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A Study for the Reproducibility of Detachable Coil used in Cerebral Aneurysm Coil Embolization

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Abstract

Background/Objectives: In this study, the outer diameter of the detachable coil used for cerebral aneurysm coil embolization was evaluated objectively through quantitative analysis. **Methods/Statistical Analysis**: Out of the helical shape coils from three companies that had failed coil embolization from January 2012 to May 2015, the outer diameter of 120 coils (20 from each company) with the diameter of 1.5 mm, and 2.0 mm were measured with an optical microscope and compared with the outer diameter of the coil before insertion. **Findings:** For the coils from all three companies, there were not any significant changes for the outer diameter after keeping the coils in a water bath at 37℃ for 10 and 20 minutes, respectively. For the 1.5 mm sized coils, the average outer diameters before insertion were 1,860µm for coils from company S, 1,530µm for C and 1,554µm for M. Similarly, for the 2.0 mm sized coils, the averages were 2,372µm for company S, 2,038µm for C, and 2,056µm for M, which were larger than the sizes proposed by the companies. After failure, the average changes in outer diameter were 2,074µm for company S, 1,535µm for C and 1,558µm for M measured for the 1.5 mm sized coils, and 2,581µm for company S, 2,043µm for C, and 2,062µm for M among the 2.0 mm sized size coils. The change in the average was the largest for coils from company S, which showed a statistical significance ($p<0.05$). Also, the shorter the length of a given coil, the smaller the changes seen in the diameter. **Application/ Improvements:** The coils from companies C and M maintained reproducibility; that is, they maintained the original shape after the insertion failure, and did not show significant changes in the outer diameter.

Keywords: Cerebral Aneurysm Coil Embolization, Coil Diameter, Detachable Coils, Reproducibility

1. Introduction

Cerebral aneurysm is an extrusion of the damaged part of the cerebral artery. It refers to the state of blood vessels in which the vessel walls swell due to the damage in the intima-media, and the vessel is about to rupture. A big bifurcation in the vessel is where aneurysms normally occur, and the vessel wall is considerably thin and easily ruptured because of the structural difference from normal blood vessels. However, most cases except in giant aneurysms do not have visible symptoms before rupturing and bleeding, and are difficult to discover clinically[1].

A rupture of cerebral artery causes mostly subarachnoid hemorrhage, causing immediate symptoms such as extreme headache, nausea and vomiting, and it occurs in 10 out of a 100,000 people each year, from whom 30 to 40 percent die as a result[2]. Also, if the rupture is not discovered early and the patient survives, even if cured, the patient can be left with considerable psychological, physical and nervous side effects[2,3].

Since the invention of Guglielmi detachable coil (GDC, Boston Scientific, USA) in 1990 and the beginning of the clinical study of endovascular treatment using detachable coil, the endovascular treatment has been considered a new method, replacing the surgical treatment, with many positive results having been reported[4,5]. The advantage of the coil is possible to finally detachment after confirming the accurate position and the result of the occlusion. Also, removal or change of position is that this is possible[6,7,8.]

In Korea, the use of coil embolization differs among various medical centers, but while until year 2000, 20 to 30% of all aneurysms were treated with coils[9], the frequency quickly increased to 53% in 2010, 54% in 2011,

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56% in 2012, 61% in 2013, and 63% in 2014, increasing its use compared to surgical treatment methods[10].

As there is, however, a potential of a blood leakage and rebleeding with the repaired cerebral artery, so tracking management is necessary after treatment. Also, recurrence prevention is crucial in coil embolization, and as part of the preventative measures, a full understanding on the characteristics of the coil used such as the diameter, length, and shape is required.

The aim of this study was to objectively evaluate the outer diameter of the detachable coil used for cerebral aneurysm coil embolization through quantitative analysis.

2. Object and Method of Study

2.1 Object of Study

This study targeted 120 helical shape (2D) coils from three companies, of 214 failed cases out of 1,876 coils used in 290 coil embolizations conducted from January 2012 to May 2015. Twenty coils each for diameter of 1.5 mm and 2.0 mm from three companies (S, C, and M) were analyzed.

2.2 Method of Study

2.2.1 Apparatus of Water Bath

A water bath, KMC-1205WP (Vision Scientific Co., Ltd., Korea), was used to measure the change in diameter of the coil used in coil embolization with time (Figure 1).

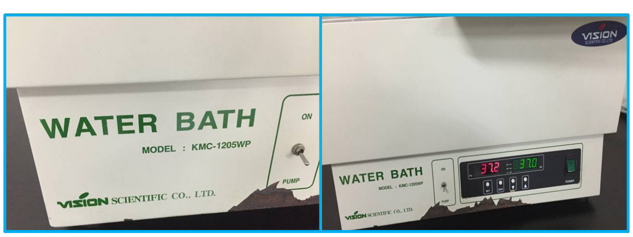

Figure 1. Water bath.

