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Short Interval Cap for Short Interval Method: Developing a Device in an Ordinary Clinical Laboratory

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Abstract

Short interval method eliminates the disadvantages of short interval method efficiently while maintaining the advantages. After then, short interval caps were designed for short interval method because conventional caps are not easy to apply for short interval method accurately. Three short interval caps with different intervals, 1.0mm, 1.5mm, 2.0mm, were made from the rubber-like plastic material of 95 shore B by 3D printing. The ex vivo and in vivo experiments demonstrated that the short interval cap with 1.0mm interval was the most appropriate device for short interval method.

Keywords: Cap-fitted colonoscopy; Cap; Colonoscopy; Short interval method; Short interval cap

Abbreviations

CFS: Cap-Fiitted Colonoscopy; LIM: Long Interval Method; SIM: Short Interval Method; SIC: Short Interval Cap

Introduction

Usefulness of short interval method

Cap-fitted colonoscopy (CFC) is an efficient method to shorten cecal intubation time and to increase cecal intubation rate and polyp detection rate [1-4]. The distance from the end of the colonoscope to the colonic mucosa prevent red-out happened by attachment of mucosa to the colonoscope. However, this method inevitably causes that the field of vision is affected by the cap. Moreover, the elongated forepart can cause laceration to the colonic mucosa. Finally, the cap can be filled with feces or food remnant easily because the cap provides enough space.

Sort interval method (SIM) was developed to minimizes the disadvantages of CFC (refer). SIM was proved to provide the most appropriate interval between the cap and the colonoscope. SIM did not cause visual field reduction. SIM did not provide a space for fecal impaction. With SIM, slalom and sliding techniques are performed smoothly.

The next step of SIM is to develop a most appropriate cap for SIM. A conventional cap can be used for SIM. However, there are two important downsides. Fitting a cap with 1mm-2mm interval can be difficult because a conventional cap was originally designed to keep 4mm or 6mm interval. Therefore, a practitioner needs to push a cap with high pressure to make the colonoscope go through the inside of the cap for adjusting 1mm-2mm interval. Second, repeated cap fitting can hurt the colonoscope. The inner caliber of the forepart of a conventional cap is much smaller than the caliber of the colonoscope. For solving this problem, a short interval cap was developed and tested in this study.

Materials and Methods

Designing short interval cap

A SIC consists of two parts. Part I is the segment creating an interval between the end of the colonoscope and the end of the SIC, and part C is the segment joining the SIC to a colonoscope (Figure 1). Specifications of the prototype of SICs were determined for applying a SIC to a most commonly used updated colonoscope (CF-H290, Olympus, Tokyo, Japan) in this experiment. The specification of part I (Figure 1) is as follows, 1) Inner diameter, 11mm, 2) Wall thickness, 0.8 mm, 3) Outer diameter, 12.6mm, 4) Length, 1mm, 1.5mm, and 2mm for three types of caps. The length of part I is responsible for the interval of each SIC. Each SIC was nominated referring interval length, length of part I, as follows: 1.0 SIC, 1.5 SIC, and 2.0 SIC. The specification of part C (Figure1) is as follows; 1) Inner diameter, 12mm, 2) Wall thickness, 0.3mm, 3) Outer diameter, 12.6mm, and 4)

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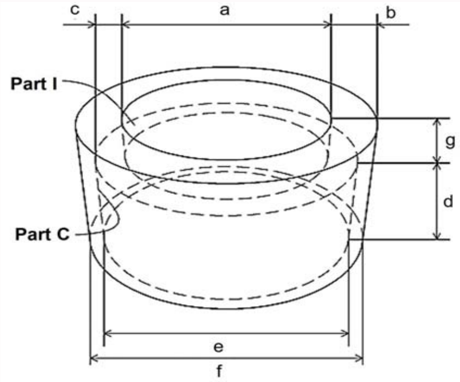

Figure 1A: The blueprint of short interval cap (SIC). 3 D view of SIC, Part I is the segment responsible for creating intervals. Part C is the segment fitted to a colonoscope. The specification of part I is as follows: a = inner diameter, 11mm; b = wall thickness, 0.8mm; c = the difference of the wall thickness between part I and part C, 0.5mm; f= outer diameter, 12.6mm; g = length, 1mm, 1.5mm, and 2mm for three types of caps. The specification of part C is as follows: e = inner diameter, 12mm; wall diameter = b - c = 0.3mm; f = outer diameter, 12.6mm; d = length, 4mm.

