

## BACKGROUND

- Biofeedback therapy (BT) is effective in improving Dyssynergic Defecation (DD) in 70% of patients.
- Its significant challenges are lack of dedicated instrument, standardized protocol and ability to perform home BT.
- The standard BT uses EMG or Anal manometry, requires 6 office visits, is not widely available and labor intensive.

## AIM

- To develop and test a new BT device-Bioanator™ system for home BT in patients with DD and compare this with standard office-BT using anal manometry in a randomized pilot study.

## METHODS

- DD patients (Rome IV) were randomized to home using BioAnator™ or office BT.
- BioAnator™ is a wireless, purposefully-designed, digital therapeutic home/office system, with 3-sensors & balloon (Fig 6).
- Bluetooth activated, it interfaces with a smartphone to provide 3-D animation display during Home BT, & uses visual, audio and text feedback (Fig 6).
- Office BT was performed using High resolution anorectal manometry (Fig 2).
- Daily electronic stool diary, PAC-QOL, ARM & BET evaluated therapeutic responses.
- Treatment duration = 6 weeks. Home BT (1/day), Office BT (1/week).
- RESPONDER**=  $\geq 1$  CSBM/week compared to baseline + Normal defecation pattern

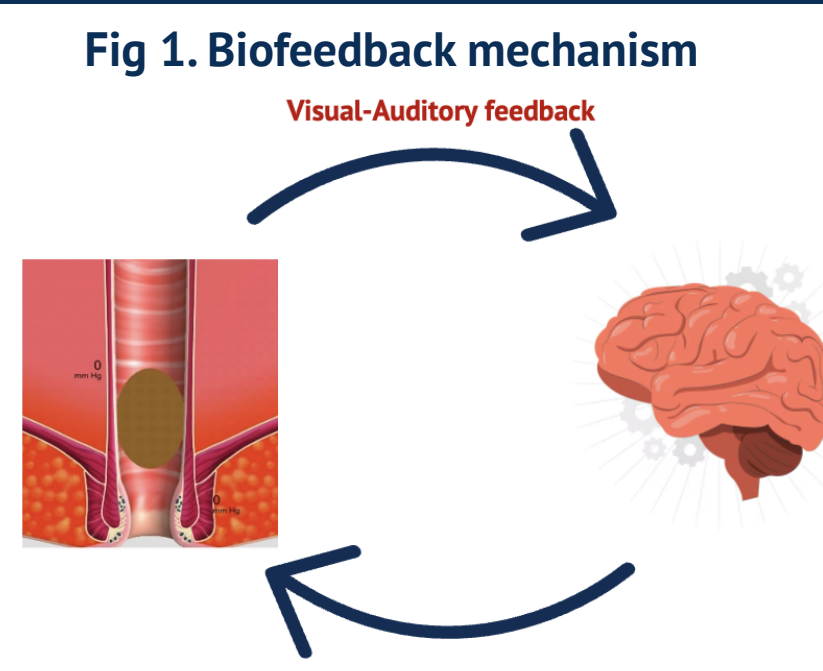


Fig 2. Home BT, ARM system

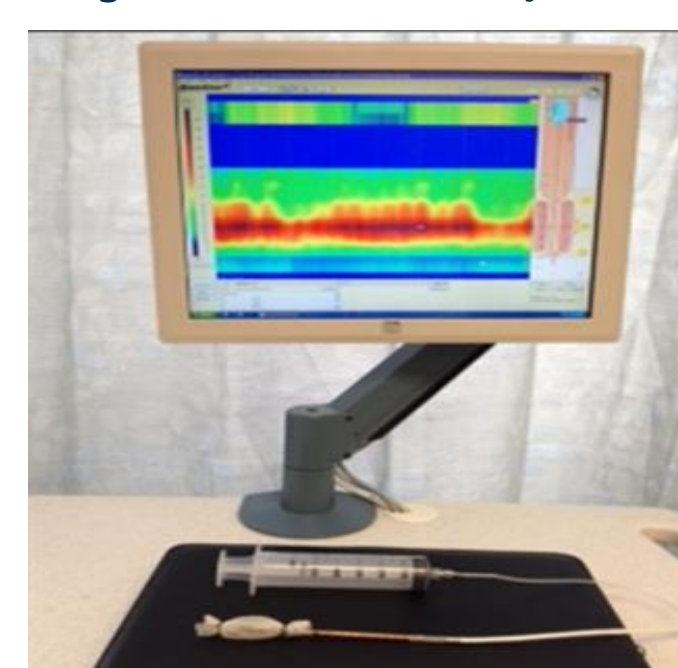


Fig 3. Electronic stool diary App



## RESULTS

13 patients completed; 7 had home (F/M=7/0, mean age=49 yrs), 6 had office BT (F/M=5/1, mean age=56-yrs), mean duration of constipation= 21 years.

