

TAI in paediatric patients

2ND EDITION
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Summary of Evidence

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Transanal irrigation (TAI) - putting children and carers in control

Introduction

This booklet summarises key data on the use of transanal irrigation (TAI) with Peristeen® in children and young people aged <18 years. TAI is a technique used to empty faeces from the bowel in a controlled manner and is an effective approach when conservative bowel management strategies fail to provide sufficient relief of symptoms.

Defecation disturbances affect many children and are not limited to neurogenic diseases

Constipation and faecal incontinence are problems that affect a large number of children, with prevalences ranging from 0.7% to 29.6%.¹ These bowel problems can be caused by a range of diseases or conditions. In some of them, such as spina bifida, the reason is a neurologic defect or damage. In other cases, such as Hirschprung's disease or anorectal malformations (ARM), bowel problems can persist after reparatory surgery has corrected the anatomical anomalies. In the third and by far largest group of patients, no anatomical or neurological reason seems to cause the bowel problems and therefore we speak of functional or idiopathic bowel dysfunction.

- Constipation is very common among children and young adults with spina bifida and approximately one third are faecally incontinent^{2,3}
- In the long-term outcome of children operated of ARM, 41% suffers from constipation and 55% from soiling⁴

The importance of an effective bowel care routine

The symptoms of bowel dysfunction cause significant physical and emotional distress in the children that suffer them,^{5,6} affecting self-esteem,⁵ personal relationships,⁵ and social life, particularly in children of school age.⁷ Children with neurogenic bowel dysfunction (for instance due to spina bifida) are more dependent on their parents and caregivers. This affects the quality of life (QoL) of carers, as well as children, causing anxiety related to bowel management and episodes of faecal incontinence.⁶ QoL decreases as the severity of bowel dysfunction increases.⁸ Conducting TAI with Peristeen on a regular basis can help prevent accidents and soiling, and in many children may eliminate the use of diapers or pads.^{9,10} In clinical studies, paediatric patients treated with Peristeen had fewer urinary tract infections (UTIs) than when treated with conservative bowel management strategies.^{7,11}

As well as being socially disabling, bowel dysfunction may be accompanied by pain, bloating and discomfort on a regular basis. Many patients spend a significant part of their day on bowel management: 14% to 63% spend more than 1 hour on each episode.^{12,13} Regular evacuation of the recto-sigmoid area promotes transport through the entire colon, thereby helping to prevent blockages in children with constipation. After an initial period of training, older children may be able to perform TAI with Peristeen without the help of a carer, taking control of their bowel management and increasing their independence.^{10,13,14} The use of TAI with Peristeen can significantly improve QoL and socialisation of children and caregivers.^{9,10,11,13}

Indications and contra-indications of Peristeen® in children

Peristeen Anal Irrigation is intended to instil water into the colon through a rectal catheter with an inflatable balloon. The catheter is inserted into the rectum to promote the evacuation of the contents in the lower colon of patients who suffer from faecal incontinence, chronic constipation and/or the need for time-consuming bowel management procedures.

Peristeen can be used by both adults and children over 3 years of age.

The Peristeen system is designed to be easy to handle so that it can be used by a wide range of patients, including those with impaired manual dexterity, helping more patients to regain independence. A smaller size of catheter is available specifically for children over the age of 3, and can also be used by adults if the size is considered more suitable than the regular catheter.

The use of Peristeen in children is documented in the following medical conditions:

- Spina bifida/myelomeningocele/lipomeningocele^{6,15,11,14}
- Anorectal malformations (diverse sub-types, in both male and female)^{10,16,17}
- Hirschprung's disease^{10,14}
- Traumatic spinal cord lesion^{14,17}
- Intractable functional constipation (with or without faecal incontinence)¹⁸
- Tay-Sach disease¹⁴
- Paraspinal neuroblastoma (resected)¹⁴
- Syringomelia¹⁴

TAI with Peristeen has a good safety profile, when used according to the instructions for use. However, it should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation. With the currently available Peristeen system, the estimated rate of perforation for the overall patient population (adults+children) is in the order of 1 per 500,000 procedures.¹⁹

Peristeen must not be used in the following cases:

- Known anal or colorectal stenosis
- Colorectal cancer
- Acute inflammatory bowel disease
- Acute diverticulitis
- Within 3 months of anal or colorectal surgery
- Within 4 weeks of endoscopic polypectomy
- Ischaemic colitis.

Since the list is not exhaustive, the physician/ health care professional should always consider individual patient factors as well.

Consult the latest valid IFU (Instructions for Use) document in your country for a complete list of contra-indications and precautions.

Coloplast has also published a Training Guide for Healthcare Professionals, where you will find information and advice regarding the contraindications and precautions, the initial training of patients and how to help them establish a personalized routine.





Index of studies with Peristeen® in paediatric patients

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Use of Peristeen transanal colonic irrigation for bowel management in children: a single-centre experience¹⁴

Pacilli M, et al. *J Pediatr Surg* 2014;49:269–272

Intervention:

TAI with Peristeen

Study design:

This was a retrospective review of children with incontinence or constipation and faecal soiling on a bowel management programme with Peristeen between 2007 and 2012

Patients:

- 23 children were treated with Peristeen from 2007–2012
- Median age at onset of Peristeen use was 7 years (range 2–15 years)
- 11 children had spina bifida and 6 had an anorectal anomaly; the remaining main diagnoses were different in each patient
- 12 children had constipation and encopresis and 11 patients had faecal incontinence
- Whilst using Peristeen for bowel management:
 - 16 (70%) children were on alternate day irrigations, 4 (17%) were on daily irrigations and 3 (13%) were using irrigation every third day
 - 9 children (39%) were taking oral laxatives
 - 7 children (30%) were self-administering the washouts, these children were typically older, with a median age of 11 years (range 7–15 years)

Key efficacy data:

- 16 (70%) reported to be clean and 3 (13%) reported a significant improvement, although they were having occasional soiling episodes

Key safety data:

- No serious adverse events related to Peristeen use were reported
- 4 patients (17%) were dissatisfied with TAI and discontinued use. The reasons for discontinuation included:
 - Difficulties and severe pain on insertion of the catheter and expulsion of the catheter during irrigation (n=2)
 - Persistent significant soiling (n=2)
 - The need for >2 daily washouts to remain clean (n=1)

Conclusions:

- TAI is well tolerated by patients with various organic diseases and multiple associated anomalies
- Peristeen TAI is an effective method of managing faecal incontinence and constipation in children, even at young ages
- Peristeen should be considered as a first-line treatment for faecal incontinence and chronic constipation and as an alternative to invasive surgery