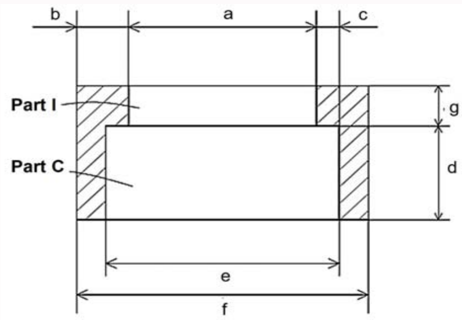

Figure 1B: The blueprint of short interval cap (SIC). Vertical sectional view of SIC. Part I is the segment responsible for creating intervals. Part C is the segment fitted to a colonoscope. The specification of part I is as follows: a = inner diameter, 11mm; b = wall thickness, 0.8mm; c = the difference of the wall thickness between part I and part C, 0.5mm; f= outer diameter, 12.6mm; g = length, 1mm, 1.5mm, and 2mm for three types of caps. The specification of part C is as follows: e = inner diameter, 12mm; wall diameter = b - c = 0.3mm; f = outer diameter, 12.6mm; d = length, 4mm.

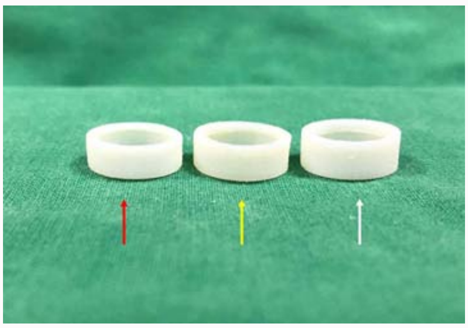

Figure 2: Three short interval caps (SICs). The shortest one is 1.0 SIC, 1mm interval (red arrow). The middle length cap is 1.5 SIC, 1.5mm interval (yellow arrow). The longest one is 2.0 SIC, 2mm interval (white arrow).

Length, 4mm.

Fabricating short interval caps

Computer-aided design (CAD) and 3 D printing were planned. 3D printing companies were evaluated by interview and paper review. The company with the experience of fabricating endoscopic

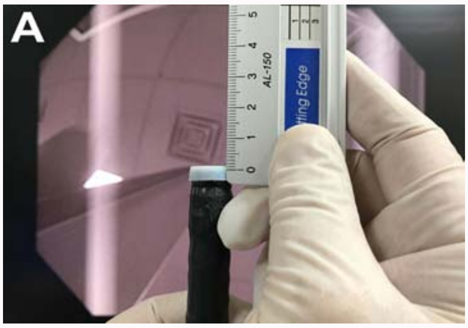

Figure 3A: An *ex vivo* experiment of short interval caps (SICs). (A) A 1.0 SIC is fitted to a colonoscope. A ruler measures 1mm interval.

Figure 3B: There is no visual field reduction with a 1.0 SIC.

Figure 3C: A 1.5 SIC is fitted to a colonoscope. A ruler measures 1.5mm interval.

Figure 3D: There is no visual field reduction with 1.5 SIC.

mucosal resection caps was selected for the project [5]. Specific details such as specification of SICs and fabricating materials for 3D printing were discussed due to the limitation of the equipped 3D printers. The information about the material for SICs was planned to be gathered from web search and conventional cap producing companies.

