Development of Retention System of the Autonomous Endoscopic Capsule and Its Functionalities

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Abstract: The aim of the research is to propose the retention system of the wireless endoscopic capsule allowing more detailed observation of stomach, small intestine as well as other parts of the digestive tract. The capsule has an outer layer or whiskers made of an electroactive polymer material that expands under influence of an applied voltage. An electroactive polymer expands up to 50% of its original size and creates a roughly ball-shaped object approximately 3 cm in diameter (in case of whiskers – they change their angular orientation). The performance (changing the size) of the mock-up of the capsule with eight whiskers made of electroactive polymer was tested using a silicone model with sensitive sensors simulating the digestive tract of a person. The probability of failure-free operation and the mean time to failure for capsule and recording device integrated circuits were calculated.

1 INTRODUCTION

Capsule endoscopy is a way to record images of the digestive tract for use in medical examination and diagnosis. The patient swallows the capsule which goes down the digestive tract as ordinary food and the capsule takes images. They can be obtained at any point of the stomach or the gastrointestinal tract. The images are sent to a recording device that the patient can carry or be close to during the procedure.

The primary use of endoscopic capsule is to examine areas of the small intestine that cannot be seen by other types of endoscopy, such as colonoscopy or esophagogastroduodenoscopy (EGD).

This type of examination is often done to find sources of bleeding or abdominal pain. The procedure was approved by the Food and Drug Administration of the United States in 2001 (Scherbakov P.L., 2010). Upper endoscopy, EGD uses a camera attached to a long flexible tube to view the esophagus, the stomach and the beginning of the first part of the small intestine called the duodenum.

A colonoscope, once inserted through the rectum, can view the colon and the distal portion of the small intestine, the terminal ileum. Unfortunately, these two types of endoscopy cannot visualize the majority of the middle portion of the gastrointestinal tract, the small intestine. (R. de Francis, 2012)

Therefore, capsule endoscopy is useful when disease is suspected in the small intestine and can diagnose sources of occult bleeding (blood visible microscopically only) or causes of abdominal pain, such as Crohn's disease or peptic ulcers (Lecheng Yu, 2012; Jebarani, W.S.L, 2013; Dongmei Chen, 2011).

Once swallowed, the capsule needs to be controlled in order to acquire images of the entire area.

There are two problems that gastroenterologists face while conducting examination. In the stomach capsule is relatively fast directed by peristalsis that does not allow to examine certain parts or areas of interest. In other parts of the digestive tract the situation is reverse. In the intestine the peristalsis may be poor (this is true especially for people with

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gastrointestinal pathologies and diseases) whereby the capsule may get stuck until it is taken out by the food. Moreover, because of its small size the capsule can be subject to a greater rotation in the small intestine, which could potentially cause missing of pathologies. (R. de Francis, 2012)

Resently many studies have been carried out to solve the problem of capsule control (Kim Y.T., 2010; Woo S.H., 2011; Park H.J., 2005; Zuo J, 2005; Chiba A, 2005; Sungwook Yang, 2011; Wenwen Chen, 2013). They show good results and present original ideas; however, the possible disadvantages of these proposals may be large capsule power consumption limiting the examination time, necessity in additional sophisticated equipment, etc.

Consider conventional capsules that may be controlled by forces of the magnetic field. For example, such a capsule is described in DE 102006019986 (Johannes Dr. Reinschke, 2007). The disclosed endoscopy capsule for use in patient's gastrointestinal tract has a magnetic element enabling rotating, swivelling and tilting of the capsule as well as an adjustable power supply unit for providing electrical voltage used for creation of the magnetic field.

However, magnetic field and additional electrical circuitry increases the cost and possibly size of the capsule. The system requires external devices that generate magnetic fields (magnetic materials, electromagnets). Furthermore, efficiency of the system can be affected by a secondary magnetic field that interacts with the metal parts of the capsule. Essentially, the secondary magnetic field with the intensity of the controlling field is sufficient for disruption of capsule’s functionality.

Moreover, because of the anatomical features of the small intestine, its tortuosity, the control system based on the magnetic field dors not always allow precise manipulation with capsule location.

Accordingly, there is a need in the art for an efficient and effective endoscopic capsule that is autonomous and can be retained in the stomach and other parts of the gastrointestinal tract for a long periods of time and provide easier passage through intestine if needed.

