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Evaluation of the characteristics of various types of coils for the embolization of intracranial aneurysms with an optical pressure sensor system

Noriaki Matsubara · Shigeru Miyachi · Yoshitaka Nagano · Tomotaka Ohshima · Osamu Hososhima · Takashi Izumi · Arihito Tsurumi · Toshihiko Wakabayashi · Akihito Sano · Hideo Fujimoto

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Abstract

Introduction In coil embolization for an intracranial aneurysm, it is important to appropriately choose the coil most suitable for coping with various unforeseen situations. Additionally, because dense coil packing of the aneurysm sac is the most important factor to avoid a recurrence, properly selecting the coil is essential. In this article, the authors measured the coil insertion pressure of various types of coils with a newly developed sensor system, and coil characteristics were investigated.

Methods The sensor consists of a hemostatic valve connected to the proximal end of a microcatheter. The sensor principle is based on an optical system. Using this, an experimental silicone aneurysm embolization was performed automatically at constant speed. The pattern of the insertion pressure and the maximum insertion pressure (MIP) were analyzed for the various types of coils. The sensor continuously monitored the mechanical force during the insertions.

Results The sensor adequately recorded the coil insertion pressure during embolization in each coil. MIP was generally ranked in order of the coil type. The soft type coils required relatively less insertion pressure than standard/helical and 3D type. As for the patterns of coil insertion pressure, each coil presented a saw-like pressure pattern, though we observed some slight differences. 3D type coils showed peak pressure at the moment of “painting”. Coil loop diameters barely affected MIP. However, as to the patterns of pressure, larger size coils more often presented the peak.

Conclusions Coil characteristics were well evaluated. The results obtained here reflected some actual clinical experience. Furthermore, collecting the in vivo study is mandatory, which may provide clinically useful data.

Keywords Sensor · Coil characteristic · Embolization · Intracranial aneurysm

Abbreviations

ES	ExtraSoft
MIP	Maximum insertion pressure
US	UltraSoft
3D	Three-dimensional
2D	Two-diameter

N. Matsubara (✉) · S. Miyachi · T. Ohshima · O. Hososhima · T. Izumi · A. Tsurumi · T. Wakabayashi
Department of Neurosurgery,
Nagoya University Graduate School of Medicine,
65 Tsurumai-cho, Showa-ku,
Nagoya, Aichi 466-8550, Japan
e-mail: mnoriaki0817@yahoo.co.jp

Y. Nagano · H. Fujimoto
Department of Computer Science and Engineering,
Nagoya Institute of Technology Graduate School of Engineering,
Nagoya, Aichi, Japan

A. Sano
Department of Engineering Physics, Electronics and Mechanics,
Nagoya Institute of Technology Graduate School of Engineering,
Nagoya, Aichi, Japan

Y. Nagano
New Product Development R&D Center, NTN Corporation,
Iwata, Shizuoka, Japan

Introduction

In endovascular coil embolization for an intracranial aneurysm, it is important to choose the most suitable coil for various situations. Additionally, in coil embolization, although the development of various new devices has continued, including new types of coil, balloon catheters, and microstents, dense coil packing of the aneurysm sac remains the most important factor to avoid an aneurysm recurrence [1–4]. When packing the coils as densely as possible, it is important to ensure that the various coils (shape, stiffness, loop size, and length) should be properly selected to fit the circumstance [5].

The authors developed a new sensor device to measure the coil insertion pressure via an optical system already reported [6–9]. In this article, the authors measured the coil insertion pressure of various types of coils with that optical pressure sensor system. The coil characteristics were investigated by analyzing the data obtained from each coil.

Materials and methods

The new optical coil insertion pressure sensor consists of a hemostatic valve connected to the proximal end of a microcatheter (Fig. 1a, b). The principle of the pressure sensor is based on an optical system. The optical line sensor detects the position of the delivery wire by measuring the shadow cast, i.e., the degree of the bend, according to the coil insertion pressure via a coil delivery wire from the surgeon's fingertip (Fig. 1c, d). Positioning data of the bend are automatically translated into an objective insertion pressure value. We omit here further technical details of the engineering physics of the device; please refer to our already published reports elsewhere [7, 8].

