cases were in the early phase (the CUSUM fitting curve continued to rise, reflecting surgical technique learning), and the later 27 cases were in the late phase (CUSUM fitting curve continued to decline, representing the mastery of surgical technique).

Table 1 compares the screw insertion time, robot setting time, registration time, operation time, screw accuracy, and screw-related complications in the two phases. The screw insertion time, robot setting time, and registration time in the late phase were significantly shorter than those in the early phase. There were no significant differences in the operation time or screw accuracy between the two phases. No cases with screw-related complications were observed in either phase. The number of pedicle screws at each vertebral body is shown in Fig. 4. There was no significant difference in the vertebral levels between the two phases ($p = 0.675$).

The screw insertion time was compared by level. The screw insertion times of the upper thoracic level (T2-T4) in the late phase tended to be shorter than those in the early phase. The screw insertion times of the middle thoracic (T5-T8) and lower thoracic levels (T9-T12) in the late phase were shorter than those in the early phase, but these did not reach significant differences. The screw insertion times of the lumbar level (L1-S1) in the late phase was significantly shorter than those in the early phase (Table 2).

Discussion

This study showed that screw insertion time, robot setting time, and registration time decreased with experience in the first 50 cases. The surgeons can pass the learning phase of robotic-assisted spine surgery after the first 23 cases. The mean screw insertion time was reduced from 3.2 min in the first 23 cases to 2.7 min in the subsequent 27 cases. Since there was no significant difference in the screw accuracy between the early and late phases, we considered that the accuracy of the screw was maintained from the early phase.

There have been different reports on the learning curve of robotic-assisted spine surgery, from no learning curve to the report that 30 cases were required to achieve proficiency^{9-12,16-19}. In these reports, the learning curves were determined by a variety of factors, including overall operation time, screw insertion time, and screw accuracy. Furthermore, the learning curves in these reports were determined without the CUSUM analysis. The CUSUM analysis was first employed in the industrial field for quality control, but it was later applied to the medical field to study the learning