For this end this paper deals with the new proposal to provide endoscopic capsule with the ability of retention enabling more detailed examination of the digestive tract.

2 EXPANDING ENDOSCOPIC CAPSULE

The proposed capsule endoscopy system provides an efficient and safe way to observe a patient’s stomach and intestinal tract. The capsule remains in the desired part of the digestive tract acquiring images and recording them to an external device. The gastroenterologist can review the images and make a diagnosis at his convenience.

The capsule does not require a special insertion system and can be simply swallowed. The expansion takes place in a standalone mode in response to an outside command.

The endoscopic capsule can expand not only inside the stomach, but in any part of the gastrointestinal tract, for example, in the large bowel. This enables the capsule to stimulate peristalsis in order to accelerate its passage through the intestinal canal.

2.1 Capsule Components

The miniature capsule consists of a light sensitive matrix, a radio frequency transceiver, a backlighting device and a battery.

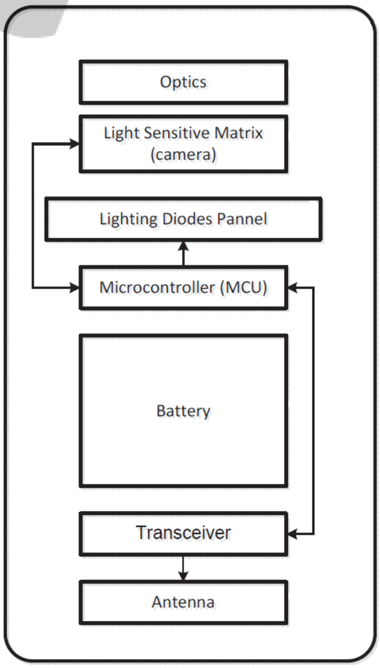

Figure 1: Block-diagram of the wireless endoscopic capsule.

Figure 1 illustrates an endoscopic capsule. The capsule includes an electroactive polymer material that increases its volume inside the patient's stomach or intestine upon receiving a control radio signal from an external device.

The endoscopic capsule can be, for example, 24 mm in length and about 10 mm in diameter. It includes a microcontroller, which controls a light sensitive matrix with optics (i.e., a miniature camera). For example, CMOS matrix with resolution of 640 by 480 pixels can be used. The optics can be a plurality of lenses.

The endoscopic capsule includes a LED panel for providing lighting for the light sensitive matrix for taking images.

The microcontroller controls the light sensitive matrix and the LED panel in order to synchronize the light flashes with the image taking (the duty cycle of the LED illumination can be 6.6%, or two flashes per second, 1/30 of a second each).

A built-in camera takes two images per second, which are then compressed and transmitted according to medical regulations. Since battery life and transmission speed are limited, a typical transmission is 240 x 240 pixels per image, with 8 bit colour, which is often insufficient for medical purposes.

To improve image resolution and reduce power consumption some data analysis can be performed locally (i.e., in the capsule), to avoid transmitting images that have not changed from previous ones. Also, images that are very similar to previous ones (even if not identical) also might not be transmitted depending on degree of similarity (e.g., 90% similar or 95% similar, etc.). Images that are too dark to contain much information also might not be transmitted.

The compression and analysis can be performed locally by the microcontroller and/or by a custom or semi-custom integrated circuit, permitting transmission of, e.g., 320 x 320 or even 480 x 480 pixels, with 16 bit colour.

In order for the images to provide more diagnosis-related information, the capsule uses a variety of colour lighting provided by colour high emitting diodes that turn on each time a picture is taken. For example, red light helps in detecting micro bleedings and blue light is beneficial for detecting structural abnormalities.

The light emitting diodes panel includes white, red, yellow and blue diodes. The colour diodes advantageously replace conventional flash lights (with colour filters) that use a lot of battery charge.

The images are taken using white red, blue and yellow illuminations in this order. However, a larger number of the diodes can be used (for example, 8, 12, etc.). The blue lighting allows for better images of the blood vessels, the red lighting assists in detection of bleedings, and yellow lighting assists in adenoma detection.

The diodes are paired by two of the same colour. This provides for even light distribution. Alternatively, multi-colour diodes can be used. Additionally, special mirrors can be used in combination with the diodes for a more even light distribution.

