

A Spacer and a method of using the same

Field of the invention

- 5 The present invention is designed for use with a new generation gastrostomy tube and generally relates to a means of ensuring the feeding outlet remains in place within the stomach.

Background Information

- 10 Diseases sometimes leave their victims unable to feed orally. For these patients, a tube may be used to convey liquid food to the stomach.

- In those cases where the tube passes through a nostril, down the oesophagus, and into the stomach, it is known as a naso-gastric tube. When the tube passes to the stomach through the anterior abdominal wall of the patient, it is known as a gastrostomy tube. The gastrostomy tube is the preferred method when feeding via a tube is required for a long time by the patient.

- There are a few methods available to insert the gastrostomy tube into the patient. Of these, the pull-through percutaneous endoscopic gastrostomy (pull-through PEG) technique is the most-widely used over the past 30 years.

- A new generation gastrostomy tube is described in WO2009/048422. This tube is looped through two stomas in the patient's abdomen ensuring the gastrostomy tube bypasses the nose; is capable of insertion under local anaesthetic; is not easily pulled out of position; and is simple and easy to change regularly by anyone. To change to a new tube, all that is required is that the new tube be connected to the old tube with a connector, then the new tube is pulled through into the same position as the old tube, and the connector and the old tube are removed with very little trauma to the patient.

- The new generation gastrostomy tube 2 is illustrated in figure 1. The tube 2 has an opening 4 designed to allow food and medicines to enter the stomach. This opening 4 should remain within the stomach. One problem with this new

generation gastrostomy tube 2 is that as the stomach contracts and moves there is a risk that the opening 4 designed to allow food and medicines to enter the stomach may slip through the aperture in the stomach and be positioned between the abdominal wall and the stomach wall within the peritoneal cavity as depicted in figures 2 and 3. This may lead to serious complications during feeding and may lead to the death of the patient.

One way to overcome this problem is to stitch the stomach wall to the abdominal wall on the outside of the two stomas at A and B in figure 1.

However, this will be uncomfortable for the patient providing a source of further pain and aggravation and increasing the risk of infection and bleeding at the two stitch sites.

Summary of the Invention

It is an object of this invention to provide a means of ensuring the opening of the new generation gastrostomy tube remains in place within the stomach and may ameliorate some or all of the problems of prior art.

In accordance with a first aspect of the present invention there is provided a device for ensuring an opening of a gastrostomy tube remains in place within a stomach comprising a spacer not permanently affixed to the tube whereby the spacer is adapted to allow the tube to be changed percutaneously.

Such a device may be advantageous in that the spacer may trap the opening within the stomach such that food or medicine may only be released through the opening into the stomach and food or medicine may be prevented from escaping from the opening into the peritoneal cavity.

In a first embodiment the spacer may comprise a coil spring defining an aperture through the center of the coil such that the tube can move independently of the spacer when in use.

The device of the first embodiment may further include an individual coil of the spacer being in an extended configuration and being spaced apart from an adjacent coil.

The device of the first embodiment may further comprise flexible coils of the spacer.

Preferably the spacer of the first embodiment may be a Shore A Hardness of at least less than 100.

- 5 Preferably the spacer of the first embodiment may further comprise a flange at an end of the coil spring.

In a second embodiment the spacer may comprise a hollow sphere with an aperture formed through the sphere allowing a tube to pass through the aperture formed through the sphere.

- 10 Preferably the sphere of the second embodiment may have perforations on the surface of the sphere.

The device of the first or second embodiment may be made of polyurethane, silicone, or a biodegradable material such as a biodegradable polymer that will absorb within a time suitable for a stoma to mature.

- 15 In a third embodiment the spacer may comprise a biodegradable polymer that may be locked over the tube such that two sections of the tube loop through the spacer. Alternatively the spacer of the third embodiment may be anchored to the tube prior to use.

- 20 Preferably the biodegradable polymer of the invention may be absorbed within 3 to 6 months. More preferably the biodegradable polymer is a d-l copolymer blend of polylactide (DLPLA).

- 25 In accordance with another aspect of the present invention there is provided a method of ensuring an opening of a gastrostomy tube remains in place within a stomach comprising the steps of: placing a spacer over the tube; placing the tube with the spacer endoscopically into the stomach; forcing a first end of the tube through the stomach and abdominal wall at a first location; and forcing a second end of the tube through the stomach and abdominal wall at a second

location, whereby the spacer retains a physical length of the tube having the opening within the stomach.

Brief Description of the Drawings

5

The invention will be better understood by reference to the following drawings in which:

Figure 1 is an illustration of the prior art new generation gastrostomy tube in use.

10

Figure 2 is an illustration of the prior art new generation gastrostomy tube in use depicting the opening that is designed to deliver food and medicines to the stomach in the peritoneal cavity.

