

Consideration of an alternative design for a Percutaneous Endoscopic Gastrostomy Tube

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OBJECTIVE:

This investigation proposes an alternative percutaneous endoscopic gastrostomy feeding tube design with optimized materials selection to be used for its construction. The candidate materials were chosen from 18 commercial catheters and 2 reference grade polymers, using tissue-catheter-friction testing and surface chemistry characterization (Infrared spectroscopy and Critical surface tension approximation). The main characteristics considered were slipping/dislodgement of gastrostomy tube/seal & subsequent peristomal leakage, and size versatility. Optimum manufacturing and sterilizing processes are sought for the new conceptual design.

1. INTRODUCTION:

WHO uses these [1]?

→The inability of certain persons to chew or swallow food s(but can digest them) leads to malnourishment and decline in the quality of life. Some of the indications include

- ✓ Oesophageal or oropharyngeal cancer
- ✓ Neurological diseases
- ✓ Injuries
- ✓ Physiological disorders

HOW is this treated?

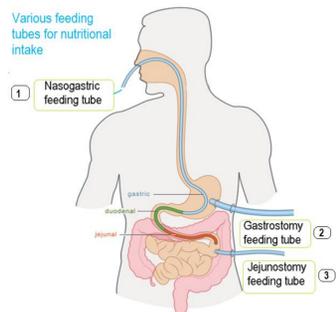


Figure 1: Food is directly injected/infused into different locations through various feeding tubes: 1) Nasogastric feeding tube, 2) Gastrostomy feeding tube and 3) Jejunostomy feeding tube based on mode and location of tube placements [2,3].

Percutaneous Endoscopic Gastrostomy(PEG) feeding tubes

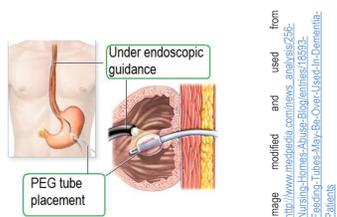


Figure 2: Percutaneous Endoscopic Gastrostomy feeding tubes are Gastrostomy feeding tubes placed/inserted with the aid of an endoscopic visualization

Surgical Procedures: 'Push' and the 'Pull' techniques

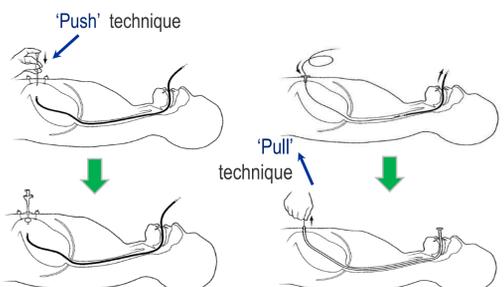


Figure 3: 'Push' technique is a simple process involving a 'push-through-puncture' at the surgical sight and the tightening of the seal [4]

Figure 4: 'Pull' technique is a more complex procedure, first using a guide wire insertion through the stomach followed by a 'snatch and pull' of the feeding tube through the patients' mouth[4]

State of the art devices:



Figure 5: Kimberly-Clark MIC-key Low Profile Gastrostomy feeding tube



Figure 6: AMT Non-Balloon Mini-One button

Complications [5]:

| Table 1: Reported Complications | |
|--|--|
| Variable length and diameter (sought by surgeons and caregivers)** (a) | Stomal & external leakage** (b) , (c) &(d) |
| Tube migration and subsequent intestinal obstruction | Granulation tissue |
| Dislodgement of tube/seal** (b), (c) & (d) | Stomal infections |
| Tube clogging | Pressure necrosis |
| Tube degradation | Skin or gastric ulceration |
| Buried bumper syndrome | |

**→ Pursued in this investigation

MATERIALS:

- 18 commercial catheters and 2 Reference grade polymeric tubings were evaluated
- Freshly cut beef tripe was used to replicate soft tissues in the human stomach

METHODS:

(a) My conceptual design



Figure 7: SolidWorks rendition of the conceptual design addresses 'variable length' feature



Figure 8: Prototype from the conceptual design, complete with the Silicone flange (2.5 :1 scale)

b) Estimation of tissue holding force against catheter/tubing simulating slipping/dislodgement of tube:

Objective→ To determine the various Coefficient of Friction (CoF) values corresponding to the holding force between the tissue and the catheter/tube surfaces