The diode panel is located perpendicular to a vertical (longitudinal) axis of the capsule, with the diodes facing upwards. The light sensitive matrix can be implemented in the centre of the diode panel.

The capsule is covered by a phosphorescent layer for additional lighting. Thus, the pictures taken by the endoscopic capsule are, advantageously, more accurate for diagnosis making.

Figure 2 illustrates phosphorescent coating of the endoscopic capsule. The capsule is covered by the phosphorescent coating (Fig. 2a). In order to project more light forward, the cover of the capsule is implemented in a corrugated shape as shown in Fig. 2b. The corrugation of the cover is implemented in a lateral plane. If the phosphorescent coating is used in combination with light emitting diodes, the frequency of light emission of the diodes and the phosphorescent coating needs to be synchronized. Phosphorescent coating of the capsule should not be affected by the electroactive polymer.

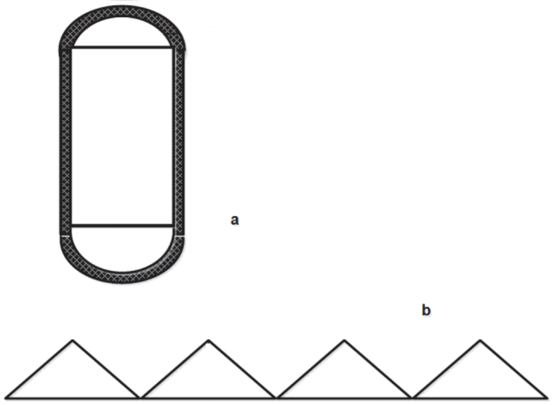

Figure 2: Phosphorescent coating.

The microcontroller is connected to a radio transceiver having an antenna. For example, a transceiver made by ZARLINK can be used. This transceiver uses standard frequency of 403-405 mHz with a power of 25 mW (Mikhaylov D.M., 2013).

The antenna can be integrated into the body of the capsule for better reception/transmission characteristics. The radio transceiver provides signals to the microcontroller for activation of the electromagnetic cover and expanding the capsule.

The capsule is wirelessly connected to a portable recording device that receives images and records them to an integrated memory for review by a gastroenterologist.

A battery powers the circuits within the capsule. The battery can be, for example, shaped as a round tablet with a diameter of 4-8 mm and a height of 9 mm (or 5-10 mm, generally).

After examination is completed, the microcontroller receives a signal through the radio transceiver for reducing the voltage and deactivating the electroactive polymer outer layer of the capsule.

Subsequently, the capsule (i.e., the electroactive polymer layer) shrinks back to an original size, goes down the intestinal tract and leaves the body in a natural way.

The recorder with the images is then provided to the gastroenterologist, who analyses the images at a workstation using medical image processing applications.

2.2 Capsule Retention System

In quite a number of cases specialists need long-term visual observation. Such long-term observation may be easily implemented if capsule endoscopy is applied using the capsule. The endoscopic capsule has a possibility of its retention in the stomach for more detailed study. It is especially important, for example, when the cancer of the stomach is suspected or diagnosed.

The system of the capsule retention in the stomach consists of the following components:

1. A balloon module that includes the following elements:

- a cover made of an elastomeric dispersive material, such as dimethylpolysiloxane;
- a valve made of a sheet dimethyl-polysiloxane (Med 2174) with a silicone adhesive (Med 4213);
- a silicone cover applied by dipping (Med 6607);
- a silicone elastomer (Med 4850) and tantalum (in order to make the valve impenetrable to irradiation).

2. The cover for a balloon module made of the following exemplary materials to facilitate the allocation and intubation of the device:

- dimethyl-polysiloxane dispersion;
- bicarbonate of soda to ease the installation of the balloon into the cover and to prevent the intermolecular cross-linkage during storage.

3. A block of the conductor material made of the following materials and components:

- stainless steel 304, covered with polytetrafluoroethylene;
- polypropylene box-coupling of Lyuer;
- an adhesive (Loctite 3201).

4. A filling tube made of the following components and materials:

- the tubes made of a silicone elastomer (Q7-4780) by extrusion;
- a tip of the filling tube made of polypropylene;
- a box-coupling of Lyuer made of polypropylene.

