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(54) Medical catheter, applications for tubefeeding and method of manufacture

(57) A catheter (1) for tube feeding comprising an elongated tube (2) having a lumen, a proximal end (3) and a distal end (4), said elongated tube (2) being provided with multiple distal holes (5), and a loop (6) provided

at the distal end (4), a kit comprising a conventional catheter (1) for tube feeding and suture material and a preparation process for manufacturing a catheter for tube feeding having a loop (6).

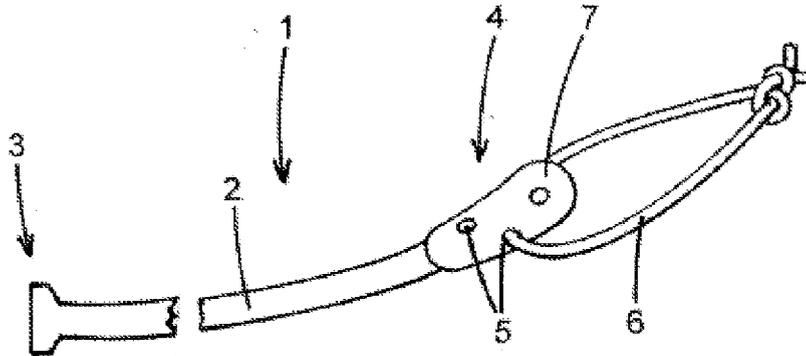


Fig. 1

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Description

[0001] The present invention relates to a medical catheter, its applications for tube-feeding and method of manufacture.

[0002] Nasogastric tubes are medical catheters inserted into the gastro intestinal tract to deliver substances directly into the stomach or into the duodenum, to remove substances from the stomach or as a means of testing stomach function or contents.

[0003] The most common aim for inserting a nasogastric tube into the gastro intestinal tract is to deliver tube feedings to a patient who is unable to eat. Patients who may need a nasogastric tube for feedings include patients in a coma, premature babies, and other patients. Tube-feeding allows providing directly into the lumen an elemental or semi-elemental liquid diet to patients who cannot eat normally. Said liquid diet is usually calories-rich and balanced in vitamins and trace elements and is therefore easily absorbed in the gastro-intestinal tract.

[0004] Other substances that are delivered through a nasogastric tube may include medications to neutralize swallowed poisons.

[0005] Another aim for inserting a nasogastric tube in the gastro intestinal tract is to remove substances from the stomach. A nasogastric tube is for example used to empty the stomach when accidental poisoning or drug overdose has occurred.

[0006] After use, the nasogastric tube is taken out of the body and discarded.

[0007] Nasogastric tubes are made of various materials, including polypropylene, latex, silicone, and polyurethane.

[0008] Nasogastric tubes are flexible tubing about 60 - 100 cm long with multiple drainage holes at the distal end. A simple nasogastric tube is the Levin tube, which has a single lumen and multiple distal holes ("eyes").

[0009] The catheter is usually pushed through a patient's nostril, past the pharynx and down the esophagus into a patient's stomach, or beyond the stomach into the duodenum. The upper gastrointestinal tract (gastric secretions and biliary-pancreatic) is therefore allowed to rest (gastric and biliary-pancreatic secretions). Because of this endoluminal provision of the diet, the use of a catheter ensures the trophicity of the gastrointestinal mucosa which is necessary for the defense the human body against infections.

[0010] Often, upon withdrawal of a guidewire which is inserted in the lumen of the tube for keeping straight the tube during its introduction by the mouth or the nose into the esophagus, the distal end takes the shape of a helix, like a basic corkscrew. The helix helps maintaining the catheter in place.

[0011] However the tubes usually easily go back into the stomach, either spontaneously or upon the withdrawal of the endoscope, when the catheter is placed with the help of an endoscope.

[0012] To prevent these disadvantages, it is often pro-

posed to secure the tubing with an adhesive tape. After correct positioning of the catheter has been obtained, the catheter is secured to the nose with a piece of plastic tape or a dressing to hold the catheter to the nose so that it will not slip in or out. It is necessary each time to stick the tape to different places of the nose or the face.

[0013] Although the use of an adhesive tape makes it possible to hold the catheter, the adhesive tape provides discomfort in addition to discomfort provided by the catheter. Research is therefore still going on into better tube feeding.

[0014] It is an object of the present invention to eliminate or at least to substantially mitigate said drawbacks of existing methods of tube feeding. It is a further object of the present invention to make minimal changes to existing catheters for tube feeding for minimizing costs.

[0015] Now the applicant has designed catheters which are efficient as regards fixation of the catheter to avoid slipping in or out. Furthermore the new catheters avoid using adhesive tapes for securing the device and are pretty similar to existing devices.