Experimental aneurysm embolization was performed using the aforementioned optical pressure sensor, which continuously monitored the mechanical force during the insertion of coils into the aneurysm (a silicone dummy aneurysm was used for this study). The complete experimental system is depicted in Fig. 2a, with panel d showing a schematic. The silicone dummy simulates the shape of a round aneurysm with no branches (Fig. 2b, c). The dome size was 3 mm in diameter, and the neck length and parent artery diameter were both 2 mm. The experimental embolization was performed automatically at a constant speed, since manual coil insertion by a surgeon might adversely affect the result. The insertion speed was set at as 1.0 mm/s, which was considered the most appropriate speed under that condition in the preliminary experiment. The tip of microcatheter was placed at the center of the silicone aneurysm dome. The catheter was placed in an almost linear position to minimize the influence of the frictional pressure exerted when a coil passed inside the lumen of the microcatheter. Movements of the coil during insertion were observed with a microscope, with the microscopic image reflected on a monitor.

The coils used in this study were as follows: GDC (Boston Scientific Neurovascular, Natick, MA, USA) 10 UltraSoft (US): 3 mm–6 cm, GDC10 US: 4 mm–8 cm, GDC10 Soft 2D SR 3 mm–6 cm, GDC10 3D 3 mm–6 cm, GDC10 360 SR 4 mm–8 cm, GDC10 Standard 4 mm–8 cm, MicroPlex (Micro Vention, Aliso Viejo, CA, USA) 10 Helical 3 mm–6 cm, MicroPlex10 Helical 4 mm–8 cm, MicroPlex10 Complex 3 mm–7 cm, and ED coil (Kaneka Medix, Osaka, Japan) 10 ExtraSoft (ES) 3 mm–6 cm. The diameter of the coil loop was 3 or 4 mm, the length range is 6–8 cm, and helical (including 2D) or complex shaped coils were used. When deciding the most proper diameter of the coil loop, any loop over 5 mm was considered so oversized that the coil frequently protruded outside the aneurysm during embolization. Thus, a 3- or 4-mm coil loop was selected.

Coil insertion pressure was measured five or more times for each coil using the optical pressure sensor. The data obtained during the final 10 s of a coil insertion was omitted because the stiffness of the detach point between the coil and coil delivery wire might adversely affect the pressure. The data obtained initial 10 s were also omitted