As one option, the balloon can be made of polyvinyl chloride (PVC), and inflated from a built-in remotely triggered compressed air storage. As a further option, the balloon can be inflated through a catheter-like thread that extends through the oesophagus when the capsule is in the stomach.

In addition the balloon can be made of an electroactive polymer shaped like a ring (torus) around the capsule that “unfolds” to a much larger diameter through a change in angular orientation. The cover is fixed to the capsule in such a way that the opaque part is located inside the transparent balloon.

The outer surface of the capsule is made of an electroactive polymer material that increases its volume under influence of a voltage, like a balloon, or changes its angular orientation.

An electroactive polymer that covers the capsule expands to 30-50% of its original size and creates a roughly ball-shaped object approximately 3 cm in diameter (Fig. 3). This size is sufficient for retention in the stomach that normally has a passage of approximately 2-2.5 cm in diameter into the digestive tract.

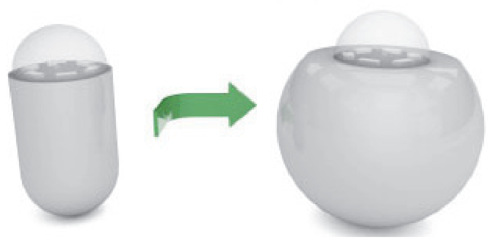

Figure 3: Expanded capsule (ball-shaped).

Electroactive polymer materials are widely used today as artificial muscles in robotics (Henry Sheppard, 2007) and manufactured by several companies, for example, Environmental Robots Inc. (Environmental Robots Inc., 2014).

The capsule is retained in the patient’s stomach and can be used for a prolonged generation of images of various areas. This can be especially useful for observation of influences of new medications (for example, stomach cancer medications).

The voltage is provided by the battery located within the capsule. The battery charge of the capsule can last for about 12 hours. As an option, in case when a longer observation is required, the battery can be charged wirelessly via magnetic coupled coils, one inside the capsule and the other (or others) outside patient's body, so the capsule in its expanded (inflated) state can remain in the stomach or in other part of a gastrointestinal tract for indefinitely long period of time (Fig. 4).

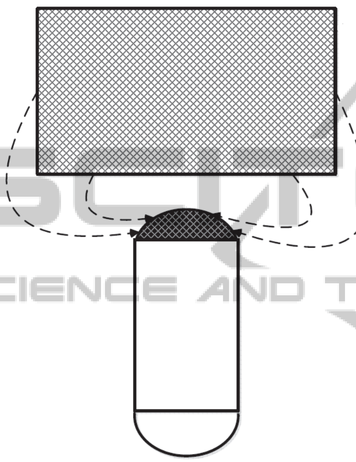

Figure 4: Capsule battery charged by magnetic field.

The capsule, as needed, can be controlled by a magnetic field as it has a magnetic element. The capsule has a magnetic element in a form of a neodymium tablet about 5 (e.g., about 4-7) mm in diameter and about 2 (e.g., about 1.5-2.5) mm in height.

Another unique feature of the capsule is a set of extendable whiskers that extend from the surface of the capsule cover. This can be used as an alternative to the balloon described above, or, as a further alternative, the whiskers can be inside the balloon (for example, made of PVC, and used to "inflate" the balloon).

Figure 5 illustrates expandable whiskers made of an electroactive polymer implemented on the endoscopic capsule. An electroactive polymer is triggered by an electric signal. The whiskers are positioned along a surface of the capsule (see Fig. 5a) for convenient swallowing by a patient. Once the capsule is swallowed, a radio signal is received and created voltage of the opposite sign is applied at the point of voltage application; the whiskers extend out (changing their angular orientation) and control movement of the capsule (see Fig. 5b and Fig.6), so

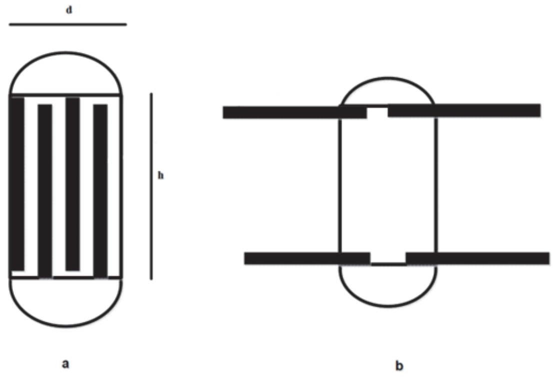

Figure 5: Expandable whiskers.

the moving stream of food does not take the capsule down the intestinal tract.

