Original article

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Acceptability, effectiveness and safety of a Renew® anal insert in patients who have undergone restorative proctocolectomy with ileal pouch–anal anastomosis

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Abstract

Introduction Restorative proctocolectomy has gained acceptance in the surgical management of medically refractive ulcerative colitis and cancer prevention in familial adenomatous polyposis. Incontinence following restorative proctocolectomy occurs in up to 25% of patients overnight. The Renew® insert is an inert single-use device which acts as an anal plug. The aim of this study was to assess the acceptability, effectiveness and safety of the Renew® insert in patients who have undergone restorative proctocolectomy. The device has yet to be assessed in patients who have undergone restorative proctocolectomy.

Method This was a prospective study exploring the acceptability, effectiveness and safety of the Renew® insert in improving incontinence in patients who had undergone restorative proctocolectomy. A total of 15 patients with incontinence were asked to use the Renew® insert for 14 days following their standard care. The Incontinence Questionnaire–Bowels was used pre- and posttreatment to assess response and patients were asked to report the perceived acceptability, effectiveness and safety of the device at the end of the trial.

Results The device was acceptable to 8/15 (53%) of patients and was effective in 6/15 (40%). Only 2/15 (13%) of patients raised any safety concerns, and these were minor. The device was associated with a significant reduction in night seepage ($P = 0.034$).

Conclusion In a small study, the Renew® insert can be both acceptable and effective and is also associated with few safety concerns. It is also associated with significant reductions in night-time seepage.

Keywords faecal incontinence, ileoanal pouch, IPAA, Renew® Anopress

What does this paper add to the literature?
To our knowledge this is the first paper to show that the Renew® anal insert can be used to treat incontinence in patients who have undergone restorative proctocolectomy; it is associated with a significant reduction in night-time seepage. The device can be both acceptable and effective in helping those with incontinence following restorative proctocolectomy. Furthermore, the device appears safe.

Introduction

The treatment of anal incontinence remains challenging. It has significant social and economic implications and can have a significant effect on a patient's quality of life [1–3]. It is likely that the prevalence of faecal incontinence is underestimated due to patients' reluctance to report it [4].

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Restorative proctocolectomy (RPC) with ileal pouch–anal anastomosis (IPAA) was pioneered by Parks and Nicholls in 1978 [5]. It has gained acceptance in the surgical management of medically refractive ulcerative colitis and cancer prevention in familial adenomatous polyposis.

Incontinence following RPC has not been widely researched. In one study, at 10-year follow-up continence for stool and gas was present in 79.3% of patients, with 74.4% being fully continent overnight. Incontinence following RPC can be multifactorial and can be related to inflammation of the pouch (pouchitis),

inflammation of the cuff (cuffitis), chronic sepsis or weakness of the anal sphincter. Despite attempts to treat the underlying cause, incontinence may remain a problem and symptomatic control may be necessary.

Treatment of faecal incontinence can include conservative approaches, such as lifestyle modifications and dietary manipulation, medications such as anti-diarrhoeal agents and barrier creams, physical and psychological therapies such as exercise and biofeedback, and surgery [6].

The Renew® anal insert (Renew Medical Inc., Foster City, California, USA) is an inert single-use silicon device which acts as an anal plug (Fig. 1). It is self-inserted using a removable applicator. The device is inserted into the anus where it acts as a seal. It is then expelled during normal defaecation, but can also be manually removed by pulling on the ring disc at the bottom of the applicator. The device costs £2.60 per insert and is freely available on the National Health Service.

The device has been shown to be successful in 78% of patients with incontinence associated with a normal bowel, with 78% of patients being satisfied with the device [7]. To our knowledge, this is the first study to assess the acceptability, effectiveness and safety of the Renew® anal insert in patients who have undergone RPC.

Method

This was a prospective study exploring the acceptability, effectiveness and safety of the Renew® anal insert in controlling and improving incontinence in patients who had undergone RPC. This was a single-centre study at a specialist centre.

