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# The Renew® anal insert for passive faecal incontinence: a retrospective audit of our use of a novel device

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## Abstract

**Aim** The Renew® anal insert is a recent treatment for patients who suffer from passive faecal incontinence (FI). Our aim was to assess the effectiveness of the insert and patients' satisfaction with it.

**Method** A retrospective audit of patients who were treated with the Renew® anal insert was undertaken. The St Mark's Incontinence Score was used to evaluate clinical outcome. Renew® size, the number of inserts used per day and per week had also been recorded. Subjective assessment of symptoms, how beneficial Renew® was and how satisfied patients were with the device were all recorded. Major events and side effects were also noted.

**Results** Thirty patients received Renew® as a treatment for passive incontinence in 2016. The median St Mark's Incontinence Score was 15 (range 7–18) at baseline and 10 (range 2–18) at first follow-up ($P < 0.0001$) at a median of 11 (range 8–14) weeks. Eleven (37%) patients used the regular size and 19 (63%) the large size. Patients used an average of 1.67 inserts per day (range 1–3) on an average of 3.58 days per week (1–7). Three patients reported a deterioration in symptoms, seven (23%) had no change and 20 (67%) showed a significant improvement. Six patients (20%) did not like the device while 24 (80%) liked it. Seventeen patients (57%) wanted to continue this treatment in the long term.

**Conclusion** The Renew® device seems to be an acceptable and effective therapeutic option for passive FI. Further work is needed to compare it with other treatments and establish its position in the treatment pathway.

**Keywords** Faecal incontinence, Renew® anal insert, anal plug, bowel leakage

**What does this paper add to the literature?**
To our knowledge, this is the first noncommercially funded paper to show efficacy of the Renew® anal insert. This newer device can be used to treat patients who suffer from passive faecal incontinence. The device seems to be safe and accepted by patients. Although this is an audit with its limitations, the nontrial nature of this study perhaps reflects 'real life' clinical practice.

## Introduction

Faecal incontinence (FI) can be a distressing and embarrassing problem which may have a significant impact on quality of life [1]. It can have an overwhelming impact on self-esteem and may lead to social isolation. Incontinence affects over 200 million people worldwide [2,3]. The reported prevalence of bowel incontinence varies from 1.4% in the general population to 46% in the institutionalized elderly [4]. The embarrassment and the social stigma attached to this condition lead patients to withdraw from their social life and may make them hesitate to seek help. There is likely to be under-reporting and it is possible that the real prevalence of FI is even higher.

Both conservative and surgical treatments are available, but most surgical treatments do not withstand the test of time [1,5,6]. Conservative management should be offered first [7–10]; this ranges from dietary modification and anti-diarrhoeal medication to bowel retraining and biofeedback. Management can be tailored to reflect the individual patient's health, general morbidity, severity and type of FI [5,11].

The Renew® anal insert (Renew Medical Inc., Menlo Park, California, USA) is a recently developed

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noninvasive therapy for FI [12]. It is a single-use anal device (Fig. 1) that is to be used continuously with the aim of managing the symptoms of passive FI. The device can be inserted by the patient with a fingertip applicator. It is made from soft, supple silicone that adapts to the patient's anal contours. It is available in two sizes, regular and large. Patients are normally advised to start with the regular size and if this falls out too easily then they should try the larger size. Renew® costs £2.60 per insert and is available on prescription on the National Health Service (NHS) in England. The prescription charge for patients in England is £8.80 per item but these charges do not apply to adults aged 60 or over, those aged 16–18 and in full-time education, pregnant women or those who have had a baby in the previous 12 months, those on certain income supports or those with a medical exemption certificate.

The older anal plug devices [13,14] have failed to gain popularity due to poor patient acceptability, despite an improvement in symptoms in those who persisted with the devices [15]. Our hypothesis is that Renew®, which is much more malleable than other anal plugs, may readily be accepted by patients and therefore prove to be an effective treatment for faecal leakage.

**Figure 1** The Renew® anal insert and its applicator.

The aim of this audit was to determine the acceptability of the Renew® anal insert and its efficacy for those with passive FI.