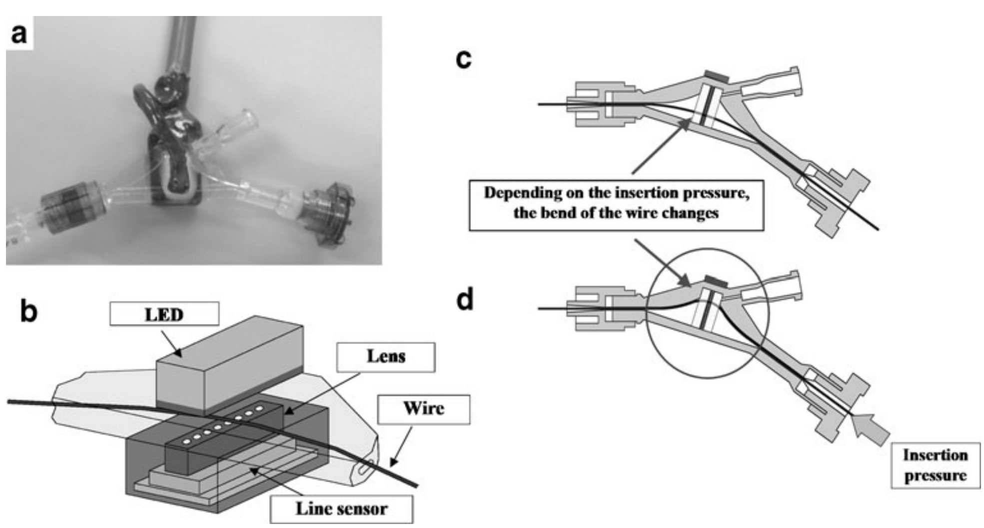

Fig. 1 **a** Photographs illustrating optical pressure sensor. **b** Schematic showing optical pressure sensor. **c**, **d** Schematics showing optical system. **c** Without insertion pressure, the coil delivery wire does not bend. **d** With insertion pressure, it does. Sensor optically detects position of bend in wire [6]

