

Proof of Concept: A Commode
Assist Device for Excessive
Perineal Descent

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IRB proposal

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Background: Constipation is a common gastrointestinal disorder, affecting 15-30% of the population. The incidence increases with age, childbearing, chronic constipation, and with chronic illness. It is associated with high healthcare costs, depression and reduced quality of life. A laxative is prescribed for nearly every office visit for constipation. A common type of constipation seen in tertiary care centers is called outlet obstruction – or pelvic floor dysfunction, which is diagnosed by tests not typically available in community hospitals or the clinical practice setting. Standard and magnetic resonance defecography, done to identify contributing causes of constipation, identifies excessive perineal descent. Excessive descent results from extreme laxity of the pelvic floor muscles, leading to refractory evacuation. While many outlet obstruction disorders respond to treatments, excessive perineal descent is a condition for which there is no known medical or surgical treatment. Standard treatments for pelvic floor disorders like strengthening exercises do not improve constipation nor raise or brace the perineum. Surgery cannot provide adequate support nor repair these weak muscles.

Aim: To address this common problem, in collaboration with Dr. Dan C. Johnson, Dr. Michael Crowell, and more recently Mayo Clinic mechanical bioengineers Malcolm B. McIntosh and Renae Forsman, a pelvic floor support device has been designed, and is ready to be tested. Testing involves comparing perineal descent during standard defecography to descent with the device in place. Radiation exposure is brief and low level.

Sample size: A proof of concept study is proposed to evaluate the feasibility of the CAD for patient use, effectiveness, and satisfaction. A sample size of 16 patients randomly, counterbalanced to both standard toilet seat and CAD was considered sufficient to evaluate potential for further study of the current version of the CAD device.

Methods: The study would include standard defecography using the standard commode (simulates normal toilet seat) under fluoroscopy using barium paste (180 ml) instilled in the rectum and five standard radiographic spot films including images at rest, with squeeze, with strain, during evacuation and post-evacuation. The patient would have additional barium paste (same quantity) instilled in the rectum for a repeat exam (same 5 spot radiographs) using the commode assist device.

Analyses: The standardized commode would serve as the control and be compared with commode assist device for differences in anorectal angle, perineal descent, and rectal emptying during the clinical maneuvers at rest, with squeeze, and with straining. Additionally, patients will complete a short Likert scale questionnaire rating sense of straining, ease of evacuation, and completeness of evacuation for each condition. Statistical comparisons will be completed using non-parametric Wilcoxon signed-rank test for repeated measurements. However, determination of sufficient efficacy for further study and potential redesign will be based on expert opinion of clinical observations.

Risks: All procedures are the standard of practice at Mayo Clinic Arizona. The radiation used for the additional exam is considered very low, and should not present a hazard to patients (see attachment for dosimetry from medical physics). Premenopausal women would be required to have a urine

pregnancy test, and if positive would be excluded from the study as is required by our standard clinical protocols.

Summary: Excessive perineal descent is an underdiagnosed, common cause of constipation. This is a medical problem for which no known treatment exists. The concept of a support device has been received well by patients with the disorder. At present, the condition is diagnosed only at tertiary medical centers that have special diagnostic equipment. A support device that fits onto any toilet is a cost effective, safe and efficacious solution to a common and difficult problem. This has substantial marketability.