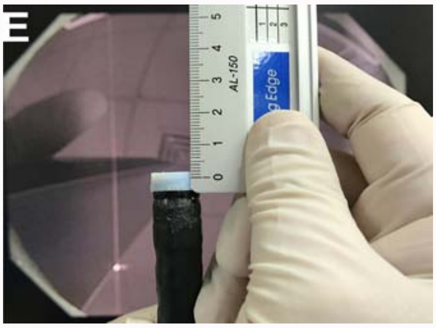

Figure 3E: A 2.0 SIC is fitted to a colonoscope. A ruler measures 2.0mm interval.

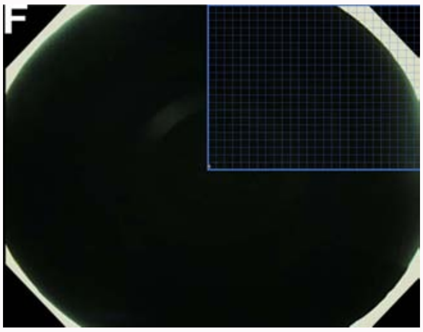

Figure 3F:

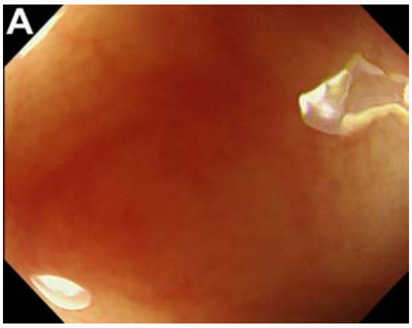

Figure 4A: Near red-out phenomenon with a 1.0 Short interval cap (SIC). (A) Near Red-out was observed during slalom technique with a 1.0 SIC (1.0 SIC-Slalom technique).

Figure 4B: Small air-insufflation results in a clear visual field.

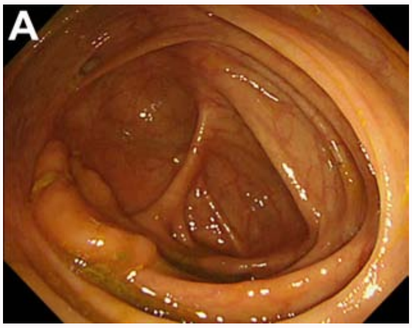

Figure 5A: The *in vivo* visual field test of short interval caps (SICs) (A) There is no visual field reduction with a 1.0 SIC in any situation.

Figure 5B: There is no visual field reduction without air-insufflation with a 1.5 SIC.

Figure 5C: Air-insufflation causes approximately 3% visual field reduction.

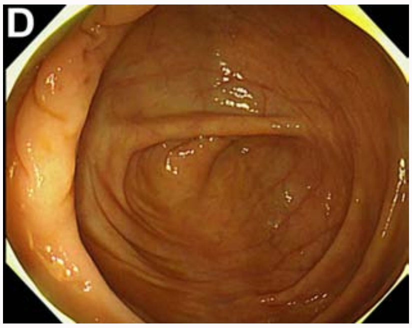

Figure 5D: A 2.0 SIC causes about 6% visual field reduction in any situation.

Ex vivo experiment

The interval was measured by the same ruler in front of the colonoscopy screen for real-time observation of the visual field reduction. Easiness of SIC fitting to a colonoscope was evaluated. For measuring the proportion of affected visual field, virtual squared paper, a lattice shape, was used after getting the photographs if there was an affected area by a cap. The proportion of affected visual field by a cap is regarded as visual field reduction rate.

In vivo experiment

The *in vivo* experiment was performed to find out an optimal SIC for SIM. Institutional review board of Kangnam Saint Peter's hospital endorsed this experiment, and written informed consents were acquired from patients. Each 5 patients were allocated for 1.0 SIC, 1.5 SIC, and 2.0 SICs. Patients were connected to monitoring devices and placed in left lateral position. The patients underwent colonoscopy under procedural sedation and analgesia with midazolam and pethidine. Oxygen was provided continuously through a nasal cannula. Intravenous medications were administered through an indwelling cannula. After adequate conscious sedation was achieved, the colonoscopy with a 1.0 SIC, a 1.5 SIC, and a 2.0 SIC was performed respectively. Checking points during in vivo experiment are as follows: 1) maintenance of the continuous visual field direction, 2) proportion of the visual field affected by the cap, 3) performance of slalom technique, 4) performance of sliding technique, 5) the presence of mucosal laceration, and 6) fecal or food remnant impaction.