Patients were identified through the hospital's biofeedback colorectal and inflammatory bowel clinics as well as through local pouch nurses. Patients were included if they had undergone RPC for any reason and had self-reported passive incontinence for more than 2 weeks and were aged 18 years or older at time of enrolment. Baseline clinical parameters were collected, including age, reason for RPC and other treatments given for passive faecal incontinence. Patients with active inflammation or undergoing treatment for pouch

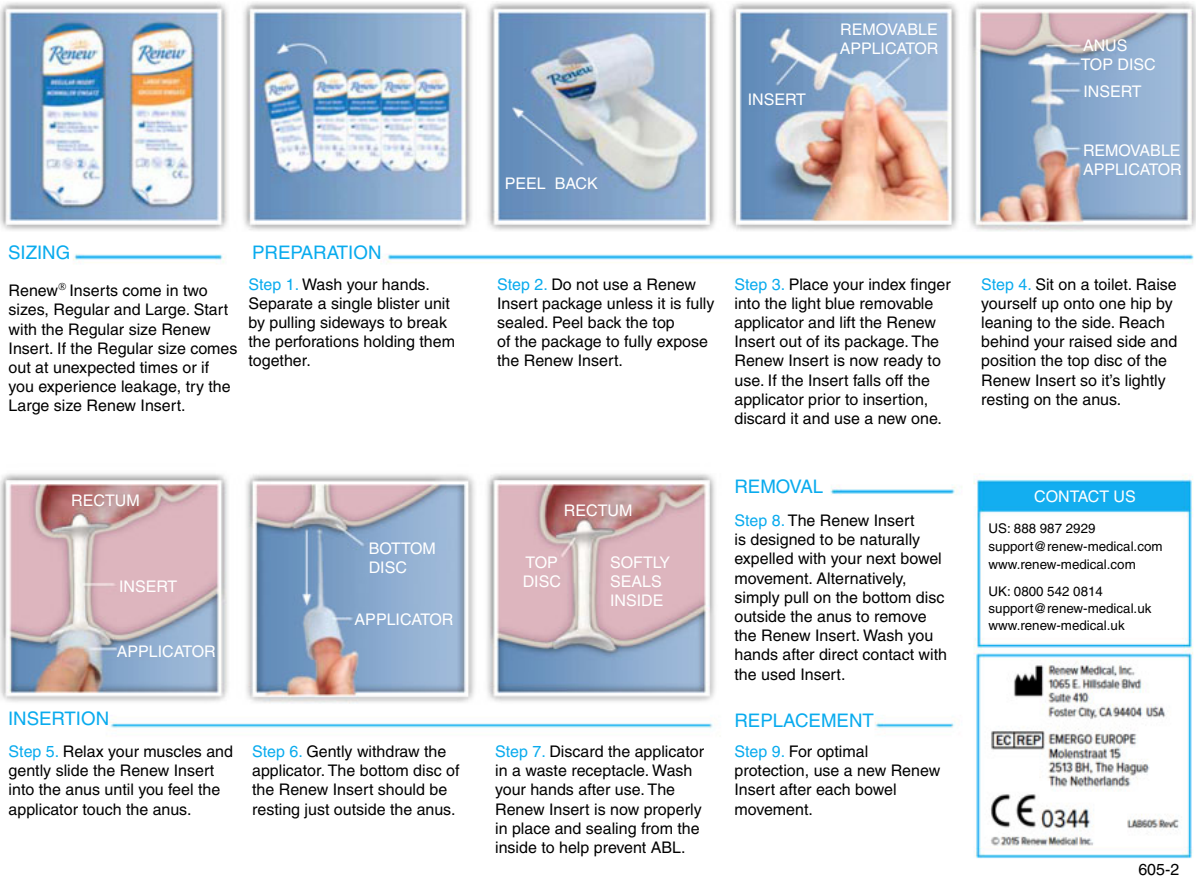

Figure 1 Renew® anal insert (reproduced with permission of Renew Medical Inc.).

inflammation (including pouchitis) within 3 months of recruitment were excluded.