Table 1. Effects of Biofeedback Therapy on bowel symptoms (Mean  $\pm$  SEM)

	Timepoint	Home	Office
Stool frequency per week	Baseline	4.71 $\pm$ 3	6.5 $\pm$ 2.3
	Post-treatment	<b>7.14 <math>\pm</math> 2.7*</b>	7.33 $\pm$ 2
No of SBM per week	Baseline	3 $\pm$ 1.9	4.67 $\pm$ 2.8
	Post-treatment	<b>4.57 <math>\pm</math> 1.8*</b>	<b>6.0 <math>\pm</math> 2.8*</b>
No. of CSBM per week	Baseline	0	0.17 $\pm$ 0.4
	Post-treatment	<b>3.0 <math>\pm</math> 2.7*</b>	1.83 $\pm$ 2.3
Straining (0-3)	Baseline	1.86 $\pm$ 0.7	2.17 $\pm$ 0.7
	Post-treatment	<b>0.29 <math>\pm</math> 4.8*</b>	<b>0.8 <math>\pm</math> 0.7*</b>
Digital maneuver use (%)	Baseline	57.1 %	50 %
	Post-treatment	<b>14.3 %*</b>	<b>0%*</b>

\*= p<0.05

Fig 4. Responder Rates

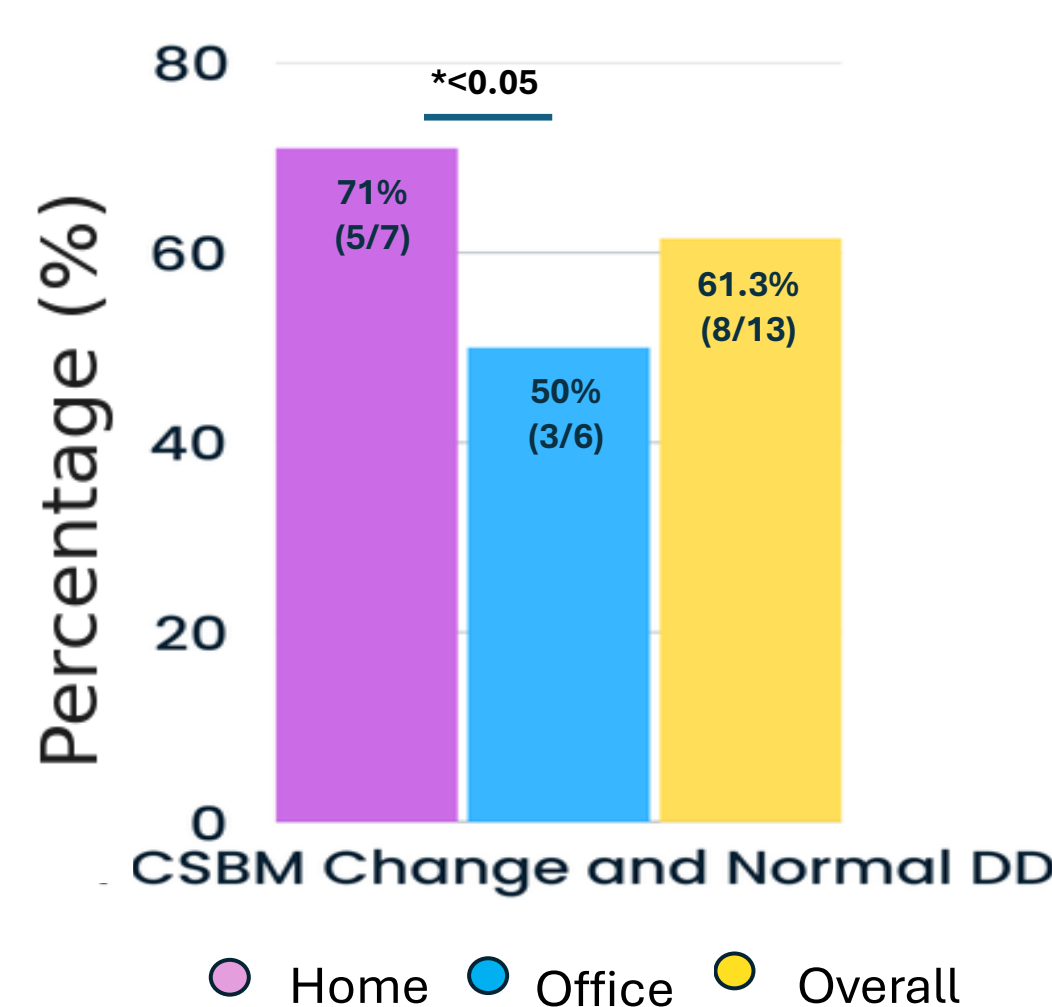


Fig 5. Effects on Quality of Life (QOL)

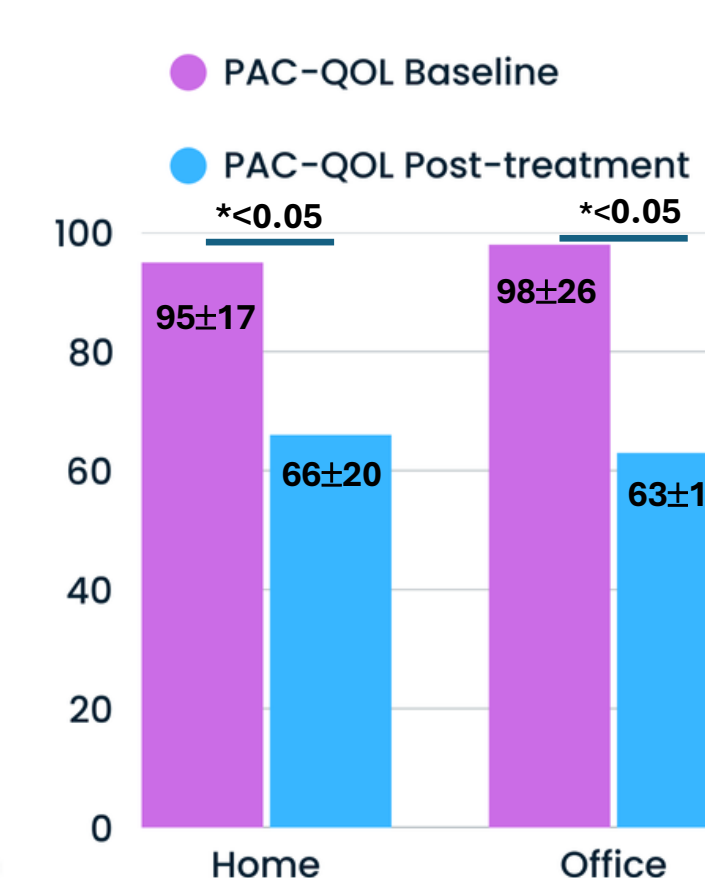


Table 3. Comparison of defecation index & Balloon expulsion (median  $\pm$ sd) between groups

	Timepoint	Home BT (n=7)	Office BT (n=6)
Defecation index when lying on bed	Baseline	0.55 $\pm$ 0.25	0.57 $\pm$ 0.23
	Post-treatment	<b>1.05 <math>\pm</math> 0.42*</b>	<b>1.38 <math>\pm</math> 0.75*</b>
Defecation index on commode	Baseline	0.86 $\pm$ 0.24	1.13 $\pm$ 0.19
	Post-treatment	<b>1.25 <math>\pm</math> 0.34*</b>	1.50 $\pm$ 0.65
Balloon Expulsion Time (s)	Baseline	124 $\pm$ 94	181 $\pm$ 84
	Post-Treatment	50 $\pm$ 101	112 $\pm$ 130