15

Figure 3 is an illustration of the prior art new generation gastrostomy tube in use depicting the opening that is designed to deliver food and medicines to the stomach in the peritoneal cavity.

20

Figure 4 is an illustration of the device according to the first embodiment of the invention in use.

Figure 5 is an illustration of the device according to the first embodiment of the invention.

25

Figure 6 is an illustration of the device according to the second embodiment of the invention in use.

Figure 7 is an illustration of the device according to the second embodiment of the invention.

30

Figure 8 is an illustration of the device according to the third embodiment of the invention in use.

Figure 9 is an illustration of the device according to the third embodiment of the invention.

- 5 **Figure 10** is an illustration of the device according to the third embodiment of the invention in use.

Detailed description of the preferred embodiments of the invention

The invention occupies space within the stomach and retains the physical length of the tube and the opening 4, designed to allow food and medicines to enter the stomach, to remain within the stomach. The spacer is not
10 permanently affixed to the tube. Thereby the tube can be moved independently of the spacer at the time the tube is due to be changed and as such can be changed percutaneously by anyone including caregivers.

The invention is designed for use with a new generation enteral feeding tube or new generation gastrostomy tube.
15

In accordance with the invention a device is provided for ensuring the opening of the new generation gastrostomy tube remains in place within the stomach comprising a spacer that is not permanently affixed to the tube. The spacer defines an aperture adapted to allow a tube to pass through the aperture
20 whereby the spacer forms a sheath or collar adapted to slide over and along the tube. The spacer has dimensions larger than each of the diameter of the two stomas in the stomach through which the new generation gastrostomy tube passes thereby trapping the device to remain within the stomach such that it cannot escape through the stomas.

25 The device of the invention will allow a wide range of tube sizes to pass through the aperture, provided the diameter of the spacer aperture is larger than the size of the tube the spacer can be used with that tube. For example a device designed to fit a 20 Fr tube can also be used with a 15 Fr sized tube or a 14 Fr sized tube, and in fact any tube size smaller than 20 Fr. Similarly a
30 device designed to fit a 24 Fr tube can also be used with a 20 Fr sized tube or a 15 Fr or 14 Fr sized tube in fact any tube size smaller than 24 Fr.

Referring to figures 4 and 5 in accordance with a first embodiment of a device for ensuring the opening of the new generation gastrostomy tube remains in place within the stomach comprises a spacer shaped like a helical coil spring 6a defining the aperture through the center of the coil such that the tube 2 can
5 move independently and freely of the spacer 6a. In its resting state, the individual coil or loop is in an extended configuration and is spaced apart from its neighboring coil or loop. At Shore A Hardness of about 50 to 75 units or at least less than 100, the spacer 6a of the first embodiment is flexible and floppy. The spacer may further have flanges at either end of the coil. As the
10 ends of the coil will abut against the gastric mucosa when in use, flanges may help to distribute pressure over a wider surface area of the gastric mucosa and reduce the risk of any trauma to the stomach lining.

The first embodiment may be made of polyurethane, or silicone, or a biodegradable material or any suitable material which can tolerate the acidic
15 environment of the stomach. Preferably any biodegradable material chosen will have a suitable rate of degradation to dissolve only after the stomas have fully matured and there is no risk of the midsection of the tube 2 where the opening 4 is located escaping into the peritoneal cavity. It is generally accepted by doctors that the stoma will mature in 4- 6 weeks. Hence,
20 preferably the biodegradable material chosen will absorb after 6 weeks or more.

To deploy the first embodiment the spacer 6a is slid over the tube 2 whereby the coil 6a forms a loose outer porous sheath over the tube. Then the tube 2, with the spacer 6a in place, is inserted into position within the stomach using
25 the pull through method of percutaneous endoscopic gastrostomy (PEG). A first end 3 of the tube 2 is forced through the stomach wall and through the abdomen forming a first stoma. A second end 5 of the tube 2 is forced through the stomach wall and through the abdomen forming a second stoma. The spacing between the coils of the spring gives an indication of the tension with
30 which the first 3 and second 5 end of the tube are tied or locked together. When in position within the stomach a caregiver may introduce fluids into the tube to flow through the tube 2 and exit from the opening 4, and pass between

the coil springs into the stomach. The spacer 6a ensures the opening 4 remains within the stomach such that food or medicine is only released through the opening 4 into the stomach and no food or medicine escapes from the opening 4 into the peritoneal cavity.

5 When the tube is changed it is done percutaneously not requiring endoscopy and as such can be changed by anyone including a caregiver. The old tube is untied or unlocked. A new tube is connected to the first end 3 or the second end 5 of the old tube. The old tube is pulled out by pulling the free end of the old tube, not connected to the new tube, thereby automatically guiding the
10 new tube into position. The old tube is then detached and the first 3 and second 5 end of the new tube are tied or locked together. The old and new tubes 2 are able to slide through the aperture formed in the spacer 6a as the coils forms a loose sheath over the tube such that the spacer 6a does not interfere with changing the tube 2.