[0016] A subject of the present application is therefore a catheter for tube feeding comprising an elongated tube having a lumen, a proximal end and a distal end, said elongated tube being provided with multiple distal holes, characterized in that a loop is provided at the distal end.

[0017] The catheter may be integral and the multiple distal holes are therefore provided in the tube. Preferably the multiple distal holes are provided on a distal piece fixed at the distal end of the tube, made of the same or of a different material. The diameter of the distal piece is usually larger than the diameter of the tube.

[0018] The loop may be integral with the catheter. For example an above-mentioned distal piece is provided with the loop.

[0019] Preferably, the loop is a separate device. Therefore the choice of a specific material for the loop is independent of the material(s) of the catheter.

[0020] Under preferred conditions for implementing the invention, distal holes of a conventional catheter are used for fixation of a separate loop to the distal end of the catheter.

[0021] The loop may pass through specific distal holes which are not in fluid communication with the lumen of the catheter. However, more particularly a subject of the present invention is an above catheter wherein the loop passes through distal holes in fluid communication with the lumen of the catheter.

[0022] In other preferential conditions, the loop is a separate device and is essentially made of biodegradable (absorbable) material. For example the loop is made of thread conventionally used for surgical suture. In such a case the loop disintegrates within a few days. The nature and size of preferred loops are for example selected such as a loop disintegrates and releases the catheter for tube feeding between 2 and 10 days, preferably between 3 and 6 days after clamping. The section, particularly the diameter of the material used for manufacturing

the loop influences the time of release. It should be noted that the catheter may be released according to a second mechanism.

[0023] "Essentially made of biodegradable material" means that more than 80%, preferably more than 90%, most preferably more than 95% of the material of the loop is made of biodegradable material. In view of the result of releasing the catheter, the man skilled in the art however understands a similar result is obtained if the loop is essentially made of non-absorbable material but comprises a short piece of absorbable material.

[0024] Non-absorbable sutures are for example made of special silk or synthetics such as polypropylene, polyester or nylon. In such a case the time of release of the catheter

[0025] Absorbable suture materials include the catgut but synthetics such as polyglycolic acid, polylactic acid, polydioxanone, and caprolactone are preferred. They are broken down by different mechanisms including hydrolysis and proteolytic enzymatic degradation.

[0026] A loop made of absorbable suture material will hold the catheter long enough, but will disintegrate so that the catheter is released. It should be noted that the catheter may be released according to a second mechanism as will be explained thereafter.

[0027] A further object of the present invention is therefore a kit comprising a conventional catheter for tube feeding and suture material, (said suture material being usable for making a loop attached to the catheter by a distal hole). To this aim the suture material may be provided with a needle for helping passing through the holes. A needle also allows piercing the distal end of a catheter for providing further distal holes. The conventional catheter for tube feeding and the suture material are preferably sterile packed in the same sealed bag.

[0028] A subject of the invention is also a preparation process for manufacturing a catheter for tube feeding of the invention by a method comprising providing a distal end of a hollow catheter having distal holes with a loop.

[0029] The distal holes may be made by the manufacturer, but in preferential conditions of implementation of the invention, a conventional catheter for tube feeding having distal holes is used as starting material. Preferably, a conventional catheter for tube feeding having distal holes is used and a thread is passed through distal holes is closed to form a loop.

[0030] In other preferential conditions of implementation of the invention, absorbable suture material is used for manufacturing the loop.

[0031] In still other preferential conditions of implementation of the invention, a distal piece provided with a loop is fixed to a catheter for tube feeding. Preferably the loop is not integral with the distal piece.

[0032] A catheter for tube feeding according to the invention can be used as follows.

[0033] A first general way consists in conventionally pushing the catheter through a patient's nostril, past the pharynx and down the oesophagus into a patient's stom-

ach, or beyond the stomach into the duodenum for setting the distal end of the catheter at the desired place. A guidewire inserted into a lumen of the catheter may be used. Using an endoscope, a conventional clip (also named endoclip or hemoclip) used for example for haemostasis is provided via the operating lumen of the endoscope such that the loop is placed between the jaws of the clip. The clip is then allowed to close and grasp the gastrointestinal mucosa, thus attaching the catheter to the stomach or intestine. For example a Resolution clip ® of Boston Scientific, USA, 235cm long is used through a 2,8mm diameter operating channel of an endoscope.

[0034] Hemoclips are available in multiple sizes and generally can be rotated or reopened while being deployed through an endoscope. Hemoclips are for example produced as disposable hemoclips by Olympus Corp. (QuickClip2® for example) or Boston Scientific Inc. (Resolution clip 235cm long for example) Their maximum opening width is usually 7-15 mm, preferably 8-12 mm.

