

## Posterior perineal support as treatment for anal fissures – preliminary results with a new toilet seat device

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**Abstract Background** Anal fissures can cause morbidity in an otherwise healthy young patient. The process of evacuation results in stretching and descent of the anoderm and perineum especially posteriorly. Posterior perineal support may provide counter pressure at the posterior aspect of the pelvic floor, balancing the pressure exerted by the faeces on the anal wall, thus improving evacuation and reducing the trauma associated with it, and reducing symptoms of anal fissures. Symptoms of constipation may also be reduced secondarily. We report the preliminary results with a novel, simple and noninvasive method of treatment provided by a toilet seat device. **Methods** A prospective study was performed in 32 patients. The study was designed mainly to investigate the patients' subjective perceptions of their symptoms related to anal fissures and constipation. Questionnaires were provided to patients before, during and after treatment. **Results** The study revealed statistically significant improvement in pain, bleeding, symptoms of constipation and abdominal discomfort after 3 months usage of the device. The odds of patients perceiving an improvement in symptoms were also significantly increased after 3 months of treatment compared to 2 weeks of treatment. **Conclusion** This preliminary study revealed that a posterior perineal support device can bring about sig-

nificant improvement in the symptoms of patients with anal fissures. There may also be secondary benefits of a reduction in the symptoms of constipation. Although not conclusive, these results should serve as a springboard for further research into this area.

**Key words** Anal fissure · Posterior perineal support · Defaecation

### Introduction

The problem of anal fissure is one that is faced commonly by colorectal surgeons. In an otherwise young healthy population, it causes significant morbidity when chronicity develops.

### Pathogenesis

Acute fissures develop as a result of passage of large hard faecal boluses or recurrent diarrhoea. The process of evacuation in these circumstances results in stretching and descent of the anoderm and perineum especially posteriorly [1]. These in turn lead to tearing of the anoderm at the posterior midline resulting in acute pain. Spasm of the internal sphincter then occurs. With chronicity, persistent elevation of resting anal canal pressures has been demonstrated [1]. Persistent hypertonicity of the internal sphincter and anal mucosa ischaemia ensues [2]. Persistent stretching and descent of the posterior perineal tissues and anoderm results in further pain, spasm and ischaemia that self-perpetuates, and may play an important role in the pathophysiology of chronic anal fissures [3]. There has also been a suggestion that although hypertonicity does

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occur, its resolution is not entirely correlated with clinical healing of the fissure [4]. Some authors have thus suggested that the reduction in the trauma of defaecation also plays a very important role in fissure healing [5].

Posterior perineal support

Based on the downward stretch of the anal verge as a result of puborectalis relaxation during defaecation, the third author designed and built a posterior anal support device (Colorec). This posterior perineal support supports and holds up the anococcygeal region just behind the posterior aspect of the anus. It provides counter pressure at the posterior aspect of the pelvic floor, balancing the pressure exerted by the faeces on the anal wall. This in turn enhances the stimulus to bring about an enhanced reflex

of defaecation leading to more effective defaecation and reducing the need for straining during defaecation. It also reduces stretching tension of the pelvic floor and posterior perineal tissues (Figs. 1 and 2). These effects ultimately reduce the trauma of the process of defaecation.

Posterior anococcygeal support is easily performed using this specially designed and commercially built toilet seat (Colorec; Mecha-Medic Solution Sdn Bhd, Penang, Malaysia) with incorporation of a mechanical posterior support device (Fig. 3). The device is patented by the above company. The first two authors do not have commercial associations that might pose a conflict of interest in connection with this device.

We report here the very preliminary results with this novel simple and noninvasive method of treating anal fissures and improving evacuation.

