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AN EXTERNAL DEVICE FOR FECAL INCONTINENCE

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An External and inexpensive device that enables the incontinent patient to control the time, frequency and place of defecation is described. It is based on the principle of the "BALL & SOCKET" valve. The "ball" is an inflatable silastic balloon whereas the "socket" is the anorectal junction. The same device can be used with minor modification in patients with terminal colostomy to make them continent and avoid the need for colostomy bags.

The new device has been used successfully in twenty incontinent children. Thirteen children were incontinent following surgery for high imperforate anus. Three were suffering from meningomyelocele and the remaining two suffered from severe incontinence following severe trauma to the perineum. Follow up period ranged from six months to three years without complications affecting the bowel and minor excoriations in skin.

Key words: Incontinence, Fecal, Device, Artificial sphincter, Anal.

INTRODUCTION

Fecal incontinence is the inability to retain rectal contents between voluntary acts of defecation. It may be partial or complete, varying in degree from slight staining to severe fecal soiling requiring constant diapering [1].

It is estimated that one person in every 650 of the population suffers from fecal incontinence [2]. Incontinence may be due to a variety of causes congenital e.g. spina bifida and imperforate anus, traumatic e.g. road traffic accidents and pelvic operations, and neurologic conditions e.g. disseminated sclerosis or tumors as well as old age [3].

In all these conditions, the patient suffers from restricted social life, psychological disturbances and limited activities. Many surgical approaches have been used to treat fecal incontinence with limited degree of success rate in all series [4,5,6,7,8,11,13,18]. Implantable artifical sphincter. have been used but they are very expensive and may have many complications [9, 10, 12, 14, 15, 16, 17, 19, 20, 21, 22, 23, 24, 25, 26].

A new, simple and inexpensive device that will enable the patient to control the time, frequency and place of defecation would be welcomed.

The Principle:

The principle of the device is that of the "BALL & SOCKET" valve that is well established and has many medical applications, e.g. Cardiac valves.

Fig. (1) The new device with balloon inflated

The new device with balloon deflated

The "ball" is an inflatable Silastic balloon (as in Foley's catheter), the "Socket" is the anorectal junction. In cases of abdominal colostomy, the socket is surgically induced by narrowing the distal 3-4 cm of the bowel by two Prolene purse-string sutures (as Tiersch Stitch) to accommodate size 16 Hegar dilator.

The device is made of silastic material to minimise the irritation of the intestinal wall. The transverse limb (b) of the device is essential to avoid slippage of the "ball" inside the bowel lumen. This transverse limb would fit well in the furrow in the perineum between the thighs.

In order to avoid the repeated use of a syringe, the balloon may be filled from a chamber in continuity via a narrow neck Fig 2). The device may come in different sizes range from F16 to 25 depending on the size at bowel opening. The balloon is designed to accommodate between 10cc to 50cc.

In cases of abdominal colostomy, the transverse limb may be replaced with circular flange like that used in cases of gastrostomy (Fig. 3).

Method of Application:

The patient will insert the device so that the "neck" will fit in the narrow bowel opening and the tip just above it.

Then he will fill the balloon with a syringe or compress the balloon (b) pushing the fluid to fill balloon (a).

The fluid is prevented from coming back through the narrow neck by means of cap (c).

The redundant balloon (b) will be hidden within the "stalk" separating the balloons.

Fig (4): The new device, the balloon deflated

Fig (5): The new device, the balloon inflated

PATIENTS AND METHODS

The new device has been successfully used in twenty children suffering from foecal incontinence. They were sixteen males and four females. Their age ranged between 5-10 years. Their inability to control bowel motions caused them and their family's severe distress at home and more importantly with their peers at school. Thirteen patients had incontinence despite surgery for high imperforate anus. They are using the new device day & night and take it off for 20 minutes three times daily, on waking up, after coming back from school and before going to bed. Five patients suffered from incontinence to urine and stools due to meningomyelocele. The remaining two sufferer from sever trauma to the perineum. They use the device during the day and take it off before they go to bed, as they are clean at night. Follow up ranged from 6 months to three years .