## Method

The study was registered with the local research and audit department (Audit Registration no. SUR.St.M.18.001, London North West University Healthcare NHS Trust) as an audit of service evaluation**.** All patients prescribed the Renew® device between January 2016 and January 2017 for passive FI were identified in the St Mark's Biofeedback Database. Patients were offered Renew® to try when they were deemed suitable by clinicians. A retrospective case note review of the identified patients was undertaken to identify outcomes of interest.

Patient demographics such as age, gender, parity and prior surgery were collected. The St Mark's Incontinence Score [16] was recorded at baseline and at the first regular clinic follow-up after a period of Renew® anal insert therapy. As this was a new treatment we had recorded the size of the insert preferred by the patient (regular or large), how many Renew® inserts were used per day, how many days of the week they were being used and if patients used other products together with this device. Also, a subjective assessment of symptoms, how beneficial the inserts were and how satisfied patients were with Renew® were all recorded to understand the efficacy and acceptability of the product. Satisfaction was assessed retrospectively from information in the medical records. Sentences such as 'patient was extremely satisfied' or 'patient did not like this treatment' were recorded. This was available for all patients as this was a new device. Major events and side effects had also been noted.

Raw values are expressed as median and range. Statistical analysis was performed using a Wilcoxon sign rank test in SPSS (2018, v.24, IBM, Armonk, New York, USA). All data for patients who received Renew® during the audit period were analysed on an intention to treat approach.

## Results

Between January 2016 and January 2017, 30 patients (24 women, median age 59.5 years, range 29–85) received Renew® as a treatment for their symptoms of passive FI. Twenty-one of the 24 women were parous and 8 of the 30 patients had a history of anorectal surgery. All received a starter pack which allowed them to try both sizes (regular and large). All had failed to improve significantly with first-line conservative treatment including biofeedback. The median follow-up was 11 weeks (range 8–14).

The median St Mark's Incontinence Score at baseline was 15 (7–18) and at the first clinic follow-up this had improved to 10 (2–18). Statistical analysis demonstrated a significant difference between pre- and posttreatment scores ($P$-value < 0.0001; Fig. 2).

Eleven (37%) patients used the regular size and 19 (63%) used the large size insert. An average of 1.67 (range 1–3) inserts were used per day. Patients used the insert for an average of 3.58 (1–7) days per week. Of the 30 patients, 18 (60%) continued to use a pad or sanitary towel for protection from bowel leakage, while 12 (40%) used only Renew®.

When reviewing the acceptability of the insert to patients, three (10%) had reported a slight deterioration in symptoms, seven (23%) reported no difference and 20 (67%) reported an improvement (Fig. 3).

All but four (13%) patients were still using the insert at the time of follow-up [median follow-up was 11 weeks (range 8–14)]. These four patients had experienced mild pain/discomfort and had stopped the treatment a few days after onset of symptoms. Of this group, one patient also had some fresh rectal bleeding. The details of the use of Renew® by each patient are presented in Table 1 by the number of days used per week and the number inserted per day.

In terms of satisfaction, six patients (20%) had said they did not like the Renew® insert, while 24 (80%) liked it. Of this group, four patients (13%) stated that Renew® did not work as expected (Fig. 3).

Of the 30 patients, 11 (37%) stated that Renew® tended to fall out easily, even using the larger size. Three patients (10%) found insertion difficult. Data are summarized in Table 1.

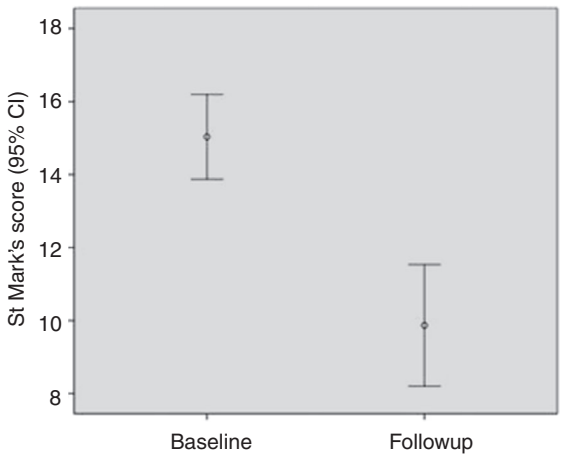


**Figure 2** St Mark's score at baseline and at the first clinic follow-up. The difference was statistically significant ($P$ < 0.0001).

