

Case description

S. was a 12 years-old girl, with anatomic proportions of a 6yr (22kg), with Trisomy 21, severe autism, mixed receptive-expressive language disorder, moderate to severe vision impairment in both eyes, self-aggressive crises, and severe chronic constipation from NBD origin ⁽¹⁾.

Prior treatments for constipation included PEG laxatives, extra fluids, extra fiver, and enemas. S. received nutrition via a G-tube but frequently pulled out the tube. She lacked intellectual capacity for behavioural modification programs.

She was placed an additional J-tube for nutrition. The G-tube was maintained for medication. The next treatment option was a surgically placed cecostomy tube for ante-grade enemas. Due to her behavioural issues, an additional tube was not likely to be successful, and S. was at high risk of infection.

The mother, a nurse professionally dedicated to her daughter, used to give S. manual colonic massage which usually provoked her tendinitis due to daily administration and force needed.

The pediatric gastroenterologist⁽²⁾, at the request of the mother asked the FDA for the compassionate use permission of MOWOOT device.

References

- Mosiello G, Safder S, Marshall D, Rolle U, Benning MA. Neurogenic Bowel Dysfunction in Children and Adolescents. J Clin Med. 2021;10(8):1669. Published 2021 Apr 13. doi:10.3390/jcm10081669
- Edward J. Hoffenberg, M.D. Professor of Pediatrics. Director, Center for Pediatric Inflammatory Bowel Diseases. Children's Hospital Colorado and University of Colorado, Denver School of Medicine.
- McClurg D, Booth L, and Herrero-Fresneda I. *Safety and Efficacy of Intermittent Colonic Exoperistalsis Device to Treat Chronic Constipation: A Prospective Multicentric Clinical Trial.* Clin Transl Gastroenterol, 2020. 11(12): p. e00267.

Methods

The MOWOOT medical device automatically gives an intermittent colonic exo-peristaltis (ICE) that has been demonstrated to be safe and effective in a previous clinical trial⁽³⁾.



• ICE treatment 20min/day for 45 days

The active elements of the belt inflate and deflate sequentially on the ascendant and descendent colon, emulating natural peristaltic contractions and colon massage techniques.

• Bowel diary (daily for 45d):

- number of bowel movements
- fecal consistency
- quantity of evacuated feces

Day	Time (morning/afternoon/evening/night)	Quantity (bowels)	Consistency (Bristol)	Professional's Name

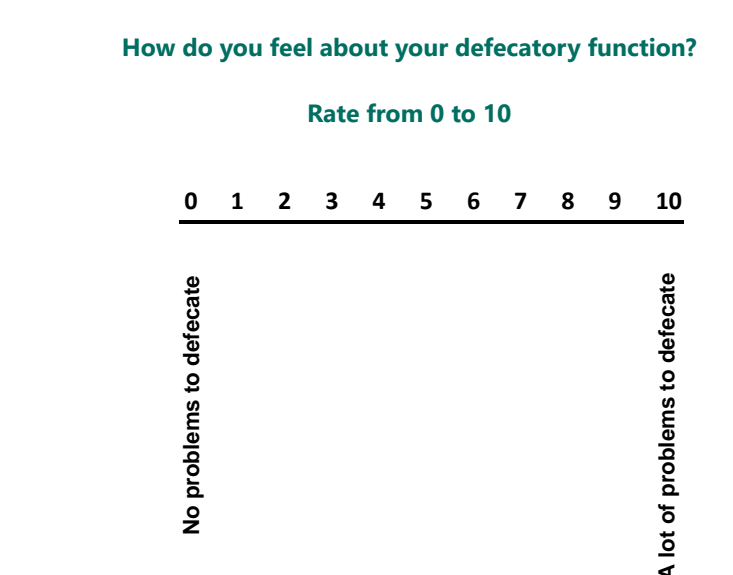
• Register of Additional help to defecation (daily for 45d):

- dose of laxative taken
- dose of enemas

Day	Name Laxative/Enemas/...	Dose	Professional's Name

• Visual Analog Scale:

- Before and after the study



• Global Impression of Clinician

- after 45d-treatment and 1w after finishing the treatment

Professional's Name	Last TREAT day	Last POST-day
dd/mm/aa		
Much better		
Better		
Without change		
Worst		
Much worst		

Contact

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Results



To use the ICE device, both G and J tubes had to be disconnected.