RESULTS

The results of the study are summarized in (Table 1).

All patients experienced dryness and no soiling for the period of application of the device(6-8 hours). They adapted to the presence of the device in the anal canal without considerable discomfort.

Complications:

The major defect in the device was technical in manufacturing the device. As it was hand made, it was not properly sealed and air or water used to leak at the junctions and usually at night. The first five devices did not last more than a week due to manufacturing defects. The current ones usually last for three to four weeks. The children feel more confident socially and are able to swim and cycle without discomfort or embarrassment. The defects in manufacuring could be overcome by major industrial companies manufacturing ballooned catheters like Folley's catheters or gastrostomies.

No injury to the colon or mucosa was experienced in any of the cases.

Table (1)*: Summary of the study.*

Pt. No.	*Age at Presentation*	*Cause of incontinence*	*Follow Up Period*	*Complication*
1	6 yr.	High imperforate anus	3 years	No complications
2	4 yr.	High imperforate anus	3 years	Perineal excoriations
3	4.5 yr.	Meningomyelocele	3 years	No complications
4	7 yr.	High imperforate anus	3 years	No complications
5	5 yr.	High imperforate anus	3 years	Ballon rupture
6	5.5 yr.	High imperforate anus	3 years	No complications
7	4 yr.	Meningomyelocele	2.5 years	No complications
8	6 yr.	High imperforate anus	2.5 years	No complications
9	8 yr.	High imperforate anus	2.5 years	Perineal excoriations
10	6 yr.	High imperforate anus	2.5 years	No complications
11	6 yr.	Meningomyelocele	2.5 years	No complications
12	4 yr.	High imperforate anus	2.5 years	No complications
13	7 yr.	High imperforate anus	2.5 years	No complications
14	9 yr.	Perineal injury	2 years	No complications
15	7 yr.	Meningomyelocele	2 years	No complications
16	4.5 yr.	High imperforate anus	2 years	No complications
17	5 yr.	Meningomyelocele	1.5 years	No complications
18	5.5 yr.	High imperforate anus	1 year	No complications
19	6 yr.	Perineal injury	6 months	No complications
20	5.5 yr.	High imperforate anus	6 months	No complications

DISCUSSION

In 1952, a patent was granted to Surface for a colostomy control deformable button [27]. The device consisted of a hollow gum rebber plug and an aluminium face plate. An introducer stretches the device to allow for insertion. The device then returns to its original shape and occludes the lumen of the bowel. It was available in a range of lenths and diameters and was accepted by the American Medical Association's Council on Physical Medicine and Rehabilitation [28]. This device was marketed but there was concern about it being used inappropriately by some patients without supervision so the effort was allowed to lapse. There is an anecdotal report that the device had been used successfully by one patient for 22 years [29]

In 1981, Beahers and others reported the use of Induelling ileostomy valve devise to achieve continence in patients with failed continent ileostomy valves [30]. Pemberton and co-workers evaluated extending the use of this device to conventional ileostomies without reservoirs in a canine model [31]. The occlusion period was increased gradually from two to six hours a day and animals were studied for a period ranging from 18 to 22 weeks. All four animals tolerated complete occlusion of up to six hours a day and were continent during that period. There was evidence od proximal dilatation of theileum acting as a reservoir. This approach has led to the development of a commercially available device.

Sanada and colleagues reported the use of a Foley type catheter to occlude the lumen of ileostomy in 1982 [32]. The catheter was kept in place by applying traction and fixing it on a surface faceplate. Nine piglets were studied (five with a constructed reservoir and four without) for six weeks. Occlusion periods were gradually increased from three to eight hours. All animals were continent during the occlusion periods and there was no morhpological evidence of bowel damage. Proximal accommodation increased more markedly in the animals with the reservoir.