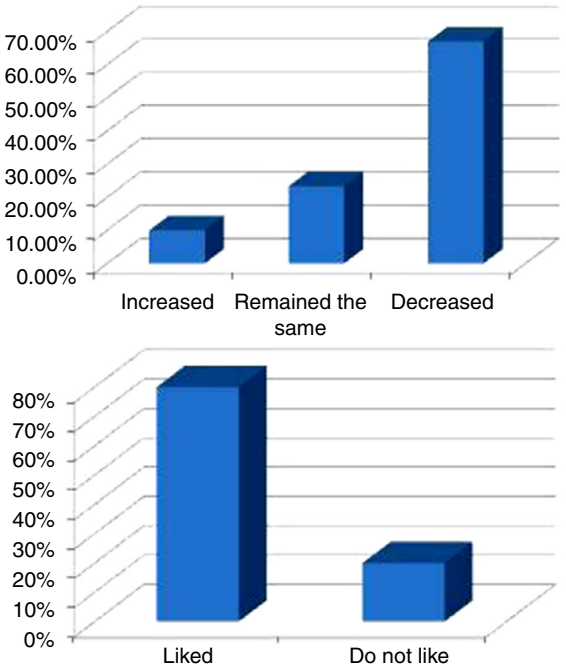


**Figure 3** Summary of incontinence episodes after Renew® treatment and patient satisfaction with the device.

Seventeen patients (56.6%) were happy to continue the treatment in the long term. There was a direct correlation when the St Mark's Incontinence Score was compared with patient satisfaction: patients reported an improvement in symptoms and satisfaction with the device when there was also a significant drop in the incontinence score.

## Discussion and conclusions

In patients with passive FI, a significant improvement in the St Mark's Incontinence Score was seen in patients using the Renew® anal insert at 12 weeks' follow-up. This audit has shown that 80% of patients liked this device. It also showed that 67% of patients experienced a subjective improvement in symptoms, correlating with the objective reduction in the St Mark's Incontinence Score. This suggests that the Renew® device is an effective conservative treatment for passive FI. However, only 56% of patients were prepared to continue with the device in the longer term.

Comparing our results with the other published work on this device, we observed similar but not identical outcomes [17]. Lukacz *et al.*, in a study funded by Renew Medical Inc., reported the outcome of 91 patients with all types of FI, who were offered the Renew® device for a 12-week treatment period.

**Table 1** The 30 patients using the Renew® anal insert

| Patient | St Mark's score [baseline] | St Mark's score [follow-up] | Days used per week | Use per day | Additional pads | Size | Adverse event | Leakage episodes | Patient's satisfaction |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 17 | 9 | 7 | 1 | Yes | L | F | Decreased | Yes |
| 2 | 15 | 10 | 7 | 3 | No | L | F | Decreased | Yes |
| 3 | 17 | 15 | 4 | 3 | No | L | F | Same | Yes |
| 4 | 11 | 12 | 3 | 1 | Yes | L | P,B | Increased | No |
| 5 | 15 | 11 | 4 | 1 | Yes | L | 0 | Same | Yes |
| 6 | 17 | 11 | 1 | 1 | No | L | 0 | Decreased | Yes |
| 7 | 17 | 5 | 1 | 1 | No | L | F | Decreased | Yes |
| 8 | 18 | 10 | 4 | 1 | No | R | F | Decreased | Yes |
| 9 | 18 | 5 | 3 | 3 | No | L | F | Decreased | Yes |
| 10 | 17 | 17 | 1 | 3 | Yes | L | F | Increased | No |
| 11 | 15 | 15 | 5 | 2 | Yes | R | 0 | Same | Yes |
| 12 | 18 | 17 | 4 | 1 | No | L | P | Increased | No |
| 13 | 17 | 10 | 5 | 3 | Yes | R | P | Decreased | Yes |
| 14 | 8 | 2 | 5 | 1 | No | R | 0 | Decreased | Yes |
| 15 | 18 | 10 | 5 | 3 | Yes | L | F | Decreased | Yes |
| 16 | 13 | 13 | 1 | 2 | No | R | 0 | Same | Yes |
| 17 | 15 | 11 | 7 | 2 | No | L | 0 | Decreased | Yes |
| 18 | 15 | 15 | 3 | 1 | Yes | L | P | Same | No |
| 19 | 7 | 2 | 2 | 1 | No | R | 0 | Decreased | Yes |
| 20 | 13 | 5 | 3 | 1 | No | R | 0 | Decreased | Yes |
| 21 | 11 | 2 | 5 | 1 | No | L | 0 | Decreased | Yes |
| 22 | 15 | 10 | 2 | 1 | No | L | 0 | Decreased | Yes |
| 23 | 18 | 11 | 3 | 2 | Yes | L | F | Decreased | Yes |
| 24 | 18 | 18 | 4 | 2 | Yes | L | F | Same | No |
| 25 | 11 | 7 | 3 | 3 | No | R | 0 | Decreased | Yes |
| 26 | 18 | 10 | 1 | 1 | Yes | L | 0 | Decreased | Yes |
| 27 | 11 | 5 | 3 | 1 | No | R | 0 | Decreased | Yes |
| 28 | 15 | 8 | 3 | 1 | No | R | 0 | Decreased | Yes |
| 29 | 18 | 7 | 2 | 1 | No | L | 0 | Decreased | Yes |
| 30 | 15 | 13 | 3 | 2 | Yes | R | F | Same | No |

