Clinical Interview with Jen Lodge

Date: 9/12/2014 **Time:** 15:00-16:00 **Present:** A. Neville, S. King, P. Culmer

Jen Lodge, a Clinical Nurse Specialist in Bowel Health, was visited at Yeadon Health Centre. An hour was spent discussing the clinical needs in faecal incontinence (FI), primarily from an assessment and patient rehabilitation perspective.

The 'Renew' anal seal system

Discussion began around a new device, the 'Renew' Anal Seal. This is essentially an anal plug designed to prevent leakage of fluid from the anal canal and improve continence.

The Renew system is single-use and inserted by the patient into the rectum, as shown in the figure to the right. It appears to be manufactured by Renew Medical, covered by several patents (Ferguson and Gil, 2009; Shalon and Kotlizky, 2013) and discussed in a good review paper on the assessment and treatment of faecal incontinence in woman (Meyer and Richter, 2014).

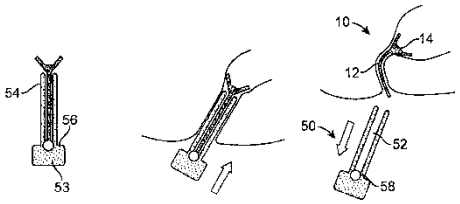

FIG. 4A FIG. 4B FIG. 4C

Potential difficulties with the current system were highlighted; essentially the system is 'one size fits all' and there is no accommodation for different patient needs, sizes, etc. There may be potential in patient specific, or a family of devices. This would need to be explored in more depth – particularly for clinical need and ability to work with existing patents in the area.

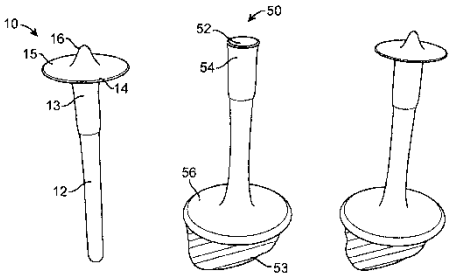

FIG. 5A FIG. 5B FIG. 5C

Biofeedback

Biofeedback systems are widely used by Nursing Specialists. They help assess patient function (ability to control pelvic floor and sphincter muscles to exert pressure and maintain voluntary continence – need to doublecheck exactly the mechanism here). The biofeedback systems use a combination of measurements from EMG pads (placement by the perineum) and an anal pressure probe. They are used in outpatient clinics by nursing staff and favoured for their simplicity and measurement reliability. The systems also play a useful role in patient feedback – enabling patients to see improvement in function due to rehabilitation exercises (or alt. interventions), providing a motivating factor to encourage further practise.

Some interesting issues were raised:

-It is unclear what the best treatment plan is with these systems – an area Jen Lodge is currently researching (i.e. 6 weekly meetings over 12 months vs weekly meetings for 6 weeks). Could we support this study in any way?
-Home use systems are available (~£150-400) using similar technology. These have the potential to provide improved information to inform treatment and motivate the patient. Currently it's unclear what the barriers to this are. To be followed up.
-The software interface used to record and monitor biofeedback systems is highly system-specific and when these are changed it becomes difficult to transition to new systems (and presumably maintain/compare records). Possible opportunities here for data management systems, telehealth etc., through HTC links?

Rehabilitation Exercise Guidance and Monitoring

Rehabilitation nurses prescribe exercises (e.g. pelvic floor) for patients to follow, often used in conjunction with biofeedback systems to monitor performance. However, it is difficult for the nurses to monitor compliance to these exercises. It may also be difficult for patients to fit these exercises into their daily life; i.e. remembering when, how and how often to do exercises.

There is potential for a smartphone based 'app' which could help patients

- Provide regular reminders about exercises
- Provide guidance on how best to do the exercises.
- Help count 'reps' and time spent exercising
- Possibility to integrate with sensors for home-use (e.g. pressure probes)
- Potential for alt. sensors that are more easily placed than anal probes (e.g. EMG on stomach wall)
- Collate data for collection and monitoring of long-term recovery etc

Manual Bowel Evacuation

A key issue that was identified was manual evacuation of the bowel. This is required in patient populations paralysed below the waist. Spinal injuries below L1 result in a 'flaccid bowel'. There is no involuntary reflex or voluntary control and this requires manual evacuation. Injuries above L1 (between S2-4) can produce a 'reflex bowel' – the patient loses the inhibitory reflex and defecation is impaired (relies upon involuntary reflex). It's a highly prevalent condition (est. ~500 in Leeds area). Similar effects also occur in those with Stroke or MS.

A tool is needed to help these people safely evacuate their bowel and maintain hygiene. The Buckingham Bottom Wiper [1] is commercially available and used by the nursing teams to help maintain hygiene.

Clinical Need: There is no system to help bowel evacuation. Such a system would need to be soft, dextrous, and 'hooked' to remove faeces from the bowel. It should do this without causing trauma to the delicate structure of the bowel.

Opportunity: This looks an ideal candidate for a soft robotic system with self-sensing to prevent tissue trauma.

Potential Links

Spinal Association, Manfred Sauer (a company developing products specifically for Spinal Cord patients)

References

Ferguson, J.W., Gil, C.E., 2009. Apparatus and method for managing incontinence. US7553273 B2.

Meyer, I., Richter, H.E., 2014. An Evidence-Based Approach to the Evaluation, Diagnostic Assessment and Treatment of Fecal Incontinence in Women. Curr. Obstet. Gynecol. Rep. 3, 155–164. doi:10.1007/s13669-014-0085-8

Shalon, T., Kotlizky, G., 2013. Fecal incontinence device, system and method. US8444546 B2.

[1] www.nrs-uk.co.uk/buckingham-easywipe-bottom-wiper.html