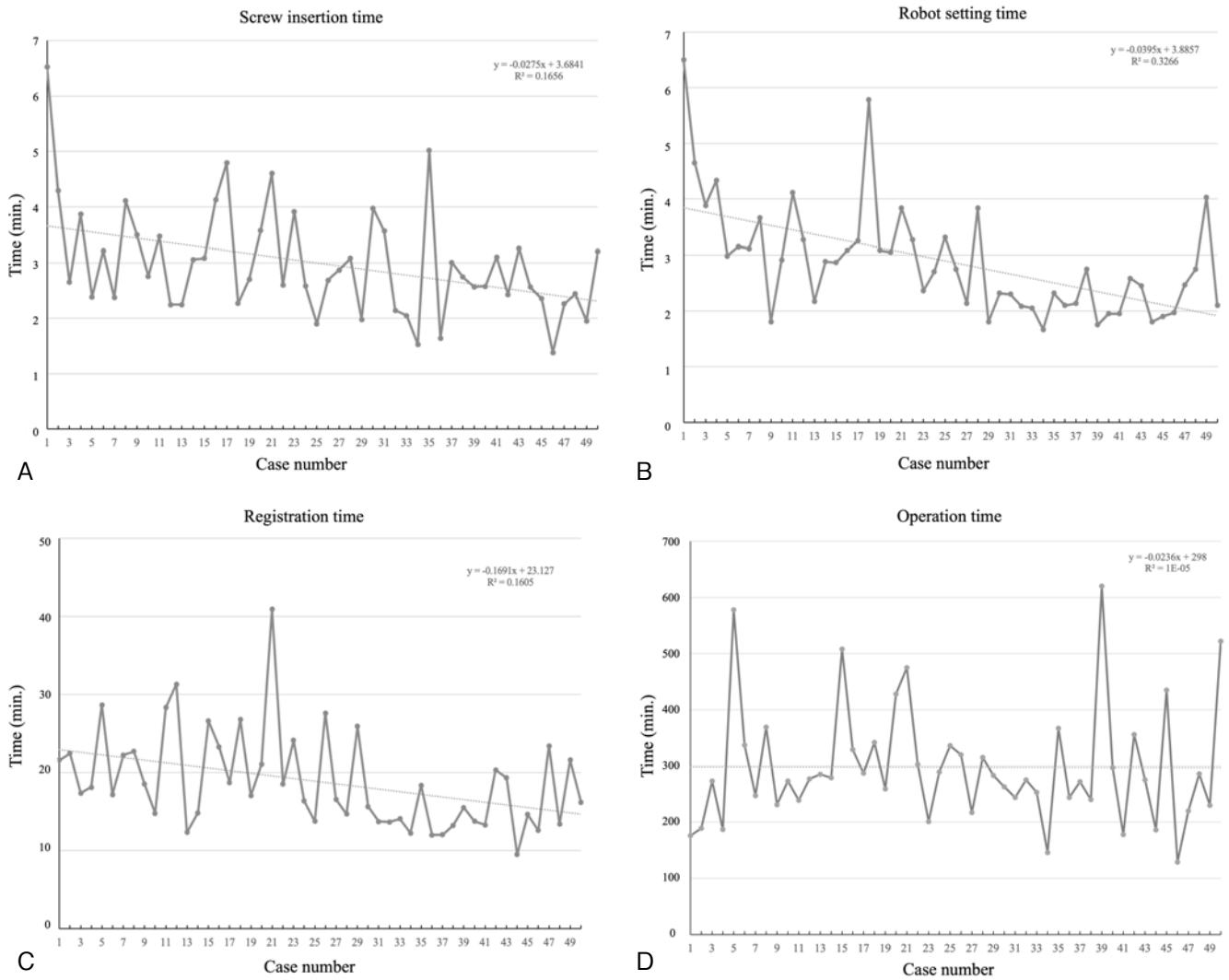


Figure 2. Time of robotic-assisted spine surgery. A: Screw insertion time. B: Robot setting time. C: Registration time. D: Operation time.

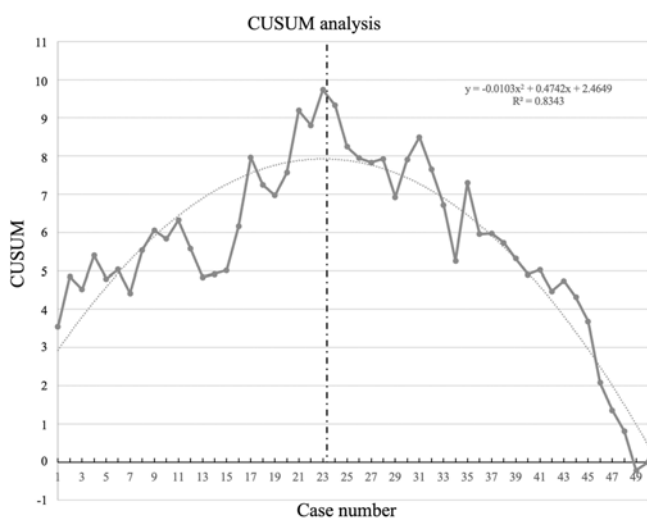


Figure 3. Cumulative sum analysis of screw insertion time.

Table 1. The Comparison of Screw Insertion Time, Robot Setting Time, Registration Time, Operation Time, Screw Accuracy, and Screw-related Complication in the Early and Late Phases.

	Early phase	Late phase	p
No. of cases	23	27	
No. of screws	203	237	
Screw insertion time (min)	3.2±1.8	2.7±1.2	<0.001
Robot setting time (min)	3.5±1.1	2.4±0.6	<0.001
Registration time (min)	22.1±6.4	16.0±4.4	<0.001
Operation time (min)	307.5±104.7	288.8±105.8	0.535
Screw accuracy	94.1%	89.5%	0.087
Screw-related complication	None	None	

Variables were expressed as mean±standard deviation.

curves for surgery¹⁴). Yu et al. reported that surgeons can complete the learning phase of robotic-assisted spine surgery after 17-18 cases based on the CUSUM analysis of the op-

eration time²⁰). However, the operation time included the time not related to the robot, such as approach, decompression, and wound closure. We showed the learning curve for screw insertion time with the CUSUM and concluded that surgeons can pass the learning phase for robotic-assisted spine surgery after completing 23 cases.

Several studies have reported that the insertion time per screw became shorter with experience in robotic-assisted spine surgery^{11,12,17,18}. Bäcker et al. reported that the insertion time per pedicle screw is 8.6 min with a decreasing trend with greater experience¹¹. Hyun et al. found that the mean insertion time per screw is reduced from 5.5 min in the first 15 cases to 4.0 min in the subsequent 15 cases¹⁷. Since the spine robotic system and measurement method were different in each research, the insertion time itself could not be compared between each research. These studies reported that the insertion time per screw became shorter with experience. The present study showed that the screw insertion time was reduced by 16% as the number of surgical cases increased. In our study, we used the CUSUM analysis of the screw insertion time for the first time to determine the learning curve.

In the early phase, the screw insertion time was 5.0 min for the upper thoracic, but only 3 min for the other levels. The screw insertion time of the upper thoracic in the late phase became the same time as the other levels. This fact might indicate that the spine robotic system was beneficial. We believe that this robotic system is particularly effective in levels where it is difficult to place screws, such as the upper thoracic vertebrae. Owing to the small sample size of upper thoracic screws, this point was not validated in this study, but it will be addressed in the next issue.