Characteristic	Number of patients
Main diagnosis:	
Spina bifida	11
Anorectal anomaly	6
Hirschsprung's disease	1
Paraspinal neuroblastoma (resected)	1
Tay-Sachs disease	1
Acute transverse myelitis	1
Syringomyelia	1
Quadriplegia following trauma	1
Associated anomalies:	
Hydrocephalus (with ventriculoperitoneal shunt)	5
Scoliosis/kyphosis	4
Arnold-Chiari malformation	4
VACTERL association	2
Single kidney	2
Pelviureteric junction obstruction	1
Hypospadias	1
Trisomy 21	1
Gastronomy feeding	2
Mobility:	
Wheelchair bound	12
Using walking aid	1
Bladder emptying:	
Clean intermittent urethral catheterisation	13
Vesicostomy button	5
Mitrofanoff channel	1
Diapers	1
Normal micturition	3

Peristeen anal irrigation as a substitute for the MACE procedure in children who are in need of reconstructive bladder surgery⁹

Alenezi H, et al. *Can Urol Assoc J* 2014;8:e12–15

Intervention:

TAI with Peristeen

Study design:

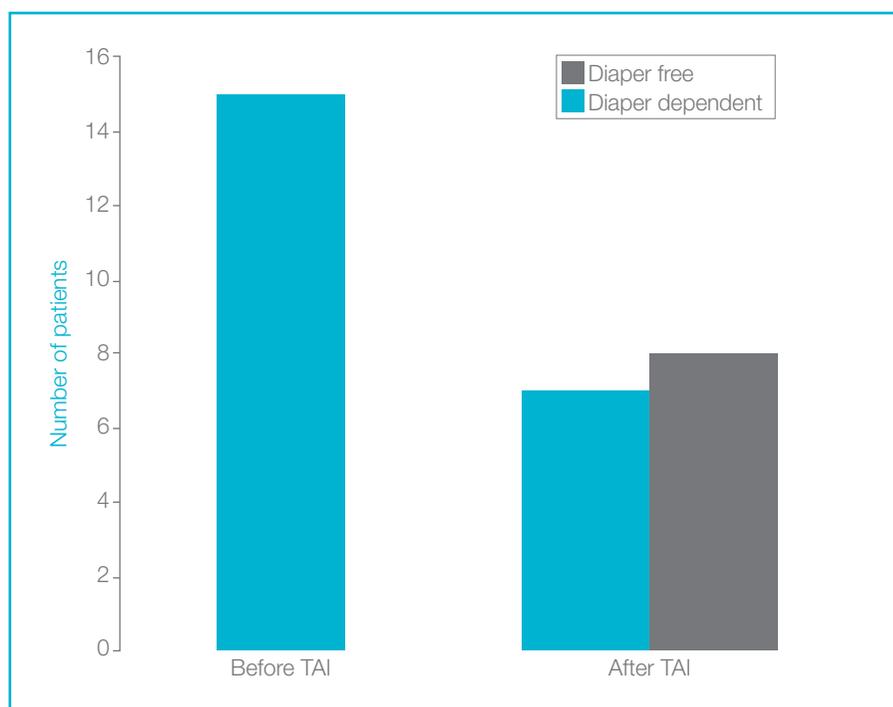
Patients with neuropathic bladder and bowel dysfunction intended for reconstructive bladder surgery and the Malone Antegrade Continence Enema (MACE) procedure were started on Peristeen at least 3 months prior to their surgery

Patients:

- 18 patients aged 4–15 years, 11 female and 7 male
- The mean post-operative follow-up was 43.4 months

Key efficacy data:

- 15 of the 18 patients responded successfully to treatment with Peristeen
- The responding patients used Peristeen once weekly (n=1), twice weekly (n=10), and three times weekly (n=4)
- Of the non-responders, poor response to Peristeen was typically due to non-compliance, where patients and caregivers were not comfortable using the TAI system or were not satisfied with its results
- The 15 responders received bladder surgery and continued with Peristeen resulting in:
 - Continued treatment satisfaction
 - 8 of the 15 patients were no longer diaper dependent
 - 6 patients continued with diapers due to fear of incontinence and 1 patient continued with diapers due to continued urinary incontinence



- Of the non-responders
 - 2 patients were treated with MACE; in one patient stool soiling was resolved, in the other patient MACE did not resolve symptoms
 - 1 patient refused surgery

Key safety data:

- 4 of the responding patients reported mild abdominal discomfort which subsided when the irrigation volume was reduced
- No serious adverse events were reported when performing TAI with Peristeen

Conclusions:

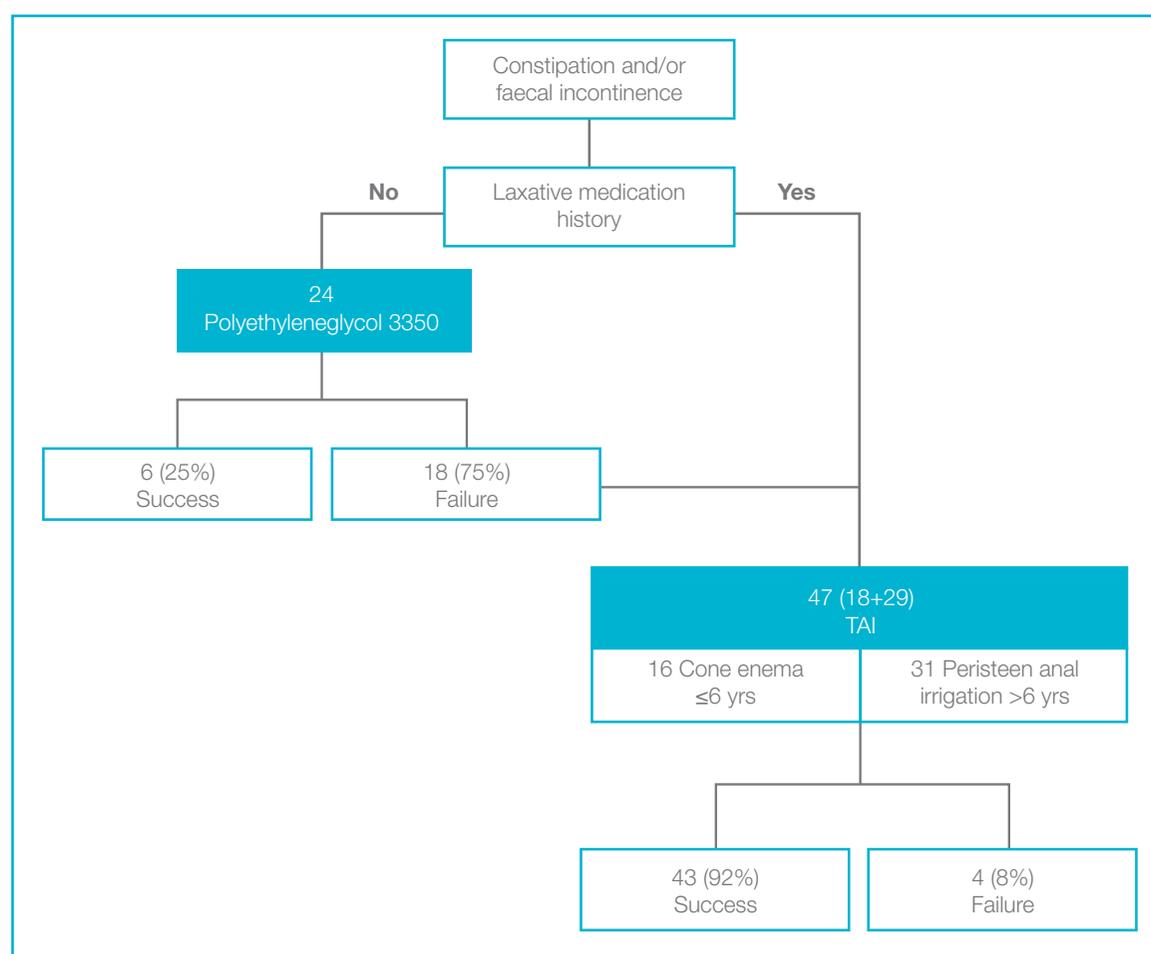
- Peristeen is an effective, conservative substitute for the MACE procedure in children with neurogenic constipation/faecal incontinence who require reconstructive bladder surgery
- Peristeen is an option that should be discussed before MACE reconstructive surgery is considered

The effects of transanal irrigation as a stepwise bowel management program on the quality of life of children with spina bifida and their caregivers⁶

Choi EK, et al. *Spinal Cord* 2013;51:384–388

Intervention:

A stepwise bowel management programme, where patients with no history of laxative use were treated with laxatives and treatment was continued unless it was deemed to have failed. Upon laxative treatment failure patients were treated with TAI. If patients had a history of laxative use at the start of the study they were directly treated with TAI. TAI was either administered with Peristeen, or Cone enema (Cone was typically used in younger patients)



Study design:

This was a prospective study where paediatric patients with spina bifida and either chronic constipation or unsatisfactory bowel management were treated with a stepwise bowel management programme. Patients and/or caregivers completed a self-reported questionnaire at the beginning and end of the study

Patients:

- Of the 53 patients included, 27 were male, 26 were female
- 28 patients were born with meningomyelocele and 25 with lipomeningomyelocele
- The median age was 5.4 years (range 3–13.8 years)
- The median duration of the programme was 4 months (range 3–7.3 months)
- At study start, 34 patients were using manual extraction/digital stimulation, 8 patients were using laxatives and 19 were using suppositories

Key efficacy data:

- 6 (11%) children were successfully treated with laxatives and did not undergo TAI
- Of the 47 children who were treated with TAI, treatment was successful for 43 (92%) patients
- Measures of clinical efficacy and QoL were significantly improved following the stepwise bowel management programme; for example, diaper changes were reduced from 1.6 to 0.2 per day (P=0.001) and faecal incontinence episodes were reduced from 6.9 to 0.5 per week (P=0.004)

	Before	After	P value
Clinical efficacy:			
Frequency of bowel movements, days	1.7±1.7	2.5±1.1	<0.001
Bristol stool form scale	2.0±1.7	3.0±1.5	0.008
Bowel care time per day, minutes	27.0±24.1	15.9±7.8	0.003
Frequency of diaper change per day	1.6±1.7	0.2±0.4	0.001
Frequency of faecal incontinence per week	6.9±8.1	0.5±0.7	0.004
QoL (the range of score)*:			
Travel and socialisation (0–32)	23.5±3.2	9.3±1.4	0.006
Caregiver support and emotional impact (0–18)	12.7±3.6	9.0±3.3	<0.001
Family relationships (0–12)	3.9±2.8	2.1±2.1	0.265
Financial impact (0–6)	1.7±1.2	1.0±0.7	0.071

*A high score indicates a poor QoL.

Key safety data:

- Safety was not specifically assessed in this study. However, the investigators concluded that TAI with Peristeen was a safe treatment for chronic constipation or unsatisfactory bowel function

Conclusions:

- Most children in this study required regular TAI to improve constipation and faecal continence. Laxatives alone were generally ineffective
- An individualised approach to bowel management in patients with NBD related to spina bifida is required
- TAI is an effective and recommended method for the treatment of neurogenic constipation and faecal incontinence in patients with spina bifida
- There was also a significant decrease in caregiver feelings of bothersomeness, depression and anxiety following the stepwise bowel management programme

NOTE:

A 3 year follow-up of this cohort of 47 children initiated on TAI was published by the authors in 2014.¹⁵

- 3 patients were lost to follow-up, leaving 44 children available for evaluation
- Of these 44 children, 38 (86%) were still using TAI. The improvements in faecal continence, diaper change, time spent and quality of life were sustained in time after 3 years of use

Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children¹⁰

Corbett P, et al. *J Pediatr Urol*.2014 Apr;10(2):219-22.

Intervention:

TAI with Peristeen

Study design:

Retrospective case note review and assessment using a validated QoL questionnaire to determine pre- and post-Peristeen bowel function and continence

Patients:

- 24 patients (13 male) aged 4 years and over (mean age 6 years [range 4–16 years])
- Median duration of follow-up after TAI, 1 year (range 2 months–4 years)
- Patients had faecal incontinence due to neuropathic bowel (n=15), anorectal malformation (n=5) or Hirschsprung's disease (n=4)
- Patients were previously using oral and/or rectal medications (22 of 24)
- 22 of 24 children were regularly using pads

Key efficacy data:

	Before Peristeen		Using Peristeen		P value
	Median	Range	Median	Range	
Stool frequency (per day)	3	0.5–18	1	0.3–5	0.0036
Soiling incidents (per week)	14	1–126	1	0–28	<0.0001
Proportion of bowel motions in toilet (%)	20	0–100	100	20–100	<0.0001
Time attending to bowel habit (min/day)	75	20–210	35	5–90	<0.0001
QoL score*	40.5	15–56	51.5	30–60	<0.0001

*A higher score indicates a better QoL.