[0035] A second general way consists in pushing the catheter and the endoscope simultaneously. To this aim, a clip is passed through the channel of the endoscope unto the distal end of the endoscope such that the jaws of the clip extend open at the said distal end. The loop is placed between the jaws of the clip. The catheter and the endoscope are therefore allowed to simultaneously be pushed into the gastro intestinal tract to reach the place where the loop and therefore the catheter are to be attached. As above, the clip is then allowed to close and grasp the gastrointestinal mucosa, thus attaching the catheter to the stomach or intestine. With the view of drawing the catheter, the clip is preferably closed during the progression of the devices in the gastro intestinal tract and reopened for later attachment to part of the gastrointestinal mucosa.

[0036] The clip spontaneously drops within a few days, and is removed by natural means with the feces in the following days. Necrosis of the gastrointestinal mucosa happens at the place of attachment of the clip and the clip drops. This is the sole mechanism of release of the catheter if a non-absorbable suture is used. If an absorbable suture material is used, the time of release will be determined by the mechanism providing the quickest release.

[0037] The use of a clip, passed in the channel of an endoscope, facilitates installation of the catheter, without requiring X-ray apparatus.

[0038] A further object of the present invention is therefore a kit comprising

- a catheter for tube feeding provided with a loop according to the invention,
- a clip with a size suitable for introduction in an operating lumen of a gastro intestinal endoscope.

[0039] Also a further object of the present invention is a kit comprising

- a conventional catheter for tube feeding provided with distal holes,
- suture material, (said suture material being usable for making a loop attached to the catheter by a distal hole),
- a clip with a size suitable for introduction in an operating lumen of a gastro intestinal endoscope.

[0040] After use, the nasogastric tube is taken out of the body and discarded. This is why the catheter must be released. Accordingly, the released is provided either by necrosis of the mucosa at the place where the clip is attached, or because the loop breaks, because it is all or partly made of absorbable material or equivalent.

[0041] Another object of the present invention is a method for preparing a patient for tube feeding comprising

- providing a catheter for tube feeding provided with a loop according to the invention
- attaching the catheter to part of the gastrointestinal mucosa of a patient by the loop.

[0042] Under preferred conditions for implementing the method, the loop is attached to part of the gastrointestinal mucosa by a clip. The maximum opening width of a clip used is preferably 7-15 mm, particularly 8-12 mm.

[0043] Of course the catheters and the components of the kits for tube feeding of the invention are preferably sterile before human or veterinary use.

[0044] It should be noted that in the present application, in a standard fashion the indefinite article "a" must be considered as a generic plural (meaning "at least one" or also "one or more"), except when the context indicates the contrary (1 or "one only"). Thus, for example, when the specification provides that a catheter for tube feeding is provided with a loop, this refers to the provision of one or more loops.

[0045] Preferred conditions for implementing the catheter for tube feeding of the invention described above also apply to the other subjects of the invention including their process of manufacture.

[0046] The following examples illustrate the present invention.

FIG. 1, 2 and 3 represent a catheter for tube feeding of the invention seen from above.

Figure 4 is an elevation view of a clip (also named endoclip or hemoclip) used for haemostasis.

Figure 5 is an elevation view of a hemoclip deployed through an endoscope

Figure 6 represents a catheter for tube feeding of the invention fixed to a gastro intestinal mucosa.

[0047] Figure 1 represents a catheter 1 for tube feeding comprising an elongated tube 2 having a proximal end 3 and a distal end 4. Said elongated tube 2 is provided with a lumen and multiple distal holes 5. A loop 6 made of

biodegradable thread for surgical suture is provided at the distal end. The multiple distal holes 5 are provided on a distal piece 7 fixed at the distal end 4 of the tube. The diameter of the distal piece is larger than the diameter of the tube. A conventional catheter 1 for tube feeding has been used and provided with the loop 6 by a surgeon.

[0048] Figure 2 represents a similar catheter 1 for tube feeding wherein the catheter 1 is integral at the distal end 4 and the multiple distal holes 5 are therefore provided in the tube 2.

[0049] Figure 3 represents a similar catheter 1 for tube feeding wherein the loop 6 is integral with the catheter. a distal piece 7 is provided with the loop.

[0050] Figure 4 is an elevation view of a clip 10 (also named endoclip or hemoclip) used for haemostasis. The jaws 11 of the clip 10 are represented open.