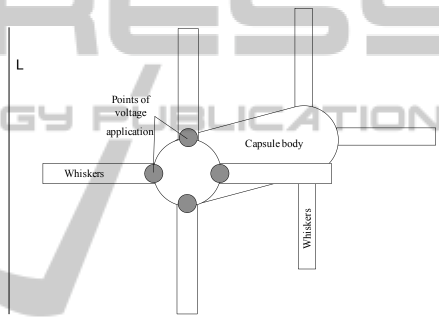

Figure 6: Expanded capsule.

The expanded capsule`s size L=d+2h≈3.5 cm (see Fig. 5a and Fig. 6).

Diameter of the small intestine does not exceed 3-5 cm and about 2.5-3 cm in ileum (Small intestine, 2009). It means that the proposed capsule can stop at any part of ileum and in some areas of jejunum as well as stay in the stomach for a long period of time (as the pylorus does not exceed 2-2.5 cm in diameter). At the same time the expanded endoscopic capsule can initiate peristalsis in case the capsule gets stuck in the intestine in order to continue the examination (R. de Francis, 2012).

The wireless endoscopic capsule uses eight extendable whiskers for movement control. However, an arbitrary number of whiskers can be used depending on desired retention of the capsule. Once all required images are taken, another radio signal is sent to the capsule and the voltage is terminated. Subsequently, the whiskers fold back to the original position depicted in Fig. 5a.

2.3 Experiments

While working on the development of the proposed wireless endoscopic capsule`s retention system the mock-up of the capsule with eight whiskers made of electroactive polymer has been created. In the initial state the capsule has the size of an ordinary pill – 13x29 mm; in the expanded state its size increases to 35x29 mm (as shown in Fig. 6).

The performance of the capsule was tested using a silicone model with sensitive sensors simulating the digestive tract of the person. The capsule was forced to change its size under influence of applied voltage (Fig. 7).

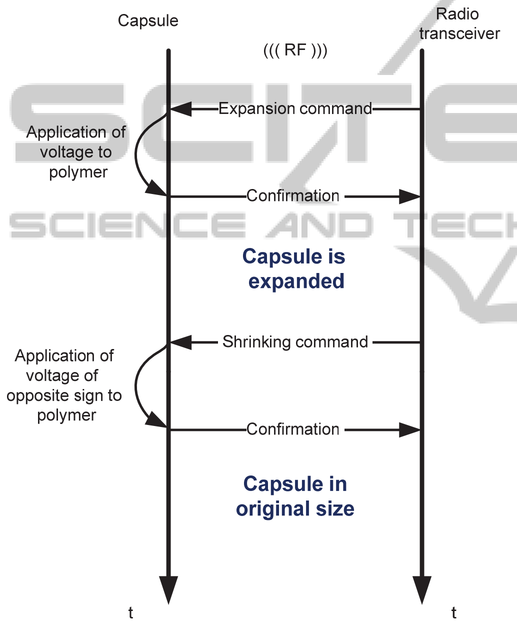

Figure 7: Experiment scheme.

50 out of 50 attempts have showed desired results.

These experiments showed that it takes on the average 3 seconds for capsule to expand and 5 seconds to take its original shape.

2.4 Reliability Expectations

The proposed wireless endoscopic capsule comprises three integrated circuits (light sensitive matrix, controller and transceiver) responsible for the execution of its functions. The circuits can be regarded as series-connected elements in the scheme of reliability calculation.

Mean time to failure of integrated circuits of average degree of integration is estimated at 300 000 hours without the presence of ionizing radiation and strong electromagnetic fields that do not occur under normal conditions in urban and rural areas.

The probability of failure-free operation is 0.99999000003 and the mean time to failure is 100 000 hours or 11.4 years.

The capsule recording device contains 31 (field programmable logic device, microcontroller, memory, and 14 sensors including microcontroller and the transceiver) microcircuits responsible for the execution of its functions. The microcircuits can be regarded as series-connected elements in the scheme of reliability calculation.