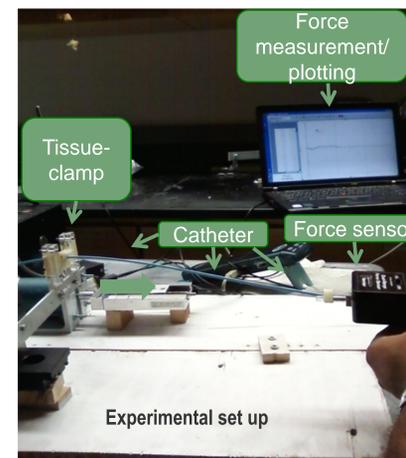


Figure 9 : Experimental set up for simulating catheter /tube dislodgement / slipping and estimating Coefficient of friction between catheter/tube and tripe tissue

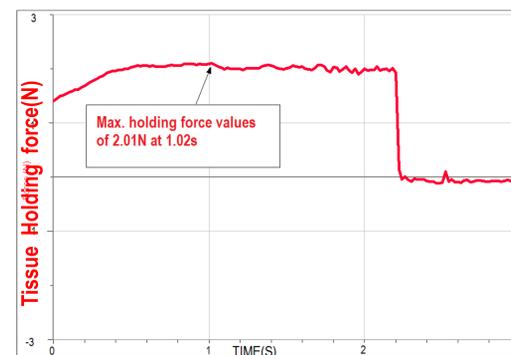


Figure 10: Representative Tissue Holding Force (N) versus time(s) plot of a catheter N2 (Polyethylene material with some surface oxidation and silicone coating/contamination)

(c) Infrared Spectroscopic analysis:

Objective→ Approximate the bulk materials and/or any additional surface coatings or contaminations on the catheter/tube samples.

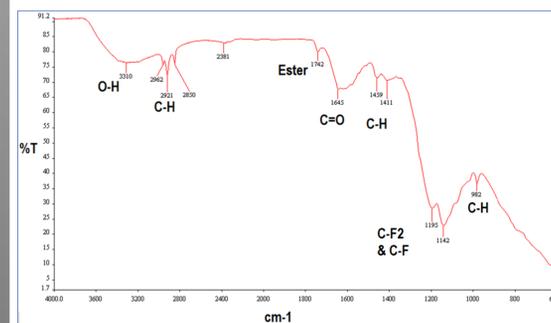


Figure 11: Representative Infrared spectrum of Catheter N2 which has been through tissue - consists of a Polytetrafluoroethylene material with some presence of fatty ester and matrix material

d) Contact angles measurement and analysis:

Objective→ To determine any correlation between Coefficient of Friction and Contact angle data through various interpretations

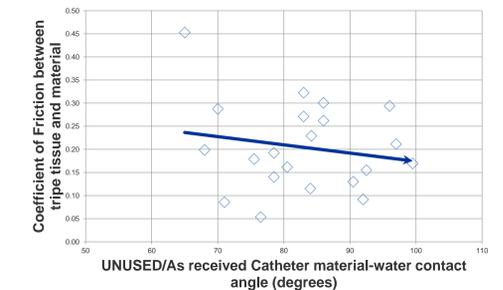


Figure 12: Coefficient of Friction versus contact angle of the material with water. Trend line suggests decreasing coefficient of friction with increasing water contact angle

4. RESULTS and DISCUSSIONS:

- Traditional Nylon with an yet undetermined filler material and Reference grade Polyethylene have been found to have higher holding force/coefficient of friction with tripe tissue
- Most of the catheters had a critical surface tension between 20-30 dynes/cm. However, Coefficient of Friction was found to be a weakly increasing function of Critical Surface Tension
- Coefficient of friction decreased with increasing water contact angle with surface

5. CONCLUSION

The optimum materials of construction are Nylon with an undetermined(as yet) filler material or/and Reference grade Polyethylene to minimize slipping/dislodgement of gastrostomy tube/seal & subsequent peristomal leakage. Fused Deposit Moulding/ 3-D printing are sought for manufacturing of the product. Radio Frequency Glow Discharge Treatment (RFGDT) is proposed as a sterilizing technique.

6. FUTURE WORK:

- Determination of any variance in the performance of the materials after Radio Frequency Glow Discharge Treatment
- To carry out pilot Finite Element Analysis of the biomechanics involved in the dislodgement of the considered designs
- Seek Scanning Electron Microscopy for determining unknown filler/opacifier materials in the sample
- Final prototype through Fused Deposit Moulding/3-D printing
- Extend and compare the investigation to commercial feeding tubes

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