[0051] Figure 5 is an elevation view of a hemoclip 10 deployed through an endoscope 11. The hemoclip 10 has been introduced via the operating lumen of the endoscope 11 and gets out of the distal end 12 of the endoscope 11.

[0052] The loop 6 may be placed between the jaws of the clip 10. The clip 10 may then be allowed to close and grasp the gastrointestinal mucosa, thus attaching the catheter 1 to the stomach or intestine. During introduction of the catheter 1, the hemoclip 10 may be closed on the loop, and then reopened to bite and grasp the gastrointestinal mucosa.

[0053] Figure 6 represents a catheter 1 for tube feeding of the invention fixed to a gastro intestinal mucosa 13. The jaws 11 of the clip 10 are closed and grasp the gastro intestinal mucosa 13. Therefore the catheter 1 is attached to the gastro intestinal mucosa 13 using the loop 6 and the hemoclip 10.

Claims

1. A catheter (1) for tube feeding comprising an elongated tube (2) having a lumen, a proximal end (3) and a distal end (4), said elongated tube (2) being provided with multiple distal holes (5), **characterized in that** a loop (6) is provided at the distal end (4).
2. A catheter for tube feeding according to claim 1, **characterized in that** the multiple distal holes are provided on a distal piece (7) fixed at the distal end of the tube.
3. A catheter for tube feeding according to one of claims 1 and 2, **characterized in that** the loop (6) is not integral with the tube (2) or with a distal piece (7) fixed at the distal end (4) of the tube, but is a separate piece.
4. A catheter for tube feeding according to one of claims 1 to 3, **characterized in that** distal holes (5) of a conventional catheter are used for fixation of a sep-

arate loop (6) to the distal end (4) of the catheter.

5. A catheter for tube feeding according to one of claims 1 to 4, **characterized in that** the loop (6) passes through distal holes (5) in fluid communication with the lumen of the catheter. 5

6. A catheter for tube feeding according to one of claims 1 to 5, **characterized in that** the loop (6) is a separate piece and is essentially made of biodegradable material. 10

7. A kit comprising a conventional catheter (1) for tube feeding and suture material. 15

8. A kit comprising
 - a catheter for tube feeding of one of claims 1 to 7,
 - a clip with a size suitable for introduction in an operating lumen of a gastro intestinal endoscope. 20

9. A kit comprising 25
 - a conventional catheter for tube feeding provided with distal holes,
 - suture material,
 - a clip with a size suitable for introduction in an operating lumen of a gastro intestinal endoscope. 30

10. A preparation process for manufacturing a catheter for tube feeding of one of claims 1 to 7 by a method comprising providing a distal end (4) of a hollow catheter having distal holes (5) with a loop (6). 35

11. A preparation process according to claim 10, **characterized in that** a conventional catheter for tube feeding having distal holes (5) is used as starting material. 40

12. A preparation process according to claim 10 or 11, **characterized in that** a conventional catheter for tube feeding having distal holes (5) is used and a suture material is passed through distal holes (5) and closed to form a loop (6). 45

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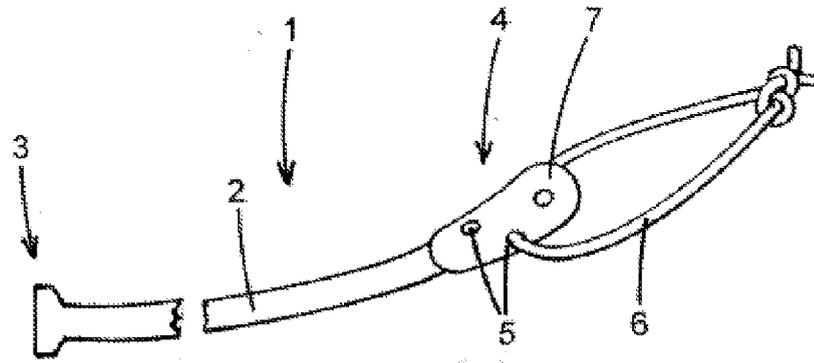