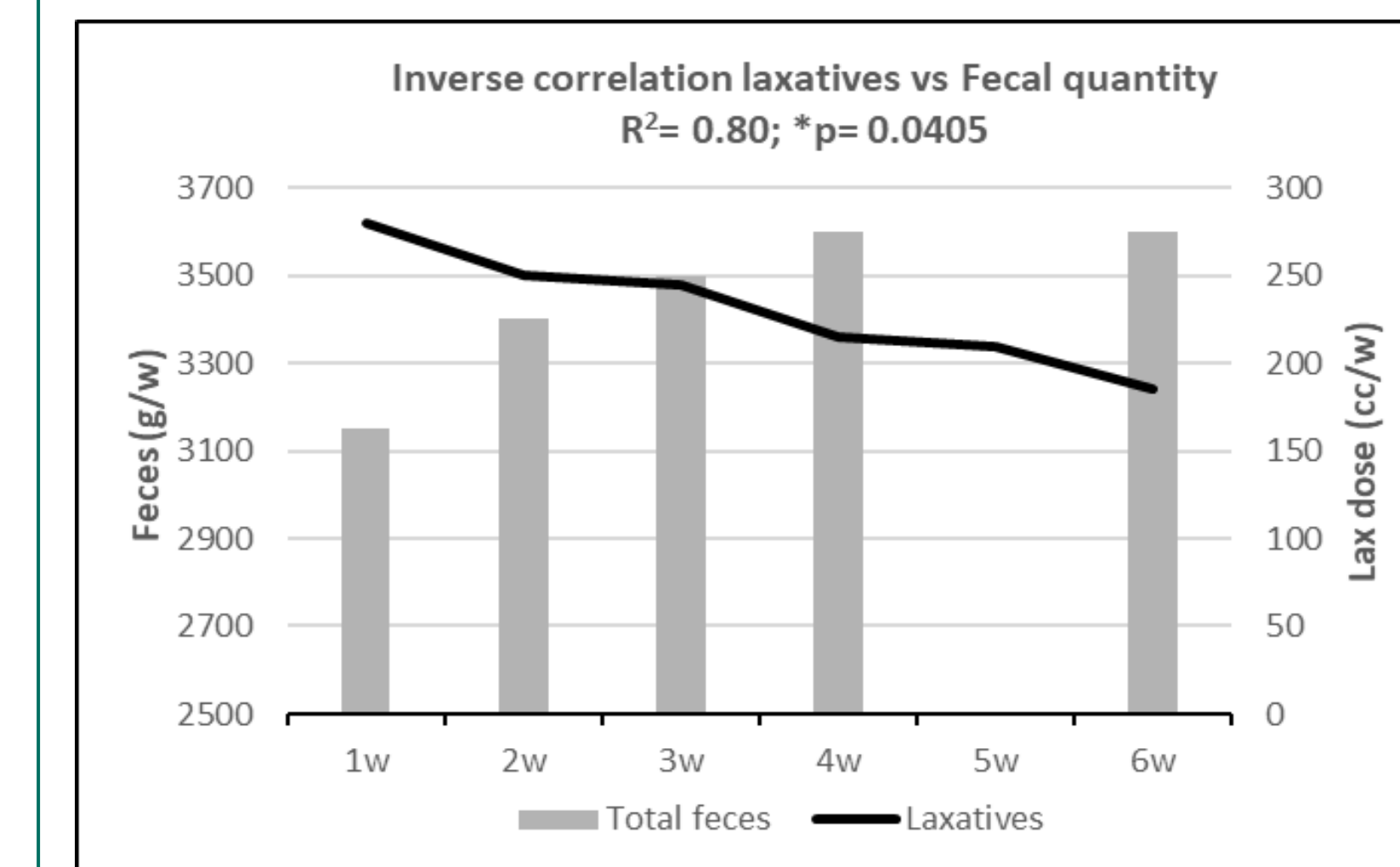
The active pneumatic elements of the belt directly worked onto the occluded osteomas.