2.2.2 Optical Microscope

U-CMAD3 microscope (Olympus, Japan) was used to measure the diameter of the coil before and after use in coil embolization and the change in diameter observed in the water bath (Figure 2).

Figure 2. Optical Microscope (U-CMAD3).

2.3 Method of Measurement

2.3.1 Measurement of Coil using the Water Bath

After submerging the 1.5 mm and 2.0 mm coils from the three companies that were not used on patients in a water bath at 37°C, the temperature of human blood, the changes in diameter were measured after incubation for 10 and 20 minutes.

2.3.2 Measurement of Coil Diameter

The coil diameter was measured with the optical microscope at a magnification of 40X, and the Image Spot was used to measure the outer diameter (Figure 3). In order to minimize measurement error, each coil was measured three times for an average value. The micrometer scale was used for the measurements, with rounding off to the nearest tenth of a millimeter.

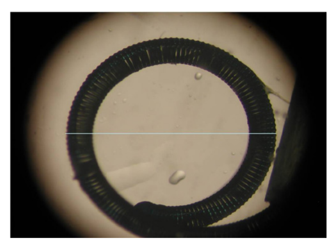

Figure 3. Measurement of Outer Diameter

2.4 Analysis

In order to compare and verify the difference in changes of the coil in each group, PASW Statistics version 18 (IBM Inc., USA) was used to compare the average of each independent groups, and the statistical differences were verified through the t-test and cross analysis.

Tests for the average values for the specimens were conducted, with 95% confidence intervals provided and with significant differences defined as having a p-value of less than 0.05.

3. Results

3.1 Analysis According to the Location of Cerebral Aneurysm

The frequency of insertion failure according to the location of aneurysm occurrence was highest in the anterior communicating artery with 39 (32.50%) failures, followed by 24 (20.00%) failures in the posterior communicating artery, 23 (19.16%) in the middle cerebral artery, and 20 (16.67%) in the basilar artery. There were no significant differences found between the 1.5 mm coils and the 2.0 mm coils according to the location of aneurysm (p>0.05) (Table 1).

Table 1. Analysis according to the location of cerebral aneurysm unit: n(%)

Location	1.5 mm	2.0 mm	Total	p-value
A-com	17	22	39 (32.50)	.976
ACA	3	2	5 (4.17)	
BA	11	9	20 (16.67)	
MCA	12	11	23 (19.16)	
Oph.	3	2	5 (4.17)	
P-com	12	12	24 (20.00)	
PICA	2	2	4 (3.33)	
Total	60	60	00)	

3.2 Analysis According to State of Cerebral Aneurysm

The number of coils that failed in an insertion according to the state of aneurysm was 75 (62.50%) in an unruptured aneurysm, and 45 (37.50%) in a ruptured aneurysm. No significant differences were seen between insertion failures for 1.5 mm and 2.0 mm coils in embolizations for unruptured and ruptured aneurysms (p>0.05) (Table 2).

Table 2. Analysis according to state of cerebral aneurysm unit: n(%)

State	1.5 mm	2.0 mm	Total	p-value
Unruptured	36	39	75 (62.50)	.353
Ruptured	24	21	45 (37.50)	
Total	60	60	00)	

3.3 Analysis According to Gender

The number of a failed insertion was 41 (34.16%) in male patients and 79 (65.84%) in female patients. No significant differences between male and female patients were shown in the number of failures of 1.5 mm coils and 2.0 mm coils (p>0.05) (Table 3).

Table 3. Analysis according to gender unit: n(%)

Gender	1.5 mm	2.0 mm	Total	p-value
Male	23	18	41 (34.16)	.221
Female	37	42	79 (65.84)	
Total	60	60	120 (100)	

3.4 Analysis According to Age

The number of failed coils in each age group was largest in the patients in their 50s as for 41 failures in total (34.16%), with 31 (25.83%) in their 60s, 19 (15.84%) in their 40s, 14 (11.67%) in their 70s, 8 (6.67%) in their 80s or older, and 7 (5.83%) in their 30s.

1.5 mm coils failed the most in insertions for the 50s age group (19 failures); the 2.0 mm coils also failed the most in the 50s group (22 failures).

No significant differences in the number of failures were shown among the different age groups for either the 1.5 mm coils or the 2.0 mm coils (p>0.05) (Table 4).