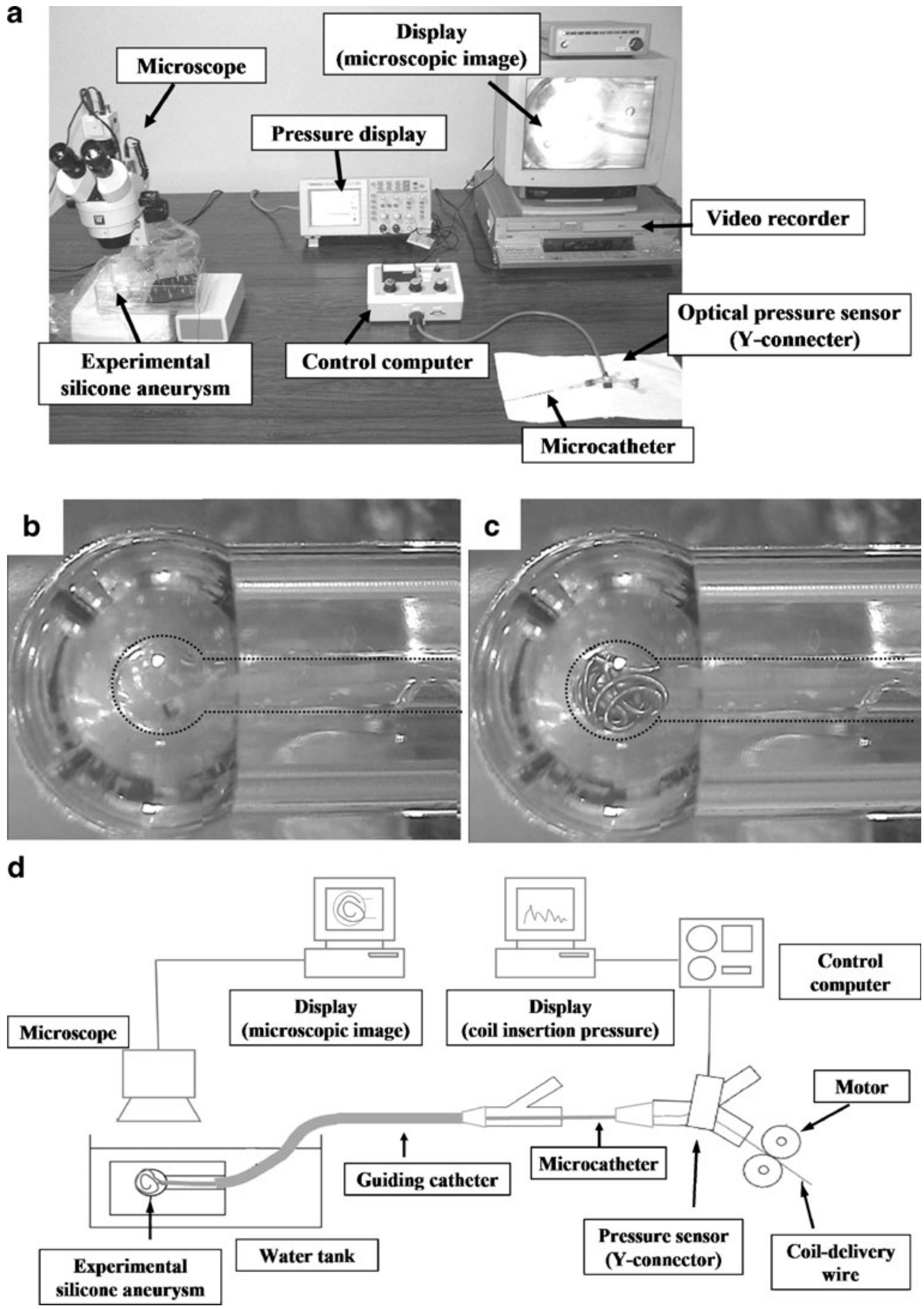

Fig. 2 **a** Photograph showing experimental system for measuring coil insertion pressure with optical sensor system during embolization in silicone aneurysm model. **b**, **c** Photograph of experimental silicone aneurysm. Aneurysm dome size was 3 mm. **d** Schematic showing the experimental system

because the distal tip of the coil, i.e., the first coil loop, sometimes adhered to the aneurysm wall, which might cause a rise in the insertion pressure. It took 60 s to insert the entire 6-cm coil at a speed of 1.0 mm/s. Therefore, the data obtained from 10 to 50 s were analyzed. To compare the performance under the same situation, even in longer 6-cm coils, only the data from 10 to 50 s were analyzed. The pattern of the insertion pressure and maximum insertion pressure (MIP) values were analyzed. To simplify the analysis, we studied only the results of the first coil insertion.

Statistical analyses were performed using Ekuseru-Toukei 2006 (Social Survey Research Information Co., Ltd. Tokyo, Japan). ANOVA was used for multiple comparisons among the coils. Bonferroni analysis was used for post hoc analysis. Additionally, these coils were classified into three coil type groups (soft, standard/helical, or 3D type). Student's *t* test was used for the comparison among each group.

Results

The new optical sensor adequately recorded the coil insertion pressure during embolization of a silicone aneurysm in each coil; the result was shown in Figs. 3, 4, 5, and 6.

Distribution of the maximum coil insertion pressure was shown in Fig. 3. MIP was generally ranked in order of the coil type (soft, standard/helical, or 3D) though no statistically significant difference was found between each of them (p= 0.0487 in ANOVA but no significance in Bonferroni analysis). The soft type coils (ED coil 10 ES, GDC10 US, and GDC10 Soft 2D) exerted less insertion pressure than the standard/helical type (MicroPlex10 Helical and GDC10 Standard) and 3D type (GDC10 3D, GDC10 360, and MicroPlex 10 Complex) (p=0.0020 and 0.0017, respectively) (Fig. 4). There was no statistical significant difference between standard/helical and 3D type coils (p=0.468). No differences were found between GDC US and GDC Soft 2D coils. GDC10 US 3 mm–6 cm showed the wider range of 95% confidence interval in comparison with other coils. That was probably caused by the sticking of coil distal tip to the aneurysm wall. Stuck coil distal tip might induce a rise in the insertion pressure (Fig. 5b). Meanwhile, in GDC Soft 2D, the first 2D loop might control a rise of the following force (Fig. 5c).

As for the pattern of coil insertion pressure, each coil produced a saw-like pressure pattern, though we noted some slight variations (Figs. 5 and 6). Coil loop diameters (3 or 4 mm) barely affected the MIP in this experimental situation. However, as to pressure patterns, compared to the 3-mm coils showing few saw-like peaks, the 4-mm coils showed repeated peaks.