- Bowel functional outcomes and QoL scores (reported by the primary carer for 20 patients) were significantly improved after using Peristeen compared with before treatment with Peristeen
- 21 patients used Peristeen for longer than 2 months and 19 (79%) continued to use Peristeen at the time of writing the published article
- Of the 19 children still using TAI at the time of writing, 9 (47%) were completely free of pads (1 child was free of pads before starting the regimen)
- 7 of the 19 children (37%) continued to take oral/rectal medications in conjunction with their TAI to regulate bowel habit compared with 92% of children taking oral/rectal medications before starting TAI
- Of the 19 patients still using TAI who completed the survey, 3 (16%) were using Peristeen entirely independently

Key safety data:

- There were no significant adverse events
- 5 of the 24 patients discontinued treatment due to non-serious adverse events

Conclusions:

- Peristeen improved functional outcomes and QoL in the majority of children
- Using Peristeen more than halved the time attending to bowel habit
- Soiling incidents and stool frequency significantly reduced with Peristeen
- Peristeen TAI is a safe and effective method of improving bowel management in children with a range of underlying disorders

Transanal irrigation and intestinal transit time in children with myelomeningocele⁷

Marte A and Borrelli M. *Minerva Pediatr* 2013;65:287–293

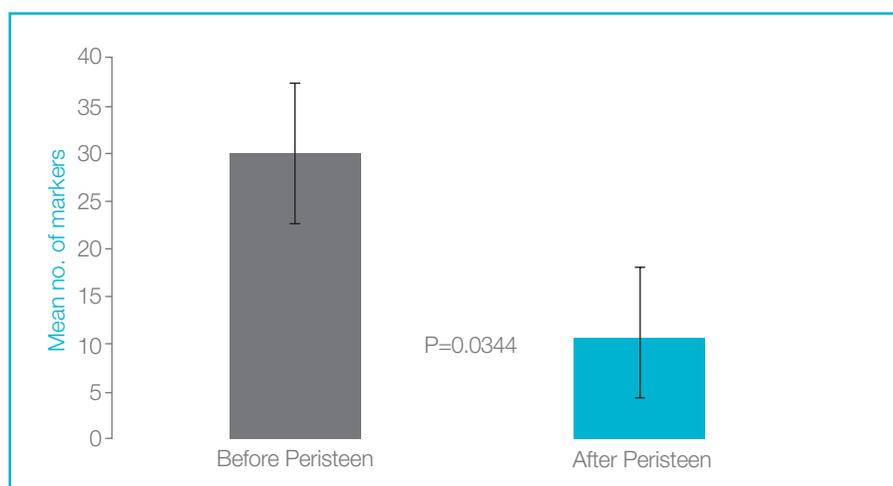
Intervention:

Patients were administered 30 radio-opaque markers in three doses (10 circles, 10 cubes, 10 cylinders) taken at intervals of 24 hours. After 72 hours patients underwent abdominal X-ray and then voided their bowels using Peristeen. Patients then underwent a second abdominal X-ray. Patients were then followed up by bi-monthly clinical assessments and phone interviews

Patients:

- 16 patients aged 4–17 years, with chronic constipation associated with myelomeningocele that did not respond satisfactorily to conventional bowel management

Key efficacy data:



- Treatment with Peristeen significantly ($P=0.0344$) reduced the number of markers present in the bowel
- The number of markers in the bowel after Peristeen ranged from 2–25 (compared with 30 before Peristeen)
- The patients who continued treatment ($n=15$) reported being satisfied with Peristeen and reported improvements in their social life

Key safety data:

- The number of UTIs decreased significantly following treatment with Peristeen
- After a median follow-up of 3 years (mean 1.8 years) only 1 patient discontinued Peristeen due to family problems
- Some younger patients reported mild abdominal pain during the procedure
- No serious adverse events were reported during this study

Conclusions:

- Peristeen is an effective treatment to promote intestinal emptying in paediatric patients with chronic constipation related to myelomeningocele resistant to conventional treatment

Transanal irrigation in myelomeningocele children: an alternative, safe and valid approach for neurogenic constipation¹¹

Ausili E, et al. *Spinal Cord* 2010;48:560–565

Intervention:

Patients with myelomeningocele and neurogenic constipation were treated with Peristeen TAI for 3 months

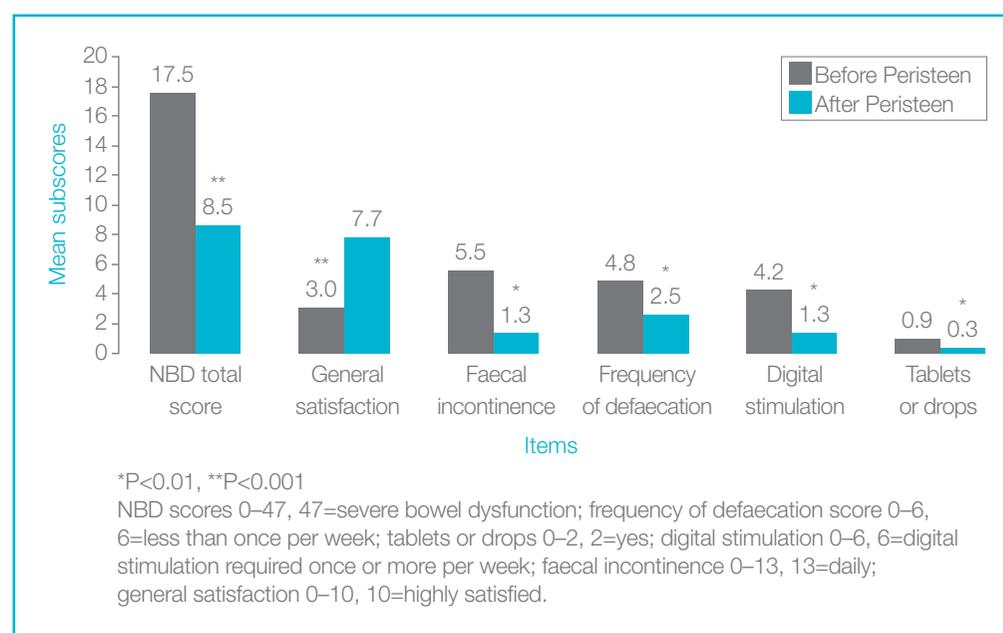
Study design:

This was a prospective study including children with myelomeningocele and neurogenic constipation. The study was divided into two phases: Phase 1, where the patients were enrolled into the study and monitored to confirm that they met the inclusion criteria and Phase 2, where patients were trained to use Peristeen

Patients:

- 60 patients, 31 male and 29 female, completed the study
- The patients were aged 7–17 years, with a mean age of 12.5±3.1 years
- All patients underwent neurosurgical intervention for neural tube defect repair within 24 hours of birth
 - In most patients the lesion was lumbosacral (n=39), or sacral (n=16)
 - The lesion was thoracic in the remaining (n=5) patients
- 31 patients were wheelchair bound, 10 patients could walk using an aid and 19 patients could walk unaided

Key efficacy data:



- Faecal incontinence decreased and bowel habits were improved after Peristeen
- Patients and parents reported improved QoL and satisfaction
- NBD total and individual scores were significantly improved following 3 months' treatment with Peristeen
- The use of laxatives and manual extraction decreased significantly during the study (Table)
- The number of UTIs also significantly decreased during the study (Table)

	Before the trial	During the trial	P value
Manual extraction	25/60	4/60	<0.01
Suppositories/enemas	18/60	5/60	<0.01
Laxatives	17/60	5/60	<0.01
Episodes of faecal incontinence	16/60	4/60	<0.01
UTIs (due to <i>E. coli</i>)	14 (9)	6 (3)	<0.01

Key safety results:

- There were no severe adverse events reported during the study
- The most frequently reported adverse event, anorectal pain, was more frequently reported in younger patients (6 of the 8 patients were aged <10 years)

Conclusions:

- Peristeen is an effective method to manage neurogenic constipation in patients with myelomeningocele. Improvements were noted in:
 - Bowel disturbances
 - The frequency of faecal incontinence
 - QoL

Transanal irrigation for the treatment of neuropathic bowel dysfunction¹³

López Pereira P, et al. J Pediatr Urol 2009;6:134–138

Intervention:

TAI with Peristeen

Study design:

Prospective study (mean follow-up 12 months [range 4–18 months])

Patients:

- 40 children and young adults with spina bifida and NBD that did not respond satisfactorily to conservative bowel management. 35 of them completed the questionnaire and were included in the study. Their mean age was 12.5 years (range 6-25 years)

Key efficacy data:

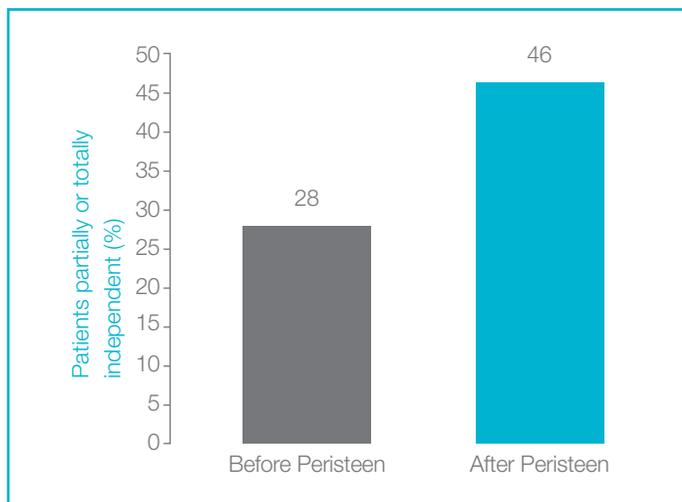
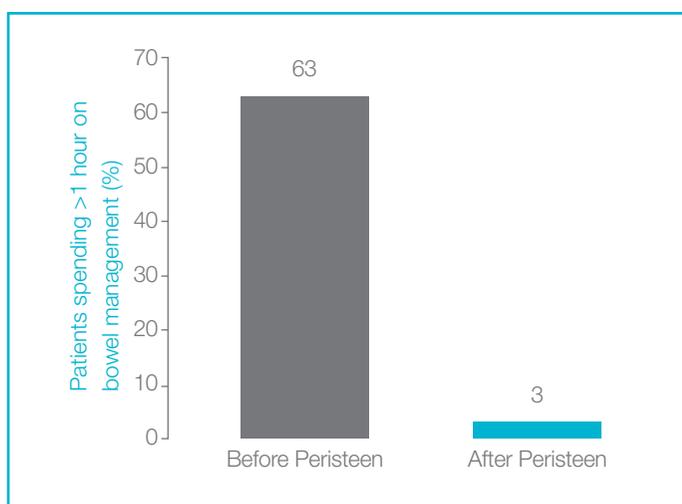
- Peristeen reduced the total time spent on bowel management; before Peristeen, 63% of children spent >1 hour; with Peristeen, this was reduced to 3%
- Independence was improved with Peristeen; before Peristeen, 28% of patients were partially or totally independent in terms of bowel evacuation; with Peristeen, 46% were partially or totally independent
- Peristeen significantly improved patients' opinion of intestinal functionality ($P<0.0001$)
- In the 35 patients who completed the study, there was a significant improvement in symptoms of bowel dysfunction while using Peristeen
- Peristeen significantly reduced:
 - Difficulty and/or pain during defaecation ($P<0.005$)
 - Feeling of incomplete evacuation ($P<0.0001$)
 - Leakage of faeces ($P<0.0001$)
 - Abdominal pain or discomfort before or after defaecation ($P<0.0001$)
 - Sweating or headache during or after defaecation ($P<0.05$)

Key safety data:

- No adverse events were reported

Conclusions:

- Peristeen is an effective therapeutic approach in children and youths with spina bifida and NBD
- After changing from conservative bowel management to Peristeen, patients experienced significantly reduced symptoms of bowel dysfunction, including faecal incontinence
- Peristeen significantly reduced the total time spent on bowel management, decreasing the proportion of children spending more than an hour on bowel management from 63% to 3%
- Using Peristeen led to greater partial or total independence, reducing the need for assistance with bowel evacuation in children and youths with spina bifida
- No adverse events were reported



Improvements in Incontinence with Self-Management in Patients with Anorectal Malformations¹⁶

Märzheuser S, Karsten K, Rothe K. Eur J Pediatr Surg. 2016 Apr;26(2):186-91

Intervention:

Transanal irrigation with Peristeen, following an individualized schedule and self-management. All patients had a history of unsatisfactory bowel management. TAI with Peristeen was individualized by adjusting the volume of irrigant, developing personal schedules and promoting self-management and self-administration of the irrigations.