Willital reported the implantation of a magnetic prosthesis to occlude the bowel [33]. The implant consisted of two halves of a samarium cobalt ring which are positioned around the upper anal canal through a sacral approach without opening the bowel. Occlusion of the bowel is achieved by a special anal tampon/plug made of polyformalvinyl foam which icorporates another magnet. The tampon is stabilized inside the lumen by means of the magnetic attraction force between the two elements of the device. The tampon is changed twice daily. Six children (age range 3-15 years) with anorectal malformations were implanted with the device [34]. Complete continence with no complications was reported in the short term, but the device suffered many infective complications and eventual erosion and was not developed any further, despite two further anecdotal reports attesting to its short term success in adults [35] and children [36].

In 1991, Mortensen and Humphreys designed a disposable anal continence device for patients with anorectal incontinence [37]. The idea is similar to the tampon used during the menstrual period. The patients change the tampon 1-3 times daily and they have complete continence inbetween. The major drawback is that the tampon is not cheap and the patient is using an average of two tampons per day.

Shoshany and Pena described a silastic anorectal sphincter placed by posterior sagittal approach in pigs [38].

In 1996, Hajivassiliou and colleagues reported a novel implantable artificial anal sphincter [39,43]. The isea is not different than the principle of urinary sphinters that are commonly used nowadays. It consists of a sphinter element which is placed around the bowel, a constant pressure balloon reservoir and a control pump. The interesting point about this device that they use acute angulation of the anorectum to decrease the occlusion pressure needed to hold back solids but not fluids and gas. This was based on an in vitro study [40]. The main drawbacks remain that the device is expensive, surgery is needed to implant the device, there is a foreign body that may get infected and erode its way through the bowel wall and the potential risk of ishaemia to the bowel wall.

Malone and colleagues developed a very interesting concept to achieve dryness and social comfort in incontinent patients [41,42]. They thought of using the appendix after reversing it and fixing the base to the skin and the tip to the coecom to arrange for antegrade washout enema. Thus allowing for complete washout of the whole colon and avoiding the disadvantage of the classic wash out enema that it does not completely empty the colon. In this way, the incontienent patient may enjoy a longer clean spel. Again, the inconvenience of having surgery done with all the potential complications and having an opening in the skin and the need to do regular washouts are factors that make this techique less than ideal although there are many patients that are having better life style using it [42].

When designing devices to be inserted inside the anus or colon, there are few major concerns; bowel wall ischaemia, abdominal distension and discomfort due to the inability to pass flatus, tolerance, accidental leakage, perineal excoriations and the price of the device.

Bowel wall ischaemia is unlikely to occur, as the pressure that keeps the valve in place is mainly the intraluminal pressure. The same principle is used successfully in gastrostomies.

The passage of flatus is achieved through the small opening in the centre of the device.

It was noticed that all patients did not feel the device in the anus after a period ranging from 1 to 5 days.The possible explanation to this is the presence of the device all the time The same thing happen with tampons, urinary catheters and contact lenses in the very sensitive eyes.

Accidental soiling happened occasionally in all patients. This was mainly at the early phase of applying the device until the patient and the mother reach the right volume inside the balloon to achieve dryness. Soiling also occurred when there was leakage from a defective valve or rupture of the ballon (only once).

Perineal excoriations were experienced in two patients (Pt. no. 2, Pt. no. 9) and were managed by allowing more time without applying the device and the use of local sothening ointments.

The price of the device should approximate the price of a Folley's catheter on mass production. It will be very inexpensive and re-usable after cleaning.

The major advantages of the device are; good control of fecal incontinence, cheap and very inexpensive device There may be decreased needs for colostomy bags, tedious stoma care, protective nappies, permanent disfiguring abdominal colostomies and easier control of fluid & electrolyte loss from ileostomies.

The presented data on this limited number of patients may suggest that the described device may save many patients the hazards, expenses and complications of major surgeries like artificial sphinter implants, gracilis muscle, Malone procedure etc. It may help many patients to lead a reasonable sociable life without a high price.

CONCLUSION

However, this is still in the early stages of development and a larger number of patients and proper manufacruring of the device are needed before objective evaluation of the device and before recommending its use with general population suffering from foecal incontinence.

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