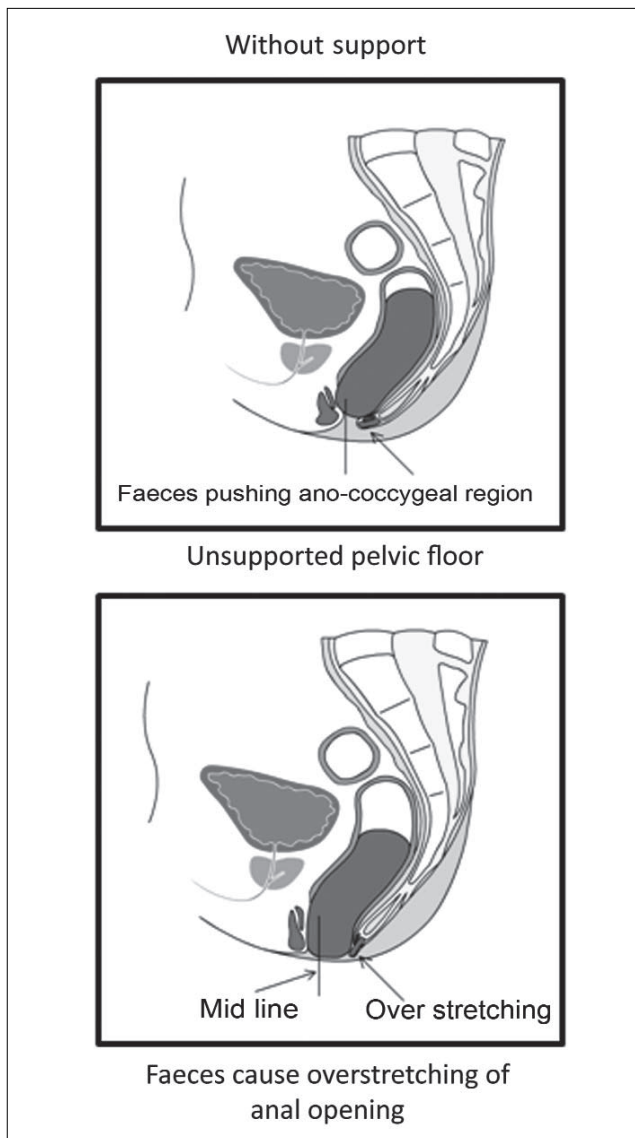


Fig. 1 Faeces causing posterior anal stretching without perineal support

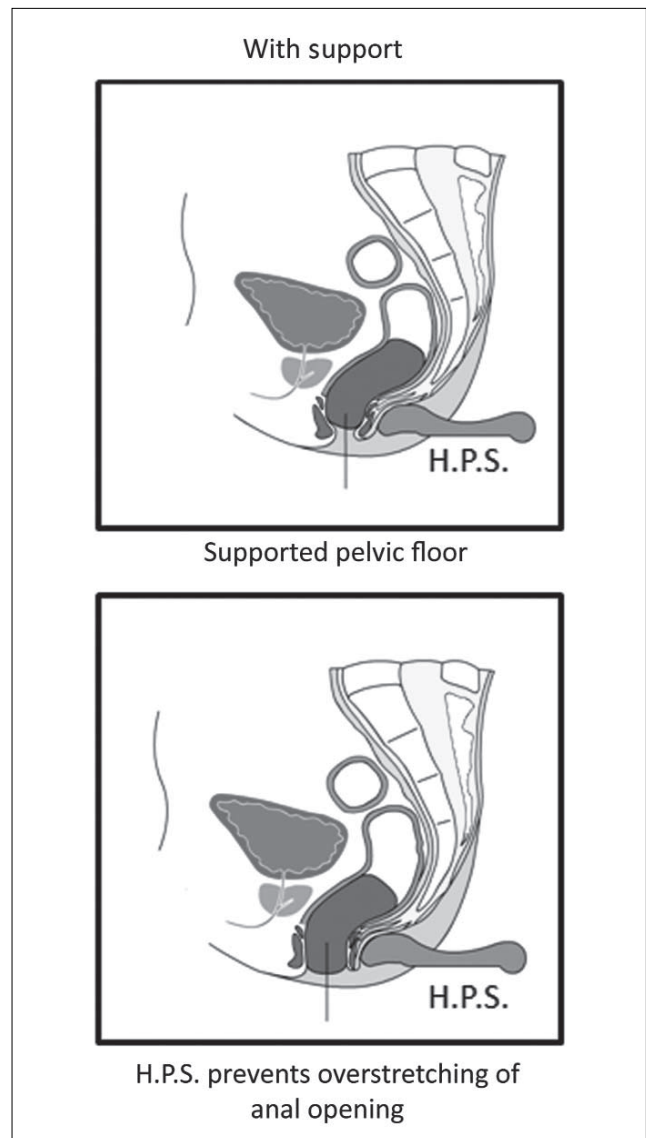


Fig. 2 Prevention of overstretching with perineal support



**Fig. 3** The posterior perineal support device

## Methods

This was a prospective study of 32 patients with symptomatic chronic anal fissures clinically diagnosed by the third and fourth authors. They were treated with the Colorec posterior perineal support device. The patients were asked to fill in a questionnaire on their symptoms prior to treatment. These questionnaires were developed by the third and fourth authors and designed mainly to assess the subjective experience of each patient. Further questionnaires were administered to the patients after 2 weeks, 1 month and 3 months of usage of the Colorec device. These questionnaires assessed the quantity of symptoms and also the perceived improvement in symptoms that these patients experienced.