Table 4. Analysis according to age unit: n(%)

Age	1.5 mm	2.0 mm	Total	p-value
30~39	2	5	7 (5.83)	.736
40~49	12	7	19 (15.84)	
50~59	19	22	41 (34.16)	
60~69	16	15	31 (25.83)	
70~79	7	7	14 (11.67)	
80~	4	4	8 (6.67)	
Total	60	60	120 (100)	

3.5 Changes in Coil Diameter in the Water Bath According to Time

3.5.1 1.5 mm Coils

The average changes in the outer diameter of the coils were measured after keeping five 1.5 mm coils in the water bath maintained at 37°C.

The outer diameter of all the coils from companies S, C and M remained almost the same after 10 and 20 minutes of incubation (Figure 4).

3.5.2 2.0 mm Coils

Five coils from each company were kept in the water bath of 37°C and the average changes in the outer diameter were measured according to time.

The outer diameter of all the coils from companies S, C and M remained almost the same after 10 and 20 minutes (Figure 5).

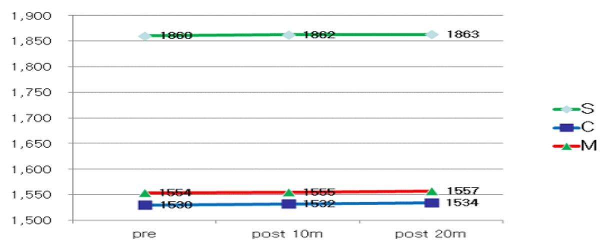

Figure 4. 1.5 mm coil diameter.

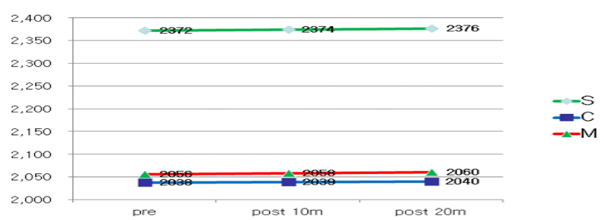

Figure 5. 2.0 mm coil diameter.

3.6 Changes in Diameter of Coils that Failed in Insertion

3.6.1 1.5 mm Coils

The measurements of the outer diameter of the 1.5 mm coil from company S before insertion turned out to be 1,860μm, which is 0.360 mm (3600μm) larger than the outer diameter of 1.5 mm (1,5000μm) reported by the company. The average outer diameter after insertion failure was 2.074 mm (2,0740μm), and the average difference between before and after insertion was 0.214 mm (2140μm). This showed a statistical significance ($p<0.05$) (Table 5). The difference between average outer diameter before and after insertion of 1.5 mm coils from companies C and M was small, no statistical significance seen ($p>0.05$) (Table 5).

Table 5. 1.5 mm coils (unit: 0μm)

Company	N	PRE	POST	Difference	p-value
		mean±SD	mean±SD	mean±SD	
S	20	1,860±3.24	2,074±81.40	214±81.40	.000
C	20	1,530±5.24	1,535±10.35	5±10.35	.054
M	20	1,554±7.25	1,558± 8.14	4± 8.14	.056

3.6.2 2.0 mm Coils

The measurements of the outer diameter of the 2.0 mm coil from company S before insertion turned out to be 2,372μm, which is 0.3682 mm (372μm) larger than the outer diameter 2.0 mm reported by the company. After insertion failure, the average outer diameter was 2.581 mm (2,581μm), which was statistically significant ($p<0.05$) (Table 6). The difference in the average outer diameter of coil C before and after insertion was 0.005 mm (5μm), and 0.006 mm (6μm) for coil M. This did not have a statistical significance ($p>0.05$) (Table 6).

Table 6. 2.0 mm coils (unit: μm)

Company	N	PRE	POST	Difference	p-value
		mean±SD	mean±SD	mean±SD	
S	20	2,372±6.16	2,581±54.01	209±54.01	.000
C	20	2,038±7.71	2,043±11.40	5±11.40	.056
M	20	2,056±3.39	2,062±12.50	6±12.50	.053

3.7 Changes in Coil Diameter According to Length

3.7.1 1.5 mm Coils

The difference in the average outer diameter of 1 cm long coils after insertion failures were measured as 5μm. The measurement did not turn out to have statistical significance ($p>0.05$) (Table 7).

Coils as long as 2 cm were measured to have a 71 μm difference in average outer diameter after insertion failure. Coils as long as 3 cm showed an average of 161 μm difference after insertion failure. This measurement showed a statistical significance ($p<0.05$) (Table 7).