Despite the challenges, the treatment worked well:

* There was **no adverse event reported.**

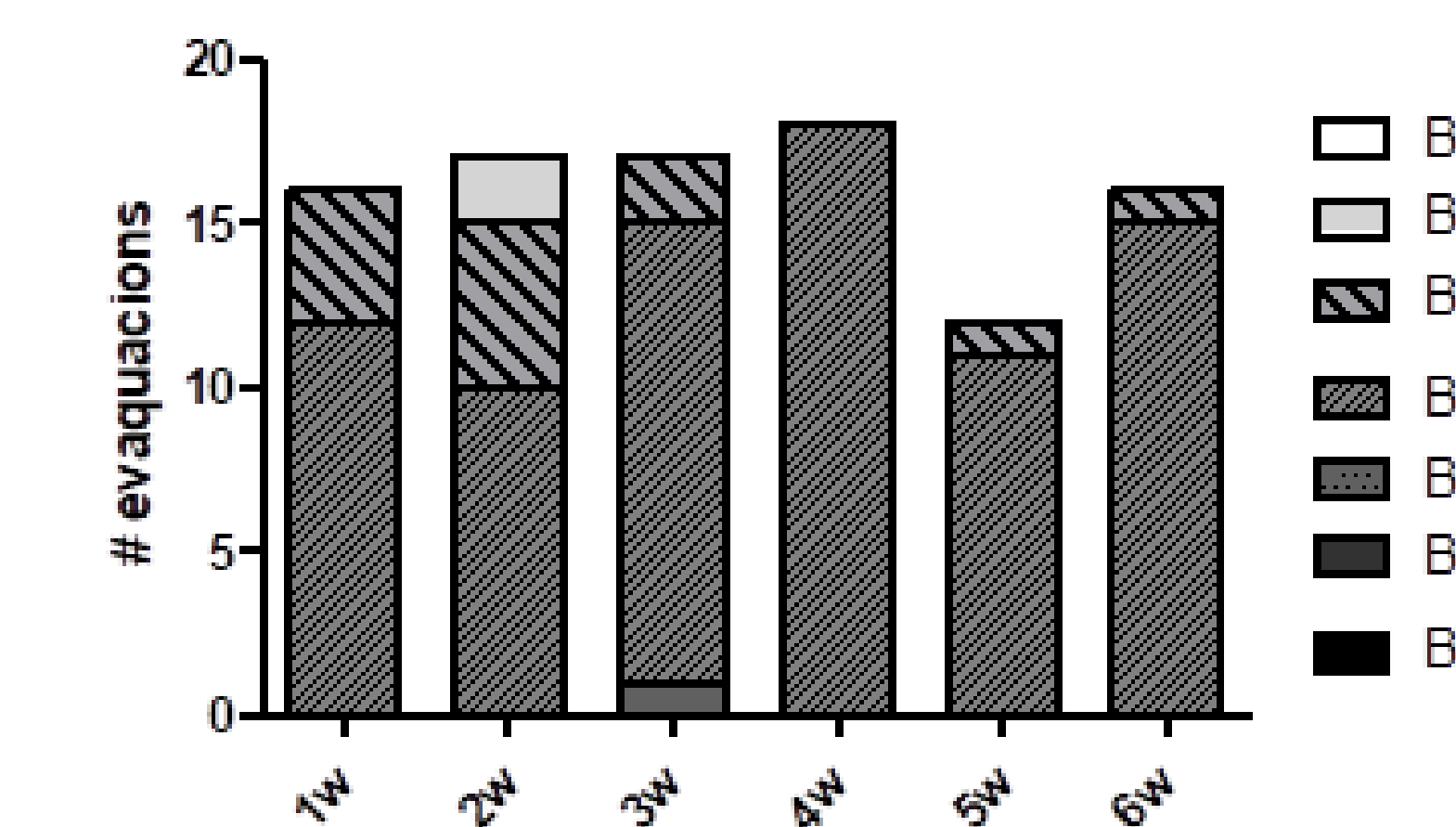
* **S. enjoyed the treatment** from the first day and **reduced her self-aggressiveness**