The primary outcome measure of the study was symptomatic improvement in terms of perceived pain and

bleeding during defaecation, assessed solely based on patient perception. As it was postulated that this device may also improve evacuation, secondary outcome measures were patient perception of having constipation, stool consistency, stool frequency, need for laxatives and perceived abdominal discomfort due to constipation. In this study, constipation was defined as perception of hard stool consistency and defaecation fewer than three times a week. These measures were based purely on the patients' perception. As this study was a preliminary hypothesis-generating study, more extensive quantitative measures using anal manometry and defaecography were excluded.

Analysis was performed using the chi-squared test and Student's *t*-test using SPSS for Windows (SPSS, Chicago, IL) version 15.0 on an IBM personal computer. The results are expressed as odds ratios with 95% confidence intervals. Questions which the patients omitted to answer were considered as missing values and percentages were expressed as that of the entire cohort.

## Results

The patients were treated between May 2007 and August 2007. There were 9 men and 23 women aged between 19 and 61 years. All 32 patients completed all four sets of questionnaires although not all the questionnaires were filled in completely. Table 1 shows the symptoms of the patients before treatment and after 3 months of using Colorec. Table 2 shows the patients' perceived symptomatic improvement at the various timees after the start of treatment. (Patients were asked to score on a four-point

**Table 1** Patient symptoms before treatment and after 3 months of treatment

Symptom	Before treatment (%)	After 3 months (%)
Pain at least once a week <sup>a</sup>	46.9	0
Bleeding at defaecation	68.8	
Bleeding more than one or two drops	40.6	0
Bleeding at least once a week	21.9	3.1
Constipation	93.8	
Hard stool consistency	68.8	31.3
Bowel action at least three times per week	65.6	93.8
Laxatives used more than once a month	15.6	0
Frequent abdominal discomfort	21.9	0

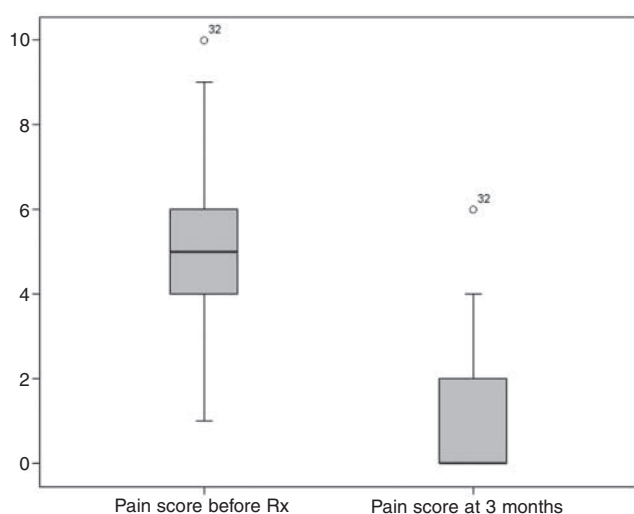
<sup>a</sup>Mean pain score 4.4 (SEM 0.5) before treatment and 1.0 (0.3) at 3 months

**Table 2** Patient perception of at least moderate improvement of symptoms after 2 weeks, 1 month and 3 months of treatment

Symptom	2 weeks (%)	1 month (%)	3 months (%)
Pain	50.0	78.1	87.5
Bleeding	46.9	56.3	65.6
Constipation	40.6	65.6	84.4
Need for laxatives	15.6	21.9	40.6
Abdominal discomfort	31.3	43.8	68.8

scale their subjective experience as no improvement, mild improvement, moderate improvement or marked improvement.)

Figure 4 shows a box plot of the pain scores before treatment and after 3 months of treatment with Colorec. Student's *t*-test revealed a statistically significant change in the mean pain score ( $p < 0.01$ ). The chi-square analysis revealed statistically significant improvement in pain, bleeding, symptoms of constipation and abdominal discomfort (Table 3). The odds of patients perceiving an improvement in symptoms was also significantly increased after 3 months of treatment compared to 2 weeks (Table 4).