Study design:

A prospective study comparing a study group (n=40) using Peristeen with individualized irrigation volumes and schedules and self-management techniques with a control group (n=18) using other irrigation systems different from Peristeen.

All patients were followed up at a minimum of 6 months and 1 year, with further yearly evaluations for up to 4 years in total.

Soiling accidents/week, time needed for irrigation (min/day) and number of irrigations/week were compared before starting with Peristeen and after starting with Peristeen, as well as between the intervention group and the control group.

Patients:

- All patients were recruited from a specialized consultancy for ARM and suffered faecal incontinence/soiling (grade 3 of soiling classified by the Krickbeck continence score)
- Study group: 40 patients aged between 4 and 18 years (mean 10.95 years)
- Control group: 18 patients aged between 6 and 17 years (mean 11.20 years)
- All patients were followed up for at least 1 year. The duration of the use of Peristeen at the time of last evaluation varied from 1 to 4 years (median 3 years)

Key efficacy data:

- In the study group (Peristeen and individualized self-management program), 32 of the 40 patients (80%) were free from symptoms of soiling after 12 months of starting the treatment regime. 6 other patients (15%) were soiling only occasionally (1 to 2 times per week)
- Only 2 patient (5%) in the study group discontinued the treatment with Peristeen and were lost to follow-up after 1 year
- No patient in the study group used other medication or followed a specific diet
- 79% of the patients used Peristeen entirely independently. Those being only partly or completely dependent on caregivers were all younger than 7 years of age
- The study group significantly reduced the number of soiling accidents per week, the time needed for each irrigation and the number of irrigations needed per week, both in comparison to before starting the treatment regime with Peristeen and in comparison with the control group
- These success rates were stable at year 2, 3 and 4 of follow-up

	Before Peristeen®		While using Peristeen		P value
	Median	Range	Median	Range	
Soiling incidents (pr wk)	14	3-84	1	0-2	< 0.001
Time needed for irrigation (min/d)	65	40-125	30	12-60	< 0.001
Irrigations/wk	7	1-21	3	0.7-7	< 0.001

	Study		Control		P value
	Median	Range	Median	Range	
Soiling incidents (pr wk)	1	0-2	3	0-15	< 0.01
Time needed for irrigation (min/d)	30	12-60	58	45-112	< 0.001
Irrigations/wk	3	0.7-7	7	3.5-7	< 0.01

Key safety data:

- Safety was not specifically assessed in this study, but the authors conclude that no serious adverse events related to the Peristeen use were reported and that there were no adverse events associated with the use of tap water
- Of the 40 patients, 10 (25%) complained of abdominal pain and anal discomfort at the initial procedure, without abandoning the treatment

Conclusions:

- The patients in the study group (using Peristeen and a personalized schedule of self-management) had significantly less soiling accidents, used less time for irrigation and needed less irrigations per week than the control group (using other devices and no personalized schedule)
- 80% of the patients in the study group were completely free from soiling while using Peristeen
- Adherence to the therapy was 95% in the study group, with stable rates after 2, 3 and 4 years
- The high adherence rates may be a consequence of the focus on time saving measures and self-management, with all children and adolescents being encouraged to establish and adjust their irrigation schedules consciously and according to their personal needs
- 79% of the patients in the study group performed the irrigation with Peristeen entirely independently

Peristeen® transanal irrigation in paediatric patients with anorectal malformations and spinal cord lesions: a multicentre Italian study¹⁷

Midrio P , Mosiello G. et al. *Colorectal Dis.* 2016 Jan;**18(1)**:86-93. doi: 10.1111/codi.13101

Intervention:

Transanal irrigation with Peristeen in children with bowel dysfunction secondary to spinal cord injury/spina bifida (SCL) or anorectal malformations (ARM).

Study design:

A prospective multicentric study in 8 Italian academic tertiary hospitals with a 3 months follow-up period. Assessment at beginning of treatment (T0) and after 3 months using Peristeen (T1) was made using:

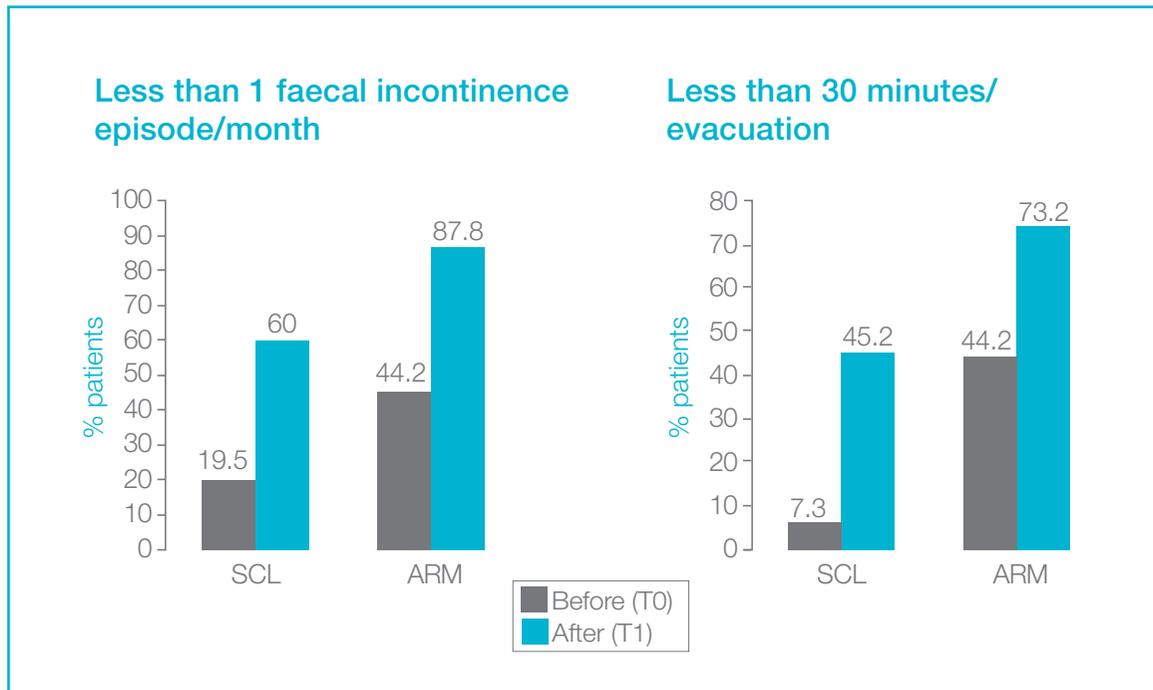
- The Bristol stool scale
- A questionnaire assessing bowel function in children, developed by the investigators
- Quality of life (QoL) questionnaire: CHQ-pf50 for the parents of patients aged 6-11 years, or SF36 for patients aged 12-17 years (completed by the patient)
- Patients were trained to use Peristeen by specialized nurses and a medical doctor. The volume of water used to start the treatment was 10/20 ml/kg, and the frequency of irrigation was every day for the first week and then three times a week in the remaining weeks