Table 7. 1.5 mm Coils (unit: μm)

Length	N	PRE	POST	Difference	p-value
		mean±SD	mean±SD	mean±SD	
1 cm	20	1,575± 98.16	1,579±125.24	5± 32.20	.526
2 cm	23	1,665±159.82	1,736±239.50	71± 80.48	.000
3 cm	17	1,710±163.83	1,871±306.07	161±143.34	.000

3.7.2 2.0 mm Coils

The average difference in the average outer diameter of 1 cm coil after insertion failure was measured to be 11μm. The difference in the average outer diameter of 2 cm coil

Table 8. 2.0 mm coils (unit: ㎛)

Length	N	PRE mean±SD	POST mean±SD	Difference mean±SD	p-value
1 cm	16	2,088±111.35	2,099±156.33	11± 45.87	.350
2 cm	13	2,122±142.76	2,167±217.76	45± 75.18	.052
3 cm	16	2,210±167.96	2,316±267.76	106±100.45	.001
4 cm	15	2,199±167.97	2,328±291.93	129±127.36	.001

after insertion failure was 45㎛. This was not statistically significant (0.05) (Table 8).

The average difference in the outer diameter of 3 cm coil after insertion failure was 106㎛. For the 4 cm coils, it was 129㎛. This showed a statistical significance ($p<0.05$) (Table 8).

4. Consideration

The most important goal in surgical treatment and the procedure for aneurysm patients is to prevent rebleeding and death or complications that follow rebleeding[11,12]. Therefore, the most preferable treatment would be surgical clipping and coil embolization.

Until 2000, surgical clipping methods were more frequently used in treatment of aneurysms, but the use of coil embolization has increased in recent years, reaching over 50% use in the recent five years and surpassing 60% in 2013 and 2014[10]. This is because surgical clipping requires cranioclasty and prolongs the hospitalization stay compared to coil embolization. Surgical clipping can also cause various complications after treatment. Also, surgical treatment is inevitable when access is difficult. The use of coil embolization is increasing rapidly as an alternative to surgery.

There are various types of coils used for coil embolization, but a deliberate choice regarding the character, length and diameter of coil is required for an outstanding treatment result.

In this study, the changes in the outer diameter of coils from different companies before and after insertion were measured in order to assess the reproducibility of the coils used for embolization.

Out of a total of 120 coils analyzed, the highest rate of failure was found in the anterior communicating artery with 39 (32.50%) failures, and a high percentage was also found in unruptures aneurysms with 75 (62.50%) failures. The rate of failure was also 41 (34.16%) in male patients and 79 (65.84%) in female patients, in accordance with preceding research showing higher incidence of aneurysm in female patients[13]. Regarding the age groups, the frequency of failure was highest for those in their 50s for both 1.5 mm and 2.0 mm coils (34.16%). According to Osborn's study (1999), the incidence of aneurysm is highest for patients in their 50s to 60s, and the analysis of failures in this study implies that the failure rate follows the incidence.

In this study, a measurement of coil diameter before insertion showed that the actual measurements differed from measurements proposed by all the companies. Among these, the coils from company S showed the biggest error. Also, in a measurement of diameter change after failure, coils from companies C and M showed minor changes in diameter, while those from company S gave a significantly different number.

Since the measurements were made without regard to special characteristics that were not addressed by the companies, it is important to consider the pros and cons of coil use and the variables for the diameter change factors, in order to improve the reliability of the results. The limitations of this study are that it did not evaluate the impact on speed of blood flow on changes in coil diameter or impact regarding the size of the aneurysm, nor did it compare more coils with diameters other than 1.5 and 2.0 mm.

5. Conclusion

This study analyzed the changes in coil diameter with time and incubation at a constant temperature, and also analyzed 120 coils that had failed in insertion for changes in shape and diameter before and after insertion failure. The following conclusions were reached:

- Neither the 1.5 mm nor the 2.0 mm coils showed significant changes in diameter according to time after incubation at a specific temperature.
- All coils for embolization had larger diameters than reported by the companies. Coil S had the largest discrepancy, of diameters of an average of 1,860㎛ instead of 1,500㎛ (1.5 mm) and 2,372 ㎛ instead of 2,000㎛ (2.0 mm).

- The 1.5 mm coils from company S showed the largest average change in diameter, which was 214㎛, and was statistically significant ($p<0.05$).
- The 2.0 mm coils from company S also showed the biggest average changes in diameter, which was 209㎛, and also had statistical significance ($p<0.05$).
- Both 1.5 mm and 2.0 mm coils with shorter lengths showed smaller changes in diameter ($p<0.05$).

It is concluded that a deliberate choice of coil regarding the length, diameter and shape of coil will reduce the rate of failure in coil embolization, lessen the patient's economic burden, and significantly shorten the length of operation and minimize exposure time for both the surgeon and the patient.

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