**Fig. 4** Box plot of pain scores before treatment and after 3 months of treatment with the perineal support device

## Discussion

Adequate perineal muscular support during defaecation is important for normal function. Whilst there is intrinsic support from the pelvic musculature [6], in some patients this may be insufficient leading to defaecatory disorders [7]. There is then undue stretching and trauma to the posterior aspect of the anoderm with the resultant pathophysiology described above. The use of manual perineal support during defaecation is not a new concept [8]. Many patients use it spontaneously to assist in defaecation. In fact even in infants who suffer from hard bulky stools that are impacted at the anal verge, gentle pressure at the posterior perineal region is the most useful method to help them evacuate the stool. It is the gentle pressure at this area that is most important.

However, posterior perineal support during defaecation is not easily obtained whilst sitting on a seat toilet. This device is an easy to use toilet seat that will provide consistent posterior perineal support during defaecation. The pressure does not have to be at a precise point or in a precise direction and so the Colorec device does not require to be custom-made. The patients can and should modify their sitting position on the device to provide themselves with maximal support from the device. We believe that this has in some way contributed to the improved results only after a period of use of the device as the patient learns which is the best position to sit on the device to provide optimal support.

The significant reduction in pain found in this cohort may reflect the reduced trauma of defaecation with the support device. The quantity of bleeding was found to be significantly reduced but not the frequency. We believe that the frequency of bleeding was not reduced as there

**Table 3** Chi-squared analysis of symptomatic improvement after treatment

Symptom	Odds ratio after treatment	95% CI	<i>p</i> value
Pain at least once a week	0.67	0.49–0.90	0.01
Bleeding more than once per week	0.29	0.03–2.89	0.27
Bleeding more than one or two drops	0.53	0.33–0.86	0.01
Hard stool consistency	0.05	0.01–0.25	0.01
Bowel action at least three times per week	11.43	1.33–98.34	0.01
Laxatives used more than once a month	0.44	0.21–0.93	0.04
Frequent abdominal discomfort	0.55	0.42–0.72	0.02

**Table 4** Chi-square analysis of patients' perception of symptomatic improvement at 3 months compared to 2 weeks

Symptom	Odds of patient perceiving more than moderate improvement in symptoms at 3 months compared to 2 weeks	95% CI
Pain	21.00	2.49–176.79
Bleeding	9.80	1.09–88.23
Constipation	9.00	2.17–37.20
Need for laxatives	5.20	0.71–37.90
Abdominal discomfort	17.60	1.93–160.30

are other concomitant anal pathologies including haemorrhoids that may have contributed to the bleeding. However, the reduced quantity of bleeding at defaecation may well have been at least in part a result of the reduced stretching and trauma to the posterior anal mucosa during defaecation. The results of improved stool consistency and perceived constipation and reduced laxative use are purely based on the patients' own assessment, and the findings of this study suggest that patients do experience easier evacuation with the use of this device. This experience of easier evacuation may be interpreted by patients differently, being reported as improved stool consistency, reduced need for laxatives or general improvement in constipation symptoms. The improved frequency of stools and reduced abdominal discomfort may well provide some objective evidence that this device actually does improve evacuation and thus reduces the symptoms of constipation.

The results of our preliminary study are very encouraging and it is a modality for the treatment of anal fissures and constipation that should not be ignored as it is noninvasive and easy to use. In our subsequent experience, however, we have found some patients with compliance problems as not all motions are passed at home and therefore are passed without using the posterior perineal support device. In this patient cohort, there is also often unreported self treatment with various laxatives and topical preparations, and this could not be well controlled in the current study. Thus this study was limited by potential confounding factors. However, in light of these good results that are hypothesis-generating rather than conclusive, we are in the process of designing a randomized trial of this device in which we will attempt to control for these confounding factors. We are also planning some more objective measures that include findings from dynamic defaecography, perineal descent and changes to the anorectal triangle during defaecation. It will be some time before the results of these studies can be published. We feel that it is important for the current findings to be published as ultimately it is the patients' symptoms that are the most important rather than objective measures which have time and again been found to show poor concordance with patient symptoms. The findings of this

study do demonstrate, albeit not convincingly, excellent improvement in patient symptoms.

There is no doubt that the data presented here are in no way conclusive, but this preliminary report should act as a stimulus for further study.

## Conclusion

This preliminary study reveals that a posterior perineal support device can bring about significant improvements in the symptoms of patients with anal fissures. There may also be secondary benefits of a reduction in symptoms of constipation. A randomized trial comparing the posterior perineal support device with other modalities for the treatment of anal fissures and constipation is warranted to further define its role in the treatment of these conditions.

**Conflict of interest statement** Dr. C.H. Hai is the inventor of the toilet seat.

Dr. G.K. Thye and Dr. C.H. Hai have commercial interest related to this device.

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