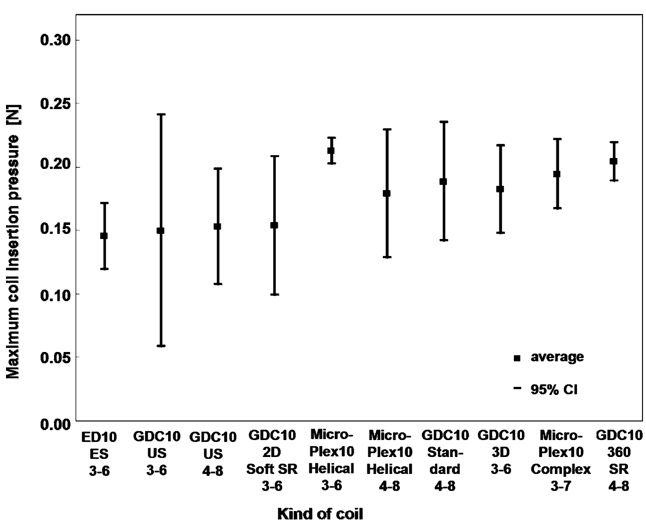

Fig. 3 Representative graph demonstrating maximum insertion pressure (MIP) of each coil (95% CI). MIP was generally ranked in order of coil type (soft, standard/helical, or 3D) though no statistically significant difference was found among the coils (p=0.0487 in ANOVA but no significance in Bonferroni analysis)

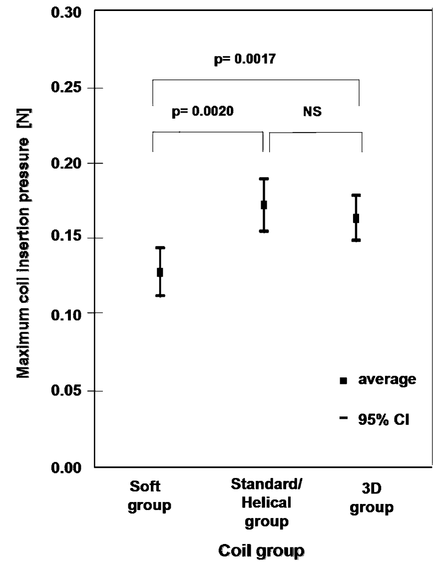

Fig. 4 The soft type coils (ED coil 10 ES, GDC10 US, and GDC10 Soft 2D) exerted less insertion pressure than the standard/helical (MicroPlex10 Helical and GDC10 Standard) and the 3D type (GDC10 3D, GDC10 360, and MicroPlex10 Complex) (p=0.0020 and 0.0017, respectively, Student's t test). There was no statistical significant difference between standard/helical and 3D type coils (p=0.468)

Discussion

Compared to neck clipping of the aneurysm, coil embolization poses a potential risk of aneurysm recurrence due to coil compaction or recanalization, especially in the case of a larger aneurysm [10, 11]. To address that problem, various kinds of coils, such as 3D/complex coils [12, 13], extremely soft coils [14, 15], bioactive coil [16, 17], and hydrogel-coated coil [18, 19], are continuously developed. Although bioactive coils or hydrogel-coated coils are expected to overcome the drawback of a recurrence, no satisfactory evidences have been forthcoming [20].

The dense coil packing of the aneurysm sac is the most important feature to avoid a recurrence. To achieve coil packing as densely as possible, it is important that the various coils (shape: helical or complex, stiffness: standard or soft, loop diameter, and length) must be appropriately selected to cope with various unforeseen situations [5]. To clearly determine the characteristics of various coils is a key factor in ensuring better coil embolization and a successful outcome. White et al. reported fundamentals of coil design and coil technology [21]. However, they basically just analyzed the coil physical properties and did not analyze the coil insertion pressure. With that in mind, the authors investigated the coil insertion pressures of various types of coils using the optical pressure sensor system.

In analysis of the MIP, soft type coils proved less pressure than standard/helical and 3D type coils. The difference between soft and standard/helical type coils

