



## META-ANALYSIS