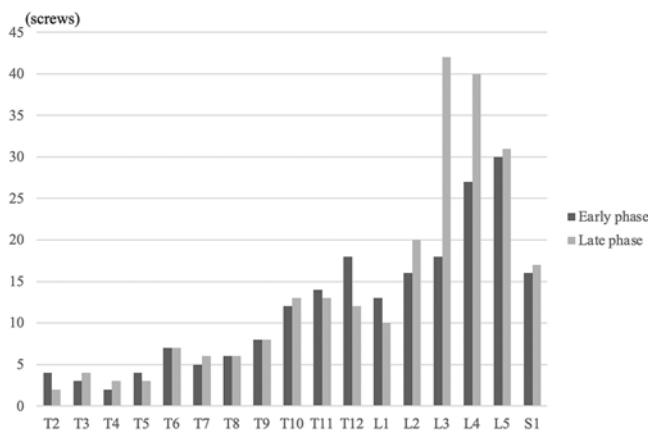


Figure 4. The number of pedicle screws at each vertebral body.

There were several limitations in this study. This study included various surgical procedures, so the learning curve was not based on a unified surgical procedure. Therefore, the CUSUM analysis was conducted using the insertion time per screw rather than the operation time. Degenerative lumbar diseases and spinal deformities were included in this study. The need for the spine robotic system for open surgery for lumbar degenerative diseases may be lower than those for spinal deformities. We will examine the learning curve of spinal deformity surgery. We believe that our result for 50 cases will not change dramatically even if the number of cases is increased, but we intend to continue to investigate the cases in the future. The experience of spinal navigation might have shortened the learning curve of robotic-assisted spine surgery. However, we did not examine a surgeon's learning curve who had no experience with spinal navigation, so we could not show how much spinal navigation experience affected. This is a topic that will be investigated in the future. We have never avoided robotic-assisted spine surgery in the first 50-case series because of severe spinal deformity or any reason. We did not exclude cases that were not suitable as early cases of robotic surgery. However, although severe spinal deformity cases were not excluded, it was probable that narrow pedicles in spinal deformity cases were avoided in the early phase. When the pedicle was narrow in patients with adolescent idiopathic scoliosis, the screw was skipped, which was the standard manner. Future research will investigate whether the spine robotic system can challenge narrow pedicles. The screw accuracy in the late phase tended to be lower than that in the early phase. Because the surgeons had progressed through the learning phase of robotic-assisted spine surgery and grew more proficient in the late phase, it is probable that the screws were inserted in narrow pedicles and screw accuracy was lower in the late phase. We will examine the relationship between pedicle size and deviation in the future. This study investigated a one-institution learning curve, not a one-surgeon learning curve. Our team involved five surgeons and operating room staff. Shortening the robot setting time and registration time required the cooperation and proficiency of assistant surgeons and operating room staff other than the operator.

Table 2. Screw Insertion Time of Thoracic and Lumbar Levels.

		Screw insertion time (min)			p (early vs. late phase)
		Overall	Early phase	Late phase	
Thoracic	Overall	3.1±1.5 (n=160)	3.3±1.9 (n=83)	2.8±1.0 (n=77)	0.052
	UT	4.1±2.1 (n=18)	5.0±2.6 (n=9)	3.3±1.0 (n=9)	0.085
	MT	2.9±1.3 (n=44)	3.1±1.6 (n=22)	2.7±0.8 (n=22)	0.266
	LT	2.9±1.5 (n=98)	3.1±1.8 (n=52)	2.8±1.1 (n=46)	0.347
Lumbar	Overall	2.8±1.5 (n=280)	3.2±1.8 (n=120)	2.6±1.2 (n=160)	0.001

Variables were expressed as mean±standard deviation.

n: number of screws, UT: upper thoracic (T2–T4), MT: middle thoracic (T5–T8), LT: lower thoracic (T9–T12)

Conclusions

We evaluated the learning curve for screw insertion time using the CUSUM analysis in the first 50 cases after the introduction of the spine robotic system. The screw insertion time, robot setting time, and registration time decreased with experience. After 23 cases, surgeons passed the learning phase of robotic-assisted spine surgery and became more proficient.

Conflicts of Interest: Tsutomu Akazawa declares research grants from Medtronic and Globus Medical. The other authors declare that they have no conflicts of interest.

Sources of Funding: None.

Author Contributions: Yoshiaki Torii and Tsutomu Akazawa wrote and prepared the manuscript. All authors participated in the study design. All authors have read, reviewed, and approved the article.

Ethical Approval: This study was approved by the Institutional Review Board of St. Marianna University School of Medicine (Approval Code No. 5567).

Informed Consent: The opt-out method was adopted to obtain informed consent for publication from the subjects.

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