

# The Efficacy of Self-administered Home Fecal Transplant in Inducing and Maintaining Remission in Crohn's Pancolitis with Perianal Fistulae

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## Abstract

A substantial proportion of patients with Crohn's Disease (CD) do not respond to the currently available medications with potential long-term consequences. Consequently, alternative safer therapies are being studied, such as Fecal Microbiota Transplantation (FMT). The Food and Drug Administration (FDA) approved the use of FMT for recurrent *Clostridium difficile* (C. diff) but has tighter restrictions for Inflammatory Bowel Disease (IBD). Those patients can only get a fecal transplant in a medical setting if they are participating in a clinical trial. A handful of case reports have shown the effectiveness of self-administered home fecal transplant in recurrent C. difficile, and the efficacy of FMT, under monitored environment, in refractory CD unresponsive to current conventional therapy. However, no reported cases showing the efficacy of self-administered home fecal transplant in patients with fistulizing CD. This is the first case report showing the efficacy of self-administered home fecal transplant as a single agent in the management of Crohn's pancolitis with perianal fistulae.

## Introduction

Fecal microbiota transplant (FMT) for the treatment of IBD is an off-label use since it has not been approved for the FDA. However, its use has been approved as one of the treatment options in recurrent C. diff infection. IBD patients might get FMT treatment by participating in a clinical trial under monitored environment to study its efficacy and safety. Nonetheless, this is the first case in the literature that shows the safety and efficacy of self-administered home fecal transplant as a single agent in the management of Crohn's pancolitis with perianal fistulae. This case shows subjective and objective improvement of the disease with a home fecal transplant from a healthy donor.

## Case Presentation

A 46 years old woman with a history of celiac disease, hypothyroidism, and Crohn's pancolitis with perianal fistulae diagnosed in September of 2013 when she presented with bloody diarrhea and had a colonoscopy which showed severe colitis characterized by deep ulcers throughout the colon (Figures 1A and 1B). Biopsies showed cryptitis and crypt abscesses. The patient was administered on prednisone (60 mg) and soon after that on azathioprine (1.2 mg/Kg). The patient refused biologics because of concerns regarding the medications' side effects. The patient self-stopped azathioprine soon after contracting multiple bouts of upper respiratory infections. The patient thereupon, initiated a series of self-administered home fecal transplants in July of 2014 and continued to receive them when she began to feel symptomatic again (*The protocol is shown below*). She presented to the GI clinic four years later. She denied any abdominal pain, diarrhea, melena, hematochezia, or weight loss. Vital signs were within normal limits. Abdominal examination was soft and non-tender. Anal examination revealed few skin tags, but no fistulae. Laboratories were within normal limits, including complete blood count; liver function test, 25 hydroxyvitamin D, and C-reactive protein. The patient subsequently had a repeat colonoscopy which showed normal terminal ileum (Figure 2A, 2C, and 2D), multiple pseudopolyps throughout the colon (Figure 2B). Random colon biopsies showed quiescent disease.

## Discussion

There is some evidence that suggests changes in the gut microbiota in patients with IBD. These changes over-activate the mucosa immune system leading to chronic inflammation and mucosal lesions [1]. A substantial proportion of patients do not respond to the currently

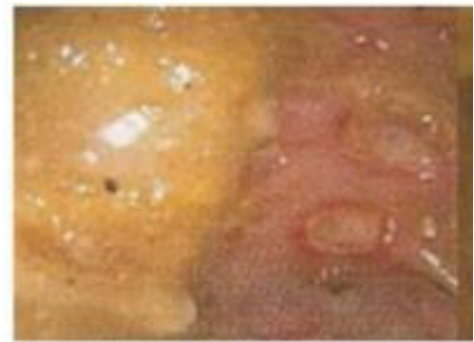


Figure 1a: Initial colonoscopy before Fecal Transplant (Descending Colon).



Figure 1b: Initial colonoscopy before Fecal Transplant (Caecum).

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Figure 2a: Post Fecal Transplant (Transverse colon post).



Figure 2b: Post Fecal Transplant (Pseudo-polyps transverse colon).



Figure 2c: Post Fecal Transplant (Terminal Ileum).



Figure 2d: Post Fecal Transplant (Rectum).

available drugs, most of the immunosuppressive therapy with potential long-term consequences. Consequently, alternative safer therapies are being studied, such as FMT [2].

FMT has become a potential alternative therapeutic option for IBD [1]. This concept was originated from China a millennium ago and has shown encouraging results in the management of patients with IBD [2]. The data was collected from eighteen studies in a systematic review, 122 patients were described 79 ulcerative colitis (UC); 39 Crohn's disease; 4 IBD unclassified), 45% of patients attained clinical remission with FMT during follow-up [3]. Among the cohort studies, the pooled proportion of patients that achieved clinical remission was 36.2%. Subgroup analyses established a pooled estimate of clinical remission of 22% for UC and 60.5% for CD4. In another research it was reported FMT use in 25 patients with CD, the initial transplantation induced clinical remission in 52.0% patients, and clinical improvement in 68% patients after three months. They stressed the remarkable effect of repeated FMT in the role of maintaining clinical remission. In their study, they continued FMT every 3 months, with clinical remission of 47.8% to 52.0% and clinical improvement of 56.0% to 68.0% patients respectively during the follow up (3-15 months) [4].

Regarding donor selection, rigorous screening is of importance. Both, infectious and gastroenterological societies recommend the utilization of the patient's partner, family, or family friend for feces donation. It is imperative to consider the heritability of IBD and gut microbiota; this warrants further investigation in the role of donor selection [3].

In the extensive pursuit of finding the perfect donor, there is a conclusion that people do better when the donor is a relative [5].

Despite all the studies and investigation in this regard, the FDA only allows the use of FMT for recurrent *C. difficile* but has tighter restrictions for IBD. In this scenery, those patients can only get a fecal transplant in a medical setting if they are participating in a clinical trial, like those mentioned above [6].

## Conclusion

A handful of case reports have shown the effectiveness of self-administered home fecal transplant in recurrent *C. difficile*, and the efficacy of FMT, under monitored environment, in refractory CD unresponsive to current conventional therapy. However, no cases have been reported about the safety and efficacy of self-administered home fecal transplant in inducing and maintaining remission in patients with Crohn's pancolitis with perianal fistulae.

## Self-administered Home FMT Protocol

Her donor is a friend who was screened for infectious diseases and had no overt history of autoimmune illnesses. Initially, she did the transplants every other day for four months in the morning fresh stools from her donor. She prepared them by putting them through a blender and adding a saline solution, then straining them. The prepared sample was self-administered as an enema. This was followed by at least 90 minutes of rubbing her abdomen, inverting, lying on one side and then the other. After a minimum of 90 minutes, she passes the stool.

After about four months, her donor had to leave on a trip, and she began freezing the stool samples. In general, the frozen samples seem only slightly less effective than the fresh ones. At some point, she was doing the transplants before bed, thawing the frozen stools. She would do the same routine of enema/inversion/rubbing. Then she would put a heating pad on her abdomen and go to sleep.

At that point she was feeling back to her general health, so she decreased the interval of transplant to once every two to three months or sooner if she developed fatigue or other symptoms of Crohn's disease. Within about 5-15 minutes of administering the enema, she begins to feel better and energetic and always experiences a reduction of symptoms within a day or two. No major side effects reported, some lack concentration, and a sensation of discomfort at the beginning of transplants which improved later. She has been doing a home fecal transplant for over three years. Her stools are formed, and she is asymptomatic now. She is on no medications.

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