The probability of failure-free operation is 0.999897 and the mean time to failure is 9 678 hours or 1.1 years.

2.5 Capsule Options

Images acquired by the capsule can be processed using known in the industry methods. A gastroenterologist can review images in a real time and make a rapid diagnosis by reviewing a colour and a texture anomalies and pathologies of the form that correspond to a visual manifestation of the disease (Alexander Kukushkin, 2012; Kukushkin Alexander, 2013; Bourbakis, N., 2005). After the capsule remains inside a patient a certain amount of time, a three-dimensional image of the areas passed by the capsule can be generated and reviewed.

As a further clinical application, the electropolymer of the capsule can be used for dilatation of narrowed areas of the digestive tract (for example, due to scarring, infection, inflammation, and similar processes).

The capsule can be used to deliver a drug or active compound from a reservoir (Fig. 8), which is covered by a lid, formed of a memory metal, such as Nitinol.

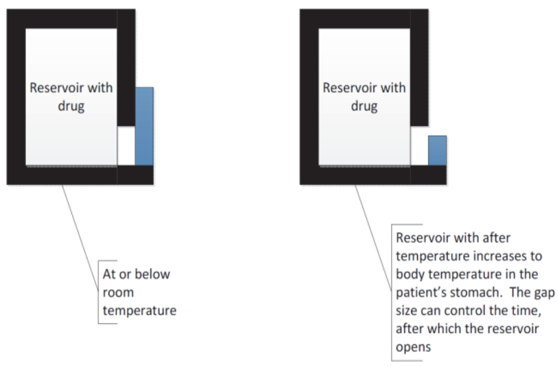

Figure 8: Drug delivery.

When heated to body temperature inside the patient's stomach, the lid opens (returns to its original shape), permitting the active compound to egress.

As a further option, the capsule can be provided with:

- a system for generating the trajectory that the capsule followed, such as by using a gyroscope and/or an accelerometer inside the capsule. The data from these sensors is sent to the external reader, together with the image data. This makes it easier to determine the location of the particular images taken by the capsule, making it easier to know where the particular problems are (and exactly where surgical intervention might be needed);
- a heating element, which is activated by an operator when the capsule is near a location where coagulation of blood leaking from cuts or wounds is occurring;
- two cameras, one for the "forward" direction, and one for the "backward" direction, which may be particularly useful for inspecting the intestine;
- additional sensors, such as a pH sensor (Stepanyan D.A., 2011), to determine acidity;
- a magnetic coil, which can be used to increase the resolution of magnetic resonance imaging. The coil can be located anywhere in the capsule, and can have arbitrary orientation.

The capsule of the present invention may be used for early diagnosis of various oncological diseases, particularly gastrointestinal cancers. For this purpose, fluorescent agents/beacons can be used. These beacons, which interact with cancerous cells, due to their chemistry, begin fluorescing at a wavelength in the visible, infrared and/or ultraviolet portions of the spectrum. This fluorescence permits diagnosing oncological diseases at an early stage (which typically does not have noticeable symptoms), without the use of a biopsy.

If the only purpose is to detect the existence of a cancerous tumour, there is no need to transmit video or image frames to a computer in real time. The processor on the capsule can, by itself, identify those frames that show fluorescence, based on the average brightness of the image, and transmit only those frames. This significantly lowers the time needed for analysis of the gastrointestinal tract using the capsule. For example, instead of 2-3 hours, the diagnosis can be made within 5-10 minutes, if oncological-related fluorescent activity is detected.

Also, there is no need for additional illumination sources in the capsule itself. This permits increasing the length of time of battery operation, since no energy needs to be used for illuminating the gastrointestinal tract.

3 CONCLUSIONS

This paper has been demonstrated the idea of creating a retention system of the wireless endoscopic capsule using the property of electroactive polymer to increase the size and change angular orientation under applied voltage. This ability of capsule to change the shape will allow gastroenterologists to carry out more detailed examination of patient`s digestive tract getting additional images of suspected areas.

The studies on further capsule construction, reliability and functionality improvements are underway. Although the proposed capsule has shown good results on the silicone model it is planned to be subjected to further field and lab studies and tests as well as clinical trials.

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