Representative Result

The blueprint of the SIC is delivered to the 3D printing company (Prototech, Seoul, South Korea), a branch office of Stratasys (Minnesota, USA) via email. Engineers enrolled CAD (Design X, Geomagic, North Carolina, USA) program for 3D designing and used 3D printer (J750, Stratasys, Minnesota, USA) to make the prototypes of SICs. The material was the mixture of tangoplus (Stratasys, Minnesota, USA) and verowhite (Stratasys, Minnesota, USA); the hardness was 95 shore B. It had taken 30 min for producing one SIC. The SICs was elastic soft and had different intervals: 1.0mm for 1.0 SIC, 1.5mm for 1.5 SIC, and 2.0mm for 2.5 SIC (Figure 2). Three sets of SICs, three 1.0 SICs, three 1.5 SICs, and three 2.0 SICs, were prepared for experiment due to the low durability of the material for the prototypes of SICs.

Three kids of caps were fitted to a colonoscope smoothly. Affected fields of vision by SICs were as follows; 1.0 SIC did not affect the field of vision (Figure 3). 1.5 SIC did not affect the field of vision (Figure 3). 6% of the field of vision was affected by a 2.0 SIC, about 6% (Figure 3).

During *In vivo* experiment, colonoscopy acquired the continuous visual field direction with all types of SICs. Near red-out phenomenon was occasionally observed with a 1.0 SIC. However, this problem was instantaneously resolved by insufflating a small amount of air (Figure 4). The affected visual field was 0% in SIM (Figure 5A). The visual field was not affected by a 1.5 SIC without air-insufflation (Figure 5B). However, approximately 3% of the visual field was affected by a cap with air-insufflation consistently, air-insufflation dependent visual field reduction phenomenon (Figure 5C). Approximately 6% of the visual field is consistently affected by a 2.0 SIC, air-insufflation independent visual field reduction (Figure 5D). With 3 types of SICs, slalom technique and sliding technique were performed smoothly. There was no mucosal trauma or laceration at the segment where the sliding technique was performed with 3 types of SICs. Fecal or food remnant were not impacted in all types of SICs.

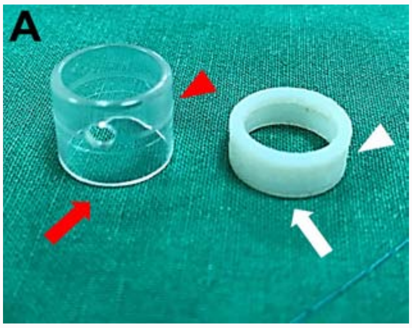

Figure 6A: The plausible mechanism of the air-insufflation dependent visual field reduction with a 1.5 short interval cap (SIC) in this experiment. (A) A conventional cap (red arrow) is transparent and smooth (red arrowhead). However, SICs used in this experiment are opaque (white arrow) and has a rougher surface (white arrowhead).

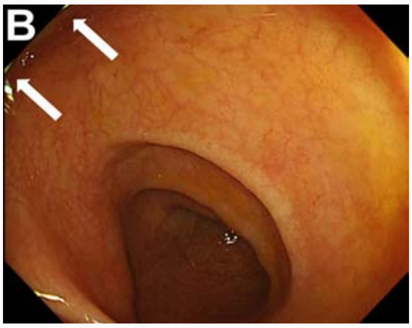

Figure 6B: A conventional transparent cap with 1.5mm interval causes insufflation dependent visual field reduction also although the area is much smaller (white arrow).