B, bleeding; F, fall easily; L, large; P, pain/discomfort; R, regular.

Seventy-three (80%) completed the treatment period. On an intention-to-treat basis, 62% of patients achieved a reduction of over 50% in the frequency of FI episodes. The mean frequency of FI episodes per day was reduced from 1.1 ± 0.9 to 0.3 ± 0.4 ($P < 0.001$) at the end of 12 weeks. Fifty-seven patients (62% on intention to treat) were extremely satisfied with the device. It is important to note that Lukacz *et al.* included in their work those with urgency as well. This may suggest that the presumption that anal inserts are suitable only for those with passive soiling may be incorrect. This deserves further investigation.

Furthermore, our results are in keeping with previous work from our group, where the Renew® device was prescribed to those who had undergone restorative proctocolectomy and were experiencing FI. In that study, the Renew® device was acceptable to 8/15 (53%) of patients and was effective in 6/15 (40%) [18].

The Renew® device appears to be well tolerated. Only four patients reported it to be uncomfortable, one of whom reported some minor rectal bleeding. The device was not easily retained in 11 patients. This may reflect the fact that this was used solely in those with passive FI. Very often, these patients will have a low resting pressure with a deformed anal canal and may not even have a closed anus at rest. This makes retention of any anal device difficult. This device is soft, comfortable and seals off the rectum from the inside. This may have overcome some of the disadvantages of the more established Peristeen anal plug [13,18] which, in a recently published systematic review, seems to have poor patient acceptability, an offensive smell, leakage, local irritation and a sensation of urgency [15,19,20].

The Eclipse System [21] is another similar treatment. However, it requires a vaginal insert and currently does not have a CE mark for use in England. A CE mark

indicates that a product conforms to relevant European Union directives regarding health and safety or environmental protection. To our knowledge, there are no other similar treatments available on the UK market.

This audit has several limitations. It was a retrospective single-institution series. The group of patients was small, follow-up was short and demographics were limited to what was available in the database. Bowel diaries were not used for all patients or, as often happens, they were incorrectly filled in; therefore patients' reported recollections of improvement in incontinence episodes may have recall bias. Our data are limited to those who actually used the device; those to whom it was recommended but who did not actually use it are not included in the paper. However, the nontrial nature of this audit perhaps reflects 'real life' clinical practice.

This audit clearly shows statistical evidence of improvement in the St Mark's Incontinence Score in patients treated with the Renew®. An improved score is likely to genuinely reflect a patient's perception of symptom improvement. [22].

In conclusion, the Renew® device appears to be a safe, well tolerated and effective treatment for passive FI. Further prospective and comparative studies are needed to evaluate it against other kinds of treatment and establish its position in the treatment pathway for FI.

## Author contributions

CAL, GT and JDH reviewed the literature and prepared the manuscript. CAL, JS, JDH, GT, YM, JM and CJV revised the manuscript critically and prepared the final version of the manuscript. All authors approved the final draft prior to submission.

## Conflicts of interest

CJV is an advisor to Renew Medical-Inc. None of all the other authors have any relevant disclosures.

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