Fifteen patients with incontinence were identified and asked to use the Renew® insert for 14 days following their standard biofeedback care. Patients were required to use the Renew® insert at least once during the day and once at night, and to increase use as required. They were asked to keep a stool diary for 14 days and complete the standardized validated International Consultation on Incontinence Questionnaire–Bowels (ICIQ-B) questionnaire prior to commencing the trial of the Renew® insert and at the end of the 14 days.

Following completion of the study, patients were asked to record the acceptability and perceived effectiveness of the Renew® anal insert device based on a three-point scale: satisfied, neither satisfied nor dissatisfied, and dissatisfied. Patients were also encouraged to report any safety concerns regarding the device. Anti-diarrhoeal medications were allowed to be continued at the same dose prior to entering the trial.

We analysed the results as an intention-to-treat analysis. If patients did not complete the trial or were lost to follow-up we assumed that their ICIQ-B scores did not change from their baseline and that they were overall dissatisfied with the device and dissatisfied with the effectiveness. Change in the ICIQ-B was calculated by subtracting the average pretreatment score from the posttreatment score.

Statistical analysis

The Wilcoxon signed rank test was used to compare the pre- and postintervention scores. Statistical significance was defined as P-value < 0.05. Statistical tests were performed using SPSS version 24, (IBM Corporation, Armonk, New York, USA).

Interventions

The ICIQ-B is a validated questionnaire for faecal incontinence. It is split into four domains to separately measure bowel pattern, bowel control, quality of life and questions that are not directly scored but taken into account. It is a psychometrically robust, self-report instrument that evaluates anal incontinence and its impact on quality of life [8]. The ICIQ-B is measured on an inverse scale (the lower the score, the better the function).

All patients recruited were also invited to undergo routine endoanal ultrasound scan (EAUS) and anal manometric testing in order to obtain objective measurements of sphincter structure and function.

Ethical approval was obtained from the London–West London & Gene Therapy Advisory Committee (GTAC) Research Ethics Committee (IRAS ID 211493).

Results

Fifteen patients were included in the study (ten men and five women). All 15 patients had undergone RPC for ulcerative colitis. The median age of the patients was 57 years (range 24–74). The median time from restoration of continuity to starting the trial was 10.5 years (range 2–36). Five patients had a hand-sewn anastomosis, four had a stapled anastomosis and information was unavailable for nine patients. One patient had a redo pouch for a long rectal cuff and two patients had a pelvic abscess following restoration of continuity, both being treated with drainage and antibiotics at the time. During the trial, six patients continued to use stable doses of loperamide and one continued cholestyramine. One patient was lost to follow-up.

A comparison of the pre- and postintervention scores was made and the results are summarized in Table 1.

The results suggest that there is no statistically significant difference between pre- and postintervention scores for the majority of the outcomes. The exception was for night seepage, where the values were significantly lower postintervention compared with preintervention.

Eight patients were satisfied with the acceptability of the Renew® device, two were neither satisfied nor dissatisfied and four were dissatisfied with the results (Fig. 2). Six patients were satisfied with the effectiveness of the device, two were neither satisfied nor dissatisfied with the effectiveness of the device and six were dissatisfied with the effectiveness of the device (Fig. 3).

Safety of the Renew® anal insert

One patient reported some contact bleeding on insertion of the device and one patient reported pain on insertion of the device. Both these patients were dissatisfied with the acceptability and effectiveness of the device and did not complete the full 14 days of the trial. They were analysed on an intention-to-treat basis. There were no other safety concerns or side effects reported.

Manometry results using Anopress

Manometry was performed in ten patients. Four declined the test and one was lost to follow-up. Manometry showed low pressures in most of the patients. The median resting pressure was 22.5 (20–73) mmHg. The

Table 1 ICIQ-B scores before and after using the Renew® device.