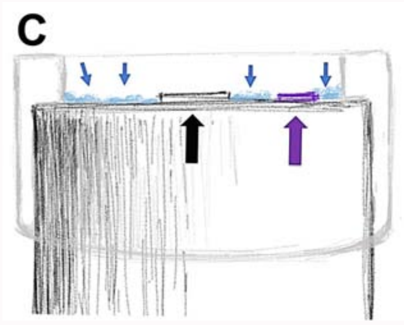

Figure 6C: Without air-insufflation, several small drops of water just stick on the surface of the end of a colonoscope, and the visual field is not affected by a 1.5 SIC. Black arrows indicate the wide-angle camera, and purple arrows indicate the air-insufflation channel. Blue arrows indicate water.

Discussion

This experiment, including my previous study [6], shows a small contemporary clinical development process: developing an idea, a clinically optimal method, and an appropriate device in an ordinary clinical field. There are several important points for this process: First, the urge to overcome the given knowledge and given situation, second, generating a solution by a logical process with gathering sufficient information, third, experiments for testing the idea step by step, and forth, developing an appropriate method and a device for better clinical performance. This experiment followed this sequential process step by step. First, there was an urge to minimize disadvantages with maintaining the advantage of CFC. Second, understanding the principle of CFC and finding out the pivotal point produced an idea that optimal interval between the end of the cap and the end of the colonoscope can maximize the performance of CFC. The *ex vivo* and *in vivo* experiments revealed that 1mm to 2mm interval is appropriate for regular colonoscopy. Finally, the concept of SIM was established, and a 1.0 SIC was proved to be an optimal device for SIM through the *ex vivo* and *in vivo* experiments. The near red

Figure 6D: Air-insufflation pushes the water to the wall of the 1.5 SIC. Black arrows indicate the wide-angle camera, and purple arrows indicate the air-insufflation channel. Blue arrows indicate water.

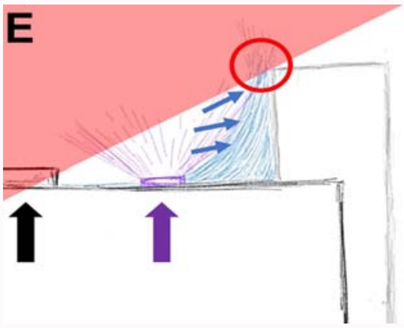

Figure 6E: The red box of the figure 18C is more delicately depicted. The pushed water goes up alongside the wall of the 1.5 SIC and generates water layer on the wall of the 1.5 SIC especially due to its rougher surface. The water layer refracts the light reflected by the wall of the 1.5 SIC, and this opaque colored water layer is caught by the camera of a colonoscope. The red semi-transparent area is the field of vision of the colonoscope. Black arrows indicate the wide-angle camera, and purple arrows indicate the air-insufflation channel. Blue arrows indicate water.

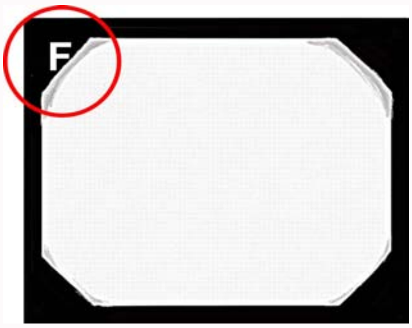

Figure 6F: At the corners of the screen, the cap is observed. The red ringed area of the figure 18D matches the red ringed area of figure 18E.

out phenomenon with 1.0 SIC is instantaneously resolved with air-insufflation, and a practitioner feels nearly no discomfort. However, a 1.5 SIC consistently shows air-insufflation dependent visual field reduction phenomenon, which annoys a colonoscopist. Gathering information about conventional caps from the world wide web was important for determining the specifications of prototype SICs. Using personalized service was another imperative point. Most 3D printing companies provide CAD, 3D printing, and 3D scanning services, so it is easy to proceed a process by contacting just one company.