Fig. 1

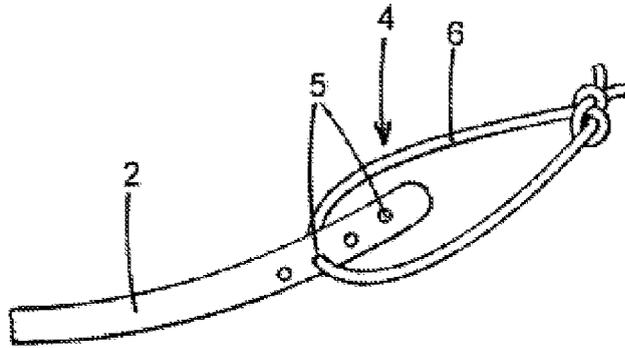


Fig. 2

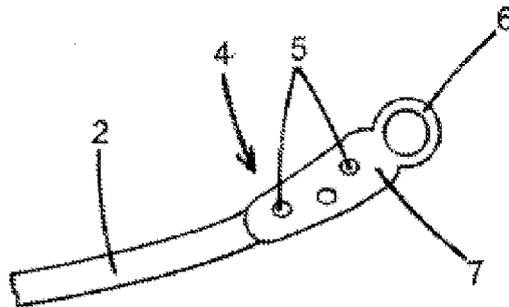


Fig. 3

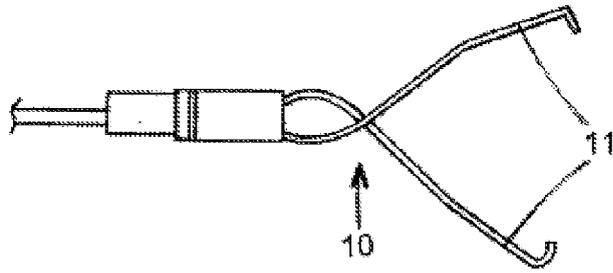


Fig. 4

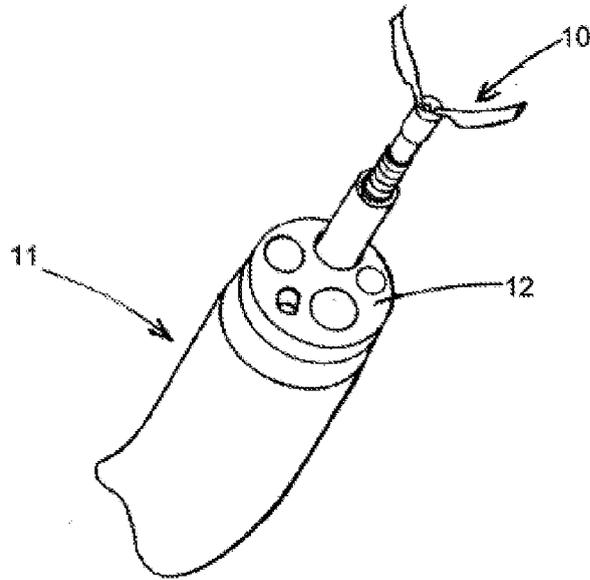


Fig. 5

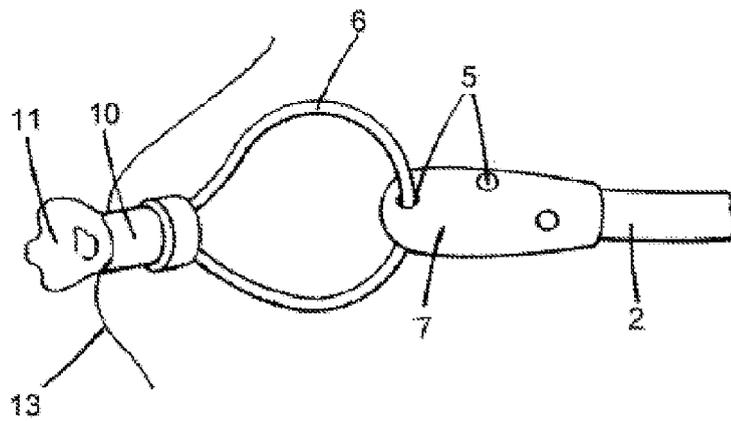


Fig. 6



EUROPEAN SEARCH REPORT

Application Number
EP 11 30 5332

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	CHUNG-JEN WU ET AL: "Clinical application of clip-assisted endoscopic method for nasoenteric feeding in patients with gastroparesis and gastroesophageal wounds.", WORLD JOURNAL OF GASTROENTEROLOGY, vol. 11, no. 24, 1 June 2005 (2005-06-01), pages 3714-3718, XP55004471, ISSN: 1007-9327 * figures 1,3 * * page 3715 *	1-12	INV. A61J15/00
X	SHIE CB: "Clip-assisted endoscopic method for placement of a nasoenteric feeding tube into the distal duodenum", JOURNAL OF THE FORMOSAN MEDICAL ASSOCIATION, EXCERPTA MEDICA ASIA, HONG KONG, HK, vol. 102, no. 7, 1 July 2003 (2003-07-01), pages 514-516, XP008140854, ISSN: 0929-6646 * the whole document *	1-12	TECHNICAL FIELDS SEARCHED (IPC) A61J
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 15 August 2011	Examiner Edlauer, Martin
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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