Outcome	Preintervention median, (range)	Postintervention median, (range)	*P*-value
Bowel pattern	50 (25–70)	40 (31–70)	0.406
Bowel control	63 (29–82)	60 (10–82)	0.507
Quality of life	35 (10–66)	38 (18–66)	0.859
Other symptoms	31 (6–52)	32 (6–52)	0.953
Daytime seepage	1 (0–2)	0.73 (0–2)	0.581
Night-time seepage	1.8 (1–5)	0.93 (0–3)	**0.034**

Bold values represent statistically significant events.

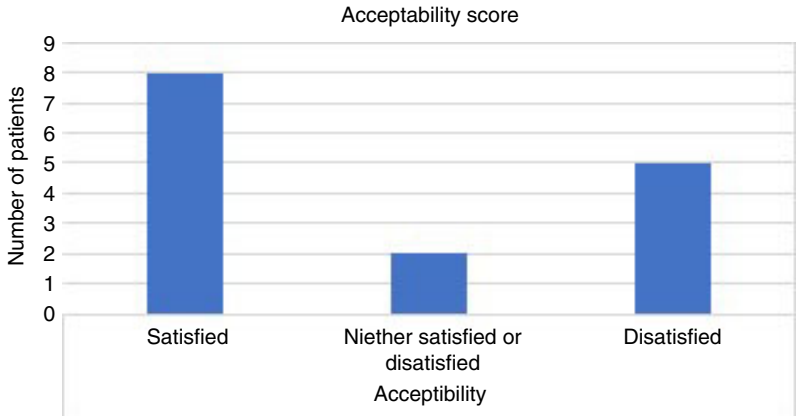

Figure 2 Acceptability of the Renew® anal insert.

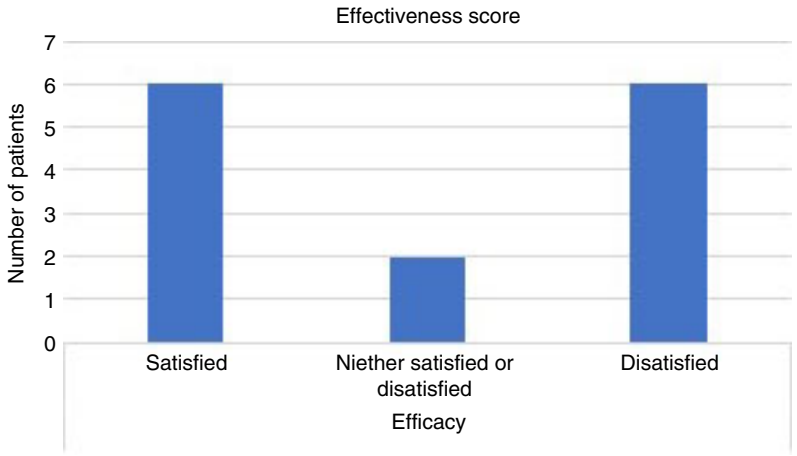

Figure 3 Effectiveness score of the Renew anal insert.

median maximum squeeze increment was 97 (60–223) mmHg. The median endurance squeeze over 10 s was 53 (8–105) mmHg. The median for involuntary maximum squeeze was 96 (35–141) mmHg (Tables 2 and 3).

(Normal values can be found in Leo *et al.* [9].)

EAUS was performed in eight patients. Seven patients did not attend the clinic or declined to have the test. Four patients had degeneration or defects in the internal anal sphincter that contributed to their incontinence.

Discussion

Our study has shown that the Renew® anal insert can be a useful adjunct in the treatment of faecal incontinence in patients who have undergone RPC; it is associated with a significant reduction in night seepage. The

Table 2 Manometric values and EAUS results in patients dissatisfied with the effectiveness of the Renew® anal insert.