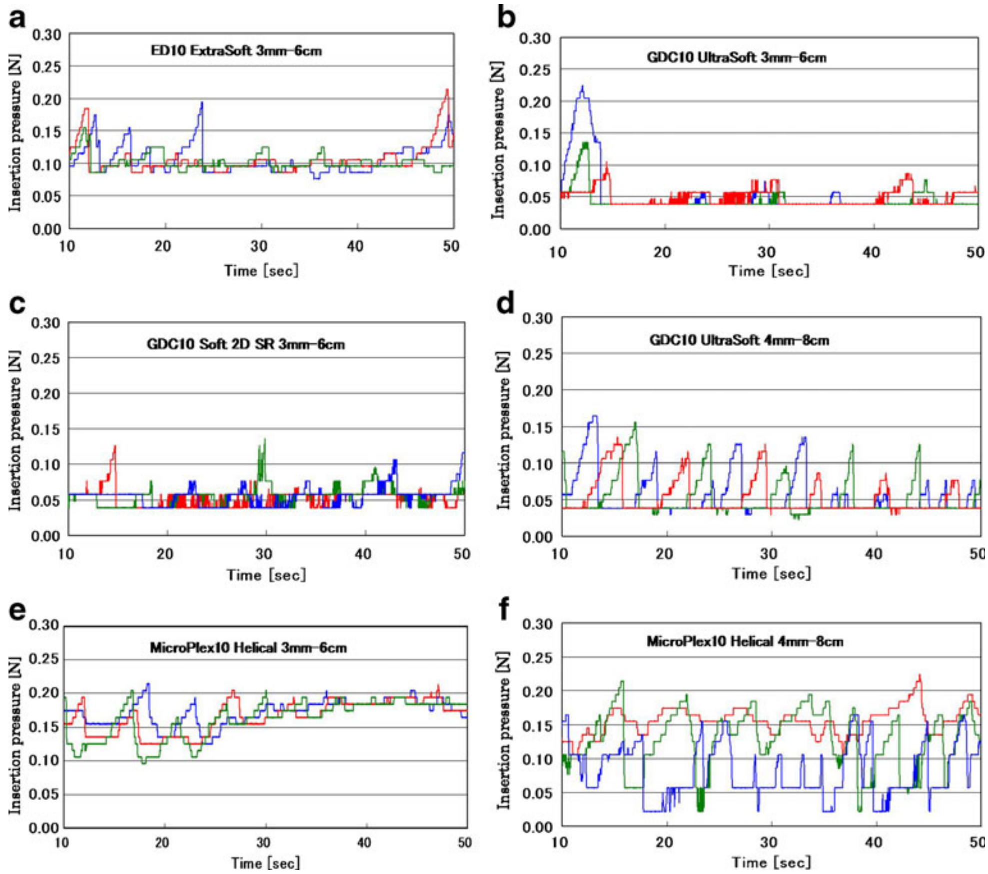

Fig. 5 Representative graphs demonstrating insertion pressure patterns measured by the optical system during embolization in silicone aneurysm (data of soft type coils and MicroPlex Helical coils). Compared to 4-mm coils, 3-mm coils showed few pressure peaks

probably depends on the coil stiffness itself. MicroPlex10 Helical 3 mm–6 cm showed relatively high MIP compared to other coils. One of the explanations was that the characteristics of MicroPlex coils influenced the force. However, MicroPlex10 Helical 4 mm–8 cm did not show similar result. Further investigation is necessary.

By microscopically observing coil movements during insertion, characteristic movements of the coils could be observed. In general, the pressure accumulates gradually as coil insertion proceeds and is released at the moment of "painting", i.e., the tip of the microcatheter moves like a pendulum when the coil slides smoothly along and is rolled