\*= p<0.05

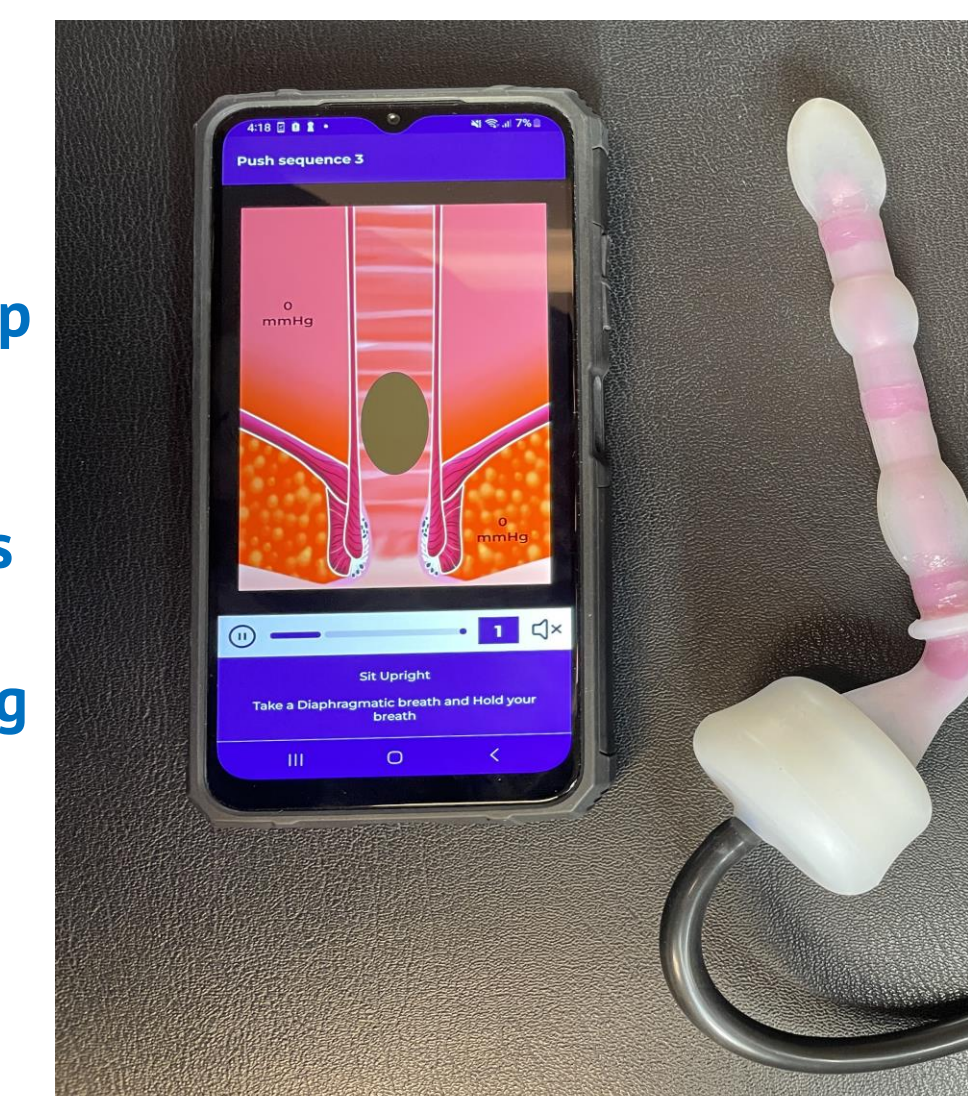
## SUMMARY

- Although Home and Office BT improved bowel symptoms and use of digital maneuvers, CSBM rate only improved in the Home group (Table 1).
- Responder rate was higher in the Home group than Office group (Fig 4).
- QOL improved in both groups (Fig 5).
- Anorectal function, Defecation index (Table 3) & Dyssynergia improved in both groups.

## CONCLUSIONS

- A purposefully-designed home biofeedback program using wireless BioAnator™ system proved useful.
- It was as effective as office BT in improving bowel function and DD.
- Hybrid systems such as BioAnator™ could facilitate wider use of anorectal BT for both Home & Office use.

Fig 6. Bioanator™ App displaying 3-D animation and Text instructions on smartphone for patient during biofeedback



Bioanator™ probe with 3 pressure sensors and balloon inflation port