15 Referring to figure 6 and 7 in accordance with a second embodiment of a device of the invention, the device comprises a spacer in the shape of a sphere 6b. Preferably the sphere 6b is hollow with a plurality of holes or perforations 7 formed on the surface of the sphere. An aperture is formed through the sphere 6b by the holes 7 adapted to allow a tube 2 to pass
20 through the aperture. Preferably more than one aperture is provided.

The second embodiment may be made of polyurethane, or silicone, or a biodegradable material or any suitable material which can tolerate the acidic environment of the stomach. Preferably any biodegradable material chosen will have a suitable rate of degradation to dissolve only after the stomas have
25 fully matured and there is no risk of the midsection of the tube 2 where the opening 4 is located escaping into the peritoneal cavity. It is generally accepted by doctors that the stoma will mature in 4- 6 weeks. Hence, preferably the biodegradable material chosen will absorb after 6 weeks or more.

30 When in use more than one sphere 6b may be strung over the tube 2. Preferably a plurality of spheres are used forming a chain or series. Typically,

the number of spheres 6b required is a matter of clinical judgement on the part of the doctor, taking the habitus of the patient, the distance between the stomas, and other factors into consideration. The tube 2 and the spacer 6b are initially inserted using the PEG method described above. As the spheres
5 6b are not affixed to the tube 2 the tube may be changed percutaneously as described above. The old and new tubes 2 are able to slide through the aperture formed in the spheres 6b as they are not affixed to the tube 2 such that the spacer 6b does not interfere with changing the tube 2. The spacer 6b or plurality of spacers 6b ensures the opening 4 remains within the stomach
10 such that food or medicine is only released through the opening 4 into the stomach and no food or medicine escapes from the opening 4 into the peritoneal cavity.

Referring to figures 8, 9 and 10 in accordance with a third embodiment of a device of the invention, the device comprises a spacer manufactured of
15 biodegradable material 6c.

Preferably one spacer 6c is used as depicted in figure 10. The one spacer 6c forms a lock over the tube 2 as the tube 2 is looped twice through the spacer 6c such that when the tube and the one spacer are initially put into the stomach via the PEG method described above the spacer 6c ensures the
20 opening 4 remains within the stomach such that food or medicine is only released through the opening 4 into the stomach and no food or medicine escapes from the opening 4 into the peritoneal cavity. Then as the stomas mature by the formation of a fibrous track securing the stomach wall to the abdominal wall the spacer 6c is absorbed into the stomach and the
25 spacer 6c no longer holds the tube 2 in the twice-looped configuration. When the stomas have matured, the tube 2 cannot migrate into the peritoneal cavity. Hence, the spacer 6c is designed to biodegrade after the stomas have matured at about 6 weeks. When the polymer is degraded, the tube can be changed without interference.

30 Similarly in figure 9, where at least two spacers 6c manufactured of biodegradable material are used the opening 4 adapted to allow food and medicine to enter the stomach is positioned between the two spacers 6c, and

cannot escape from the stomach. The two spacers are not permanently affixed to the tube 2 but are anchored to the segment of the tube in such a way that the spacers 6c are temporarily affixed to the tube but as they are made of biodegradable material the spacers 6c absorb over time allowing the tube to be changed percutateously without interference after the stomas have matured.

When in use the tube 2 and the at least two spacers 6c are initially inserted using the PEG method described above. As the spacers 6c biodegrade, when it is time to change the tube 2, the tube 2 may be changed percutaneously as described above. The at least two spacers 6c ensures the opening 4 remains within the stomach such that food or medicine is only released through the opening 4 into the stomach and no food or medicine escapes from the opening 4 into the peritoneal cavity.

Biodegradable material includes both natural and synthetic polymers that will dissolve over time. Such material should also be suitable for medical use.

Many biodegradable polymers are prepared from glycolic acid, lactic acid and other α -hydroxy acids. Suitable biodegradable material may include poly dioxanone poly trimethylene carbonate, poly ϵ - caprolactone homo polymers and copolymers, polyanhydrides, polyorthoesters, polyphosphazenes or any other suitable biodegradable material known to those skilled in the art.

Biodegradable polymers with a shorter degradation time may include polyglycolide (PGA) or the d-l copolymer blend of polylactide (DLPLA) or poly (dioxanone) (a polyester-ester) (PDS) or poly (lactide-co-glycolide) or any other biodegradable polymer known to absorb within 3 to 6 months.

Biodegradable polymer with a longer biodegradation time may include the l isomer of polylactide (LPLA) or poly (ϵ -caprolactone) or any other biodegradable polymer known to absorb within 1 to 2 years, or at least more than 6 months.