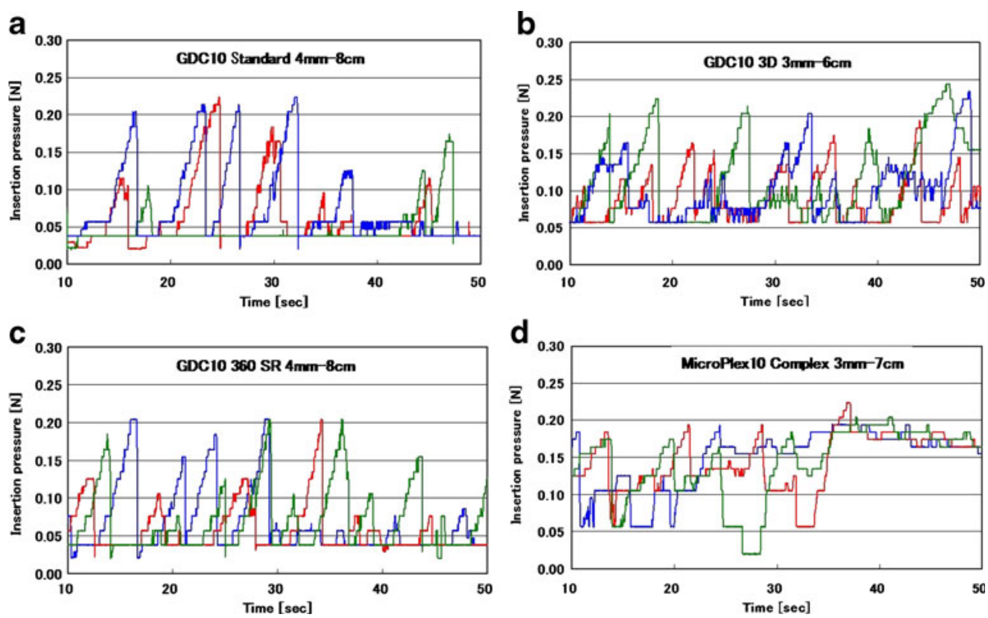

Fig. 6 Representative graphs demonstrating insertion pressure patterns measured by the optical system during embolization in silicone aneurysm (data of GDC Standard coil and 3D type coils). The repeated saw-like pressure patterns were observed

against the aneurysm wall. This movement enables a saw-like pressure pattern to be created during the coil insertion. However, there was some difference noted between the helical type coils and 3D type coils. The former types were able to slide smoothly along the aneurysm wall during "painting," whereas the latter types did not slide readily along the wall, so that the coil mass rolled abruptly against the wall at the moment of "painting." This abrupt movement caused the pressure peaks. These results suggested that 3D type coils could potentially exert undue insertion pressure during the first coil insertion.

Another interesting finding from this experiment was that coil loop diameters of 3 or 4 mm barely affected the MIP. For that reason, the 3-mm coil generally slid smoothly along the aneurysm wall with less stress, though occasionally it failed to do so, which elevated the MIP, presenting the peak pattern. In contrast, the 4-mm coil often exerted the peak pressure. These results suggested that larger size coils often produce the peak pressure. Overall, the results obtained in this study reflected the actual clinical experience and the impression of surgeons in daily interventions.

Although several clinical papers investigating coil characteristics have already published [22, 23], they could not objectively investigate the coil insertion pressure itself feeding back to the surgeon's hand. This optical system can evaluate the pressure at the proximal portion of the microcatheter and can objectively measure and record the coil insertion pressure, so that, hereafter, collecting in vivo data would be highly desirable. A main in vivo factor of coil insertion pressure varies depending of the vessel curves and kinking within the microcatheter access to the aneurysm. This factor might also be an interesting objective for future investigations with this optical system in a tortuous vessel model.

In this study, only the pressure exerted by the first coil insertion was evaluated, allowing for considerable remaining space within the aneurysm, so that the difference among several coils may not be especially remarkable. Therefore, the theme of further detailed research will be to examine under various situations when some coils have already been inserted into the aneurysm. Additionally, because only a limited variety of coils were available in this study, data obtained from more coil types may prove valuable.

Conclusions

The characteristics of various coils could be evaluated with the optical coil insertion pressure sensor system. A saw-like pressure pattern was presented in each coil. Soft type coils potentially exert lower insertion pressures. 3D type coils showed the peak pressures at the moment of "painting". Larger size coils more often present the peak pressure. The results obtained here reflected some actual clinical experience. We consider an in vivo study to be mandatory, which may therefore provide clinically useful data.

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Conflict of interest statement Y. Nagano is an employee of NTN Corporation and this study was financially supported by NTN Corporation.

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