Determining the material for 3D printing was the most difficult job during this development process. It was impossible to get accurate information about the material of conventional caps because of confidentiality policy of companies. Numerous materials were compared with the material of conventional cap, and thermoplastic polyurethane was finally chosen for 3D printing. However, unfortunately, thermoplastic polyurethane was not used for 3D printing in South Korea. Therefore, the rubber-like material, mixture of tangoplus and verowhite with a hardness of 95 shore B, was inevitably chosen. This rubber-like material presented unanticipated phenomenon. Air-insufflation dependent visual field reduction phenomenon was evidently observed with a 1.5 SIC (Figure 5B and 5C). This phenomenon can be explained by the opacity and rougher surface of SICs (Figure 6A); a conventional transparent cap with 1.5mm interval causes insufflation dependent visual field reduction (Figure 6B). However, it has not been seriously recognized by a practitioner because the area is much smaller, and easily resolved during the procedure with suction. The proposed hypothesis for air-insufflation dependent visual field reduction of a 1.5 SIC is as follows. Several small drops of water sticks on the surface of a colonoscope without air-insufflation (Figure 6C) and the visual field is not affected by the cap. However, air-insufflation makes the water pushed to the wall of the cap and go up alongside the wall of the 1.5 SIC (Figure 6D). The pushed water generates a water layer inside the cap. The water layer refracts the light reflected from the wall of the cap, and the field of the vision of the camera of a colonoscope includes opaque areas (Figure 6E and 6F). If transparent thermoplastic polyurethane had been used for making a 1.5 SIC, air-insufflation dependent visual field reduction phenomenon might not be easily observed, and the result can be biased. Consequently, using the opaque substance for SICs was an appropriate choice to test visual field reduction although it had not been intended; it was an important lesson.

The most important obstacle to this kind of development process must be the fixed idea restrained by pre-existing knowledge. The knowledge of 'CFC has an advantage and several disadvantages and period' must be the most critical hurdle in this process. Forgetting adverb 'currently' prohibits further thinking. The second important obstacle must be a misunderstanding that a small idea would be trivial. A small idea is not trivial. There might be many people whom that small idea can help. A small idea, in fact, can have an enormous effect. The third obstacle might be an idea that research is a specialized job away from an ordinary clinical field. If research should enroll complicated processes such as whole genome analysis or conventional large-scale clinical trials or complicated statistical analysis, such an idea might make sense. However, for clinicians, clinical spaces such as medical offices, wards, and clinical laboratories are research places. These spaces are connected interactively by clinicians' activities to improve clinical performance and outcome. Developing an idea for improving clinical performance is an imperative activity, which can be exclusively available in clinical fields.

The medicine is an applied science assisted by many basic types of research and tools. What clinicians need to do and can do is developing an idea to overcome the current limitation or to move one step forward for better clinical performance because clinicians can do these activities exclusively. In the modern society, realizing a personal idea is easier than the past. Many personalized tools, such as CAD, 3D scanner, and 3D printer, have been invented. Clinicians do not need to equip such tools in their warehouses. Many companies are providing specialized services to enable a clinician to realize ideas. Even, a clinician does not need to meet engineers in a space at a designated time. A clinician can have communication with engineers via email, web drive, and real-time video call such as face time of an iPhone. Such an environment gives a clinician opportunity to transform an idea into a real product.

The human capability has been extended step by step according to the technological advance from a stone ax to a smartphone. In the 21st century, a person can extend not only one's physical and intellectual capability but also can enroll the specialized system providing personalized services and tools without serious economic burden. Moreover, information of cyber-space, created by countless people, incessantly supplies the source of ideas. The invention of artificial intelligence and its evolution are expected to accelerate this phenomenon without a doubt. Shortly, clinicians will be able to solve many problems and overcome limitations in clinical fields with the aid of technological advance. The most important thing must be the free-thinking not restrained by pre-existing conventional knowledge.

Disclosure

The SICs are applied for patent by the author.

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