The matured stoma has a fibrous track that forms between the stomach wall and the abdominal wall, thereby securing the stomach wall to the abdominal wall. In such a circumstance tube migration cannot occur. Hence, the spacer

6c is no longer needed and is allowed to biodegrade when the stomas have matured.

In another embodiment, a combination of the first, second and/or third embodiment may be used. For example a combination of one sphere and 2 coils may be used. Alternatively, a combination of the at least two biodegradable spacer and a sphere may be employed. Alternatively, a combination of a coil spring and the at least two biodegradable spacer may be employed. Any combination which is deemed by the doctor to be appropriate for the patient may be used.

10 In surgical operations, tension is an important consideration. Too much tension can diminish blood supply and strangle the living tissues. The present invention provides endoscopic visual clues to the doctor regarding the tension in the system. In the first embodiment, the spacing between the coils of the spring has a relationship to the degree of tension placed on the system. 15 Similarly for the second embodiment, the hollow feature of the sphere ensures that the deformity of the sphere has a relationship to the degree of tension placed on the system.

The invention can be manufactured using techniques known in the art at relatively low cost.

20 In the situation a patient has recovered from his illness and the enteral feeding tube is no longer required the tube is removed percutaneously and the spacer is preferentially left in the stomach and allowed to pass spontaneously through the intestines and out via the anus. Alternatively, the spacer is left to biodegrade or be absorbed. Alternatively, the spacer may be 25 removed endoscopically via the mouth.

Throughout this document, unless otherwise indicated to the contrary, the terms "comprising", "consisting of", and the like, are to be construed as non-exhaustive, or in other words, as meaning "including, but not limited to".

Various embodiments and extra features are envisioned in relation to the present invention. They include:

30

- The invention can be modified for use in veterinary surgery.
- The spacer may be made radio-opaque to become visible on X-rays. In the situation where the tube is radio-translucent and the spacer is radio-opaque an estimation of the length of tubing within the stomach can be determined by taking an X-Ray.
- The spacer may be made of any size, provided it is larger than the stomas cut through the stomach wall and abdominal wall.
- The spacer may be any shape although preferably with smooth contours to minimize trauma to the stomach lining.
- The spacer can be used as an intussusceptum to lead a fine bore feeding tube into the small intestines.
- The spacer may contain one or more sensors able to transmit data on the use of the system or relating to the patient's health wirelessly to a microprocessor. For example a microprocessor at a nursing control station

Modifications and variations as would be apparent to a skilled addressee are deemed to be within the scope of the present invention.

I Claim:

1. A device for ensuring an opening of a gastrostomy tube remains in place within a stomach comprising a spacer not permanently affixed to the tube whereby the spacer is adapted to allow the tube to be changed percutaneously.
2. The device of claim 1 wherein the spacer comprises a coil spring defining an aperture through the center of the coil such that the tube can move independently of the spacer when in use.
3. The device of claim 2 wherein an individual coil of the spacer is in an extended configuration and is spaced apart from an adjacent coil.
4. The device of claim 2 or 3 wherein the coils are flexible.
5. The device of claim 4 wherein the spacer is a Shore A Hardness of at least less than 100.
6. The device of any one of claim 2 to 5 wherein the spacer further comprises a flange at an end of the coil spring.
7. The device of claim 1 wherein the spacer comprises a hollow sphere with an aperture formed through the sphere allowing a tube to pass through the aperture formed through the sphere.
8. The device of claim 7 wherein the surface of the sphere has perforations.
9. The device of any one of the preceding claims wherein the spacer is made of polyurethane.
10. The device of any one of claims 1 to 8 wherein the spacer is made of silicone.

11. The device of any one of claims 1 to 8 wherein the spacer is made of a biodegradable material polymer that will absorb within a time suitable for a stoma between the stomach wall and the abdominal wall to mature.

5 **12.** The device of claim 11 wherein the spacer is anchored to the tube prior to use.

13. The device of claim 1 wherein the spacer comprises a biodegradable polymer locked over the tube such that two sections of the tube loop through the spacer.

10 **14.** The device of any one of claims 11 to 13 wherein the biodegradable polymer is absorbed within 3 to 6 months.

15. The device of claim 14 wherein the biodegradable polymer is a d-l copolymer blend of polylactide (DLPLA).

15 **16.** A method of ensuring an opening of a gastrostomy tube remains in place within a stomach comprising the steps of:

- a. placing a spacer over the tube;
- b. placing the tube with the spacer endoscopically into the stomach;
- c. forcing a first end of the tube through the stomach and abdominal wall at a first location; and
- 20 d. forcing a second end of the tube through the stomach and abdominal wall at a second location,

whereby the spacer retains a physical length of the tube having the opening within the stomach.