Patients:

- 83 patients were enrolled in the study period, of whom 5 were excluded owing to difficulty in obtaining the device through the National Health System, leaving 78 patients who participated in the study; 41 with anorectal malformations (ARM) and 37 with spinal cord injury/spina bifida (SCL)
- The mean age was 11.3 years for the ARM group, and 14.2 years for the SCL group
- The gender distribution was 28/41 (68%) male in the ARM group, and 13/37 (35%) male in the SCL group
- The inclusion criteria for both groups included age from 6 to 17 years, weight above 20 kg and the need for mechanical emptying of the colon and/or unsatisfactory bowel management

Key efficacy data:

- At the end of the 3 months trial, the Bristol tool scale improved in both the ARM and SCL patient groups. At T0, hard stools (type 1 and type 2) were reported in 47.5% and 77.5% of the ARM and SCL patients respectively. At T1, hard stools were recorded by 0% of the ARM and 2.5% of the SCL patients
- Fecal incontinence (FI) recorded in the bowel function questionnaire was reported in 50% of ARM and 39% of SCL patients at start of the trial. At 3 months of follow-up, it was reported by 18.6% and 9.8% of patients respectively
- Constipation was the most common symptom at T0 (69% of ARM and 93% of SCL). At T1 it was reduced to 50% and 39%, respectively
- Use of laxatives at T0 was reported by 31% of ARM patients and 48.8% of SCL patients. At T1 the reported use of laxatives was reduced to only 7% of ARM and 5% of SCL patients
- A significant improvement in time spent on bowel evacuation was observed in both groups
- Quality of life in patients 6-11 years (using CHQ-pf50 score) improved for both ARM and SCL patients in aspects such as global health, bodily pain/discomfort or social limitations. QoL increased more in the SCL patients, with significant increases in 9 of the 15 items evaluated
- Quality of life in patients 12-17 years (using SF36 questionnaire) was significantly improved in the SCL patient group in 9 of the 10 items evaluated in the questionnaire, including overall physical and mental components. The same was not observed in the ARM group, where increases were recorded in 9 of the 10 items, but only reached statistical significance in the physical component of QoL



Key safety data:

- Treatment with Peristeen was safe and no severe adverse events were recorded.
- Complications were related only to minor problems. The most common complications were leakage during irrigation (in 21% and 17% of ARM and SCL patients, respectively) and balloon expulsion (21% and 10% of ARM and SCL patients, respectively)

Conclusions:

- First multicentre trial in children with bowel dysfunction due to either spinal cord lesions (congenital or acquired) or anorectal malformations
- Bowel dysfunction improved at 3 months follow-up in a high proportion of patients. Peristeen is significantly effective in reducing constipation in patients with ARMs and SCL by a factor of 3 and 2, respectively
- QoL improved in both groups, with larger improvements in the SCL group
- Time spent on bowel evacuation was reduced in both patient groups
- All 78 patients completed the 3 months of trial and there were no drop-outs, but other 5 patients had to be excluded due to lack of access to the product

Transanal irrigation in the treatment of children with intractable functional constipation¹⁸

Koppen I.J.N, Kuizenga-Wessel S., Voogt H.W, Voskeuil M.E, Benninga M.A. JPGN (J Pediatr Gastroenterol and Nutr). Accepted April 2016 (e-pub ahead of print).

Intervention:

Transanal irrigation with Peristeen® in children with intractable functional constipation (FC).

Study design:

A cross-sectional survey study among parents of children (until 18 years of age) treated with Peristeen for intractable functional constipation (with or without faecal incontinence) at a tertiary referral center for paediatric defecation disorders in the Netherlands. Anonymous surveys sent by mail between March and October 2014 and consisting of 25 multiple-choice questions regarding:

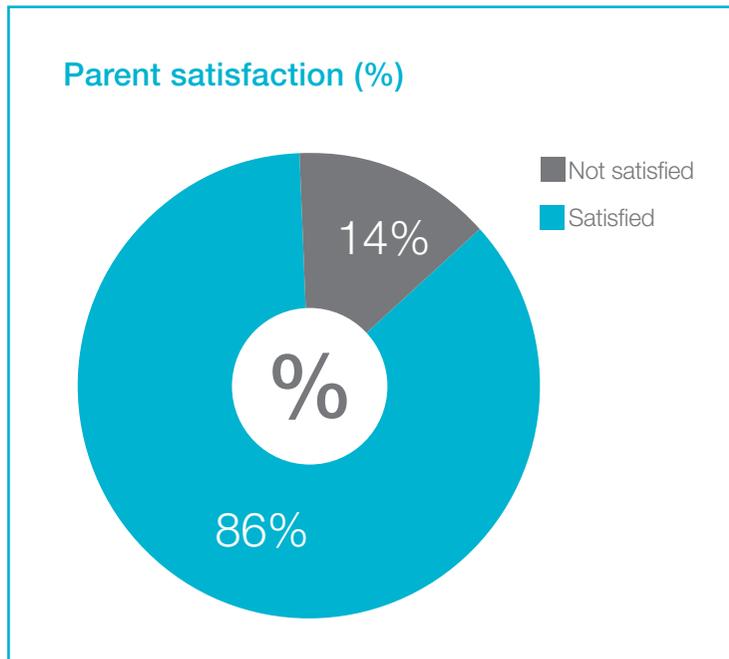
- The use of Peristeen
- Gastrointestinal symptoms
- Adverse events
- Concomitant medication use
- Parental satisfaction

Patients:

- 91 families of children with FC fulfilled the Rome III criteria, based on clinical assessment. 67 (74%) responded to the survey
- In all children, TAI with Peristeen was initiated when they were no older than 18 years of age
- All patients had previously failed intensive pharmacological treatment
- The majority of children (84%) suffered from faecal incontinence before initiating treatment with Peristeen
- The median age at the time of survey was 11.2 years (range 4-19). 55% were male
- The median duration of symptoms was 7 years

Key efficacy data:

- At the time of survey, children had used Peristeen for a median of 11 months (range 1 month-3 years)
- Of those children whose parents responded the survey, 73% were still using Peristeen at the time of the study. Another 6% were in remission of their symptoms and hence did not need Peristeen anymore
- Tap water alone was used by the vast majority of children (78%), with 20% reporting the addition of laxatives to the irrigation water and 1 patient reporting use of saline solution for irrigation with Peristeen
- Out of those still using Peristeen at the time of survey, faecal incontinence had resolved in 41% and 12% suffered from infrequent episodes (<1 episode per week)
- 72% of parents reported that Peristeen was an improvement in the management of their child's symptoms compared to the previous treatments used
- A large majority of the parents (86%) reported to be satisfied with Peristeen



Key safety data:

- 42% of children reported having experienced pain during rectal irrigation
- No severe adverse events were reported by the participants of the study

Conclusions:

- Peristeen can be a feasible and effective bowel management method for children with intractable functional constipation, also those with concomitant faecal incontinence
- Overall, parental satisfaction was high (86%) and 72% of parents considered Peristeen an improvement compared to the previous treatment
- The most common adverse event was pain. No severe complications or side effects were reported
- At the time of publishing (May 2016), this study describes the largest population of children with FC using transanal irrigation

Prospective evaluation of Peristeen Transanal Irrigation System with the validated Neurogenic Bowel Dysfunction Score sheet in the pediatric population²⁰

Kelly M.S, Dorgalli C, McLorie G, Khoury A.E. *Neurourol Urodyn* 2016 Feb 16. Epub ahead of print

Intervention:

Transanal irrigation with Peristeen (20 ml/kg of tap water, daily irrigation).

Study design:

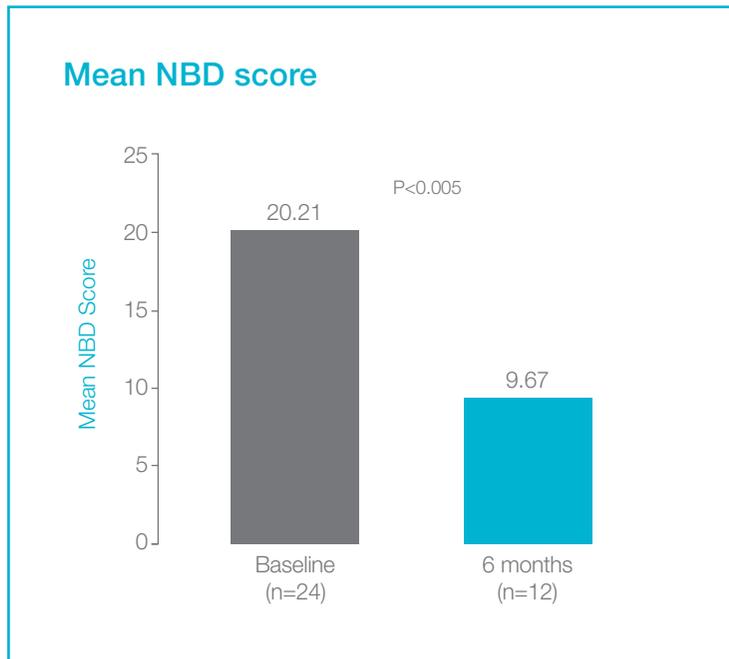
Patients were evaluated prospectively at baseline and after 2 weeks, 2 months and 6 month of starting treatment with Peristeen. The clinical efficacy of the treatment was measured by changes in the score of the neurogenic bowel dysfunction (NBD), a validated score in the pediatric population with spina bifida.²¹ The score consists of 15 questions with a maximum score of 60 points. A score above 8.5 is associated with neurogenic bowel dysfunction.

Patients:

- 24 patients were enrolled at baseline
- Mean age was 10.5 years (range 3-21 years), all with a diagnosis of spina bifida
- Inclusion criteria included: faecal incontinence at least monthly, spending more than 30 minutes daily on their current bowel regime and having regular constipation
- All patients included had a history of unsuccessful current bowel regime. 16 of the 24 patients (67%) were using a cone enema prior to starting Peristeen. Other methods such as stool softeners or mini-enemas were used by a smaller proportion of the children prior to starting the new treatment with Peristeen
- Mean NBD score at baseline for the 24 patients was 20.21 (\pm 5.56)

Key efficacy data:

- After 2 weeks of use, the mean NBD score in the 24 patients had decreased significantly by 7.46 points (95% CI 5.07-9.48) ($p < 0.0005$)
- After 6 months of daily use, the mean NBD score had decreased on average by 8.83 points (95%CI 5.39-12.28, $n=12$, $p < 0.005$) versus baseline score. The mean score at this point was 9.67 points
- Only 12 of the 24 children could attend the follow-up. Most common reasons for lack of follow-up was difficulty coming to the appointments or disconnected phone lines
- It was however possible to contact all 24 children and their families at a later stage. All 24 were still using Peristeen at least once every third day. The NBD score of these children was not included in the results due to the variable follow-up period



Key safety data:

- Safety was not evaluated in this study

Conclusions:

- Already after 2 weeks of daily use, Peristeen decreased the mean average NBD score by 37%
- Overall the scores at 6 months still showed significant decrease versus baseline
- Due to difficulty with the timing of follow-up, only half of the patients were evaluated at 6 months
- At a later contact, it was verified that all 24 patients were still using Peristeen at least once every third day
- The results seem to support previous studies carried out in adults with spinal cord injury in whom Peristeen has been found to improve neurogenic bowel function scores

TAI with Peristeen®

for the management of bowel dysfunction in paediatric patients:

Summary of benefits

	Reference
Peristeen is well tolerated and effective in children with various conditions and/or associated anomalies with no serious adverse events	6, 10, 11, 13, 14, 15
Peristeen significantly improved bowel function and faecal continence	6, 9, 11, 13, 17
Peristeen should be considered as an effective alternative to surgical intervention for the treatment of chronic constipation/faecal incontinence in paediatric patients who are resistant to conservative therapy	7, 9, 10, 13, 18, 20
QoL and socialisation of children and caregivers were significantly improved with Peristeen	6, 11, 15, 17
Some (typically older) children are able to self-administer Peristeen, allowing them independence from their parents/caregivers	1, 9, 14
Peristeen has the potential to free children from the need to wear diapers	9
Peristeen is effective in patients from a young age (>2 years)	14
Peristeen significantly reduced the amount of time that patients and caregivers spent on bowel management	10, 13, 15, 17
UTIs were significantly reduced in patients treated with Peristeen	7, 11

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Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 10,000 people.