* After 4 weeks of use, the **bowel movements increased** by 2/week, while the dose of **laxatives decreased.**

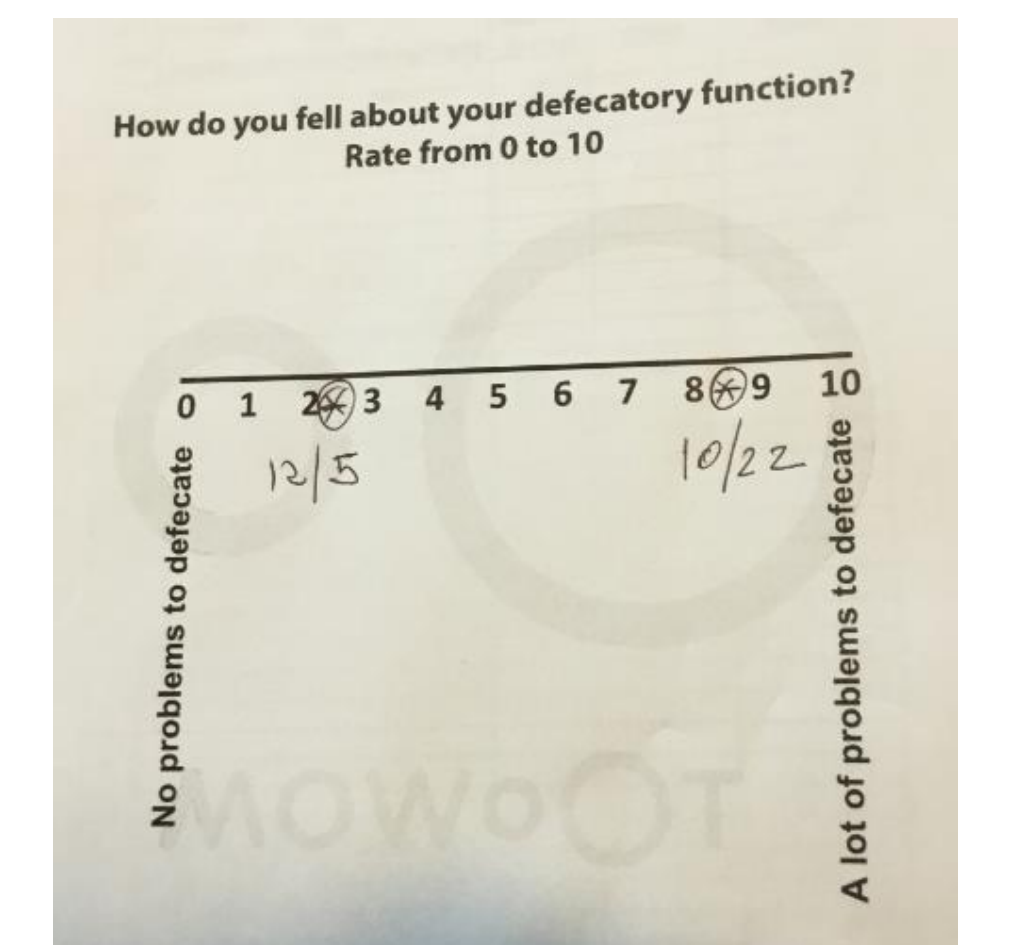


* **Fecal consistency (Bristol scale) ameliorated** with time.

$P(\chi^2)=0,0111$



* The **defecatory function ameliorated** from **VAS 8.5** (baseline) to **VAS 2.5** (day 45).



The improvements **progressed over time.** The FDA approved the continuation of the ICE treatment beyond the initial 45 days-study period. Three months later, the **patient had gained 8 Kg weight and was notably calmer.**

Conclusions

The safety, tolerability, and effectiveness of the ICE system was demonstrated in this case.

The **patient's and family's whole quality of life was significantly increased.**