Patient no.	Resting pressure	Max. squeeze	Mean squeeze	Involuntary max. squeeze	Endurance	EAUS
1	23	114	91	36	8	No sphincter defects. Distorted and poorly defined IS
2	19	25	6	10	12	Poor definition of the IS with defect between 10 and 12 o'clock
3	21	60	39	51	35	ES and IS intact
4	45	159	114	132	78	DNA

ES, external sphincter; IS, internal sphincter.

Table 3 Manometric values and EAUS results in patients satisfied with the effectiveness of Renew® anal insert.

Patient no.	Resting pressure	Max. squeeze	Mean squeeze	Involuntary max. squeeze	Endurance	EAUS
1	73	184	111	141	105	ES and IS intact
2	22	189	167	60	55	
3	20	51	31	35	34	
4	20	51	31	35	34	
5	54	157	103	135	95	

device was acceptable to 8/15 (53%) of patients and showed effectiveness in 6/15 (40%) of patients. There were no safety concerns reported in 13/15 (87%) of patients who used the device, and those that were reported were minor. Despite not reaching significance, the Renew® anal insert was associated with a trend towards improvement in bowel control, bowel pattern and daytime seepage.

Anal manometry tests confirmed low resting pressures in most of the patients. Some patients also had degeneration of the internal sphincter which may have contributed to the symptoms. Interestingly, a small case series that followed up women with and without sphincter defects before and after RPC found that a sphincter defect was not predictive of long-term incontinence [10]. Our study suggests that patients with intact sphincters and patients with damaged sphincters suffer with incontinence following RPC, and that patients with intact external *and* internal sphincters are more likely to respond well to the Renew® anal insert.

Normal pressures following RPC have yet to be established; however, a study of 12 patients showed that patients with an ileoanal pouch had no significant differences in resting anal pressures compared with healthy controls [11], suggesting that resting pressures are not altered following RPC. This is further supported by another study which suggested that there was no significant difference in anal manometry readings in patients with a colonic j-pouch and a coloplasty pouch [12]. However, this must be interpreted with caution in the absence of validated normal manometry readings in patients following RPC.

Previous studies have shown limited benefit in the use of Coloplast anal plugs as they have been reported to be poorly tolerated by patients and difficult to use [13,14]. It has been suggested that a major reason for this is the size of the plugs [7]. The Renew® insert is designed to fit the contours of the anus and is made of soft silicon, so may provide more comfort to patients with incontinence compared with standard anal plugs.

Faecal incontinence in patients with an ileoanal pouch is reported as much more common than in the general population. It has been reported that 12 months following RPC 19% of patients suffered with occasional daytime incontinence and 49% suffered with nocturnal incontinence [15]. The reason for such a high rate of night-time incontinence is probably due to the sphincter muscles relaxing at night. Our study has suggested that the Renew® anal insert can be particularly helpful with night-time incontinence.

The limitations of this study include the small sample size. As this was a pilot study a larger scaled study is needed, and power calculations could be based on the results documented here. Furthermore, one patient was lost to follow-up. We analysed the results as an intention-to-treat analysis which could have influenced the results.

Further larger studies should validate these findings and may be able to risk stratify those patients who may benefit from using the device based on baseline characteristics, physiology and other investigations. Future studies should also help to define normal manometry and EAUS results in patients with a pouch to help assess normal and diseased states.

Conclusion

In a small series, the Renew® anal insert can be considered as a treatment that can help with faecal incontinence in patients who have undergone RPC. The Renew® anal insert was found to be acceptable in just over half of patients and effective in just under half of patients. Importantly, the device was associated with few safety concerns and significant reductions in night-time seepage.

Disclosures

None of the authors have any relevant disclosures.

Author contributions

JPS, CAL and JDH reviewed the literature and prepared the manuscript. JPS, CAL, JDH, EC, EB, PFCL, ALH, SKC, CJV and ODF revised the manuscript critically and prepared the final version of the manuscript. All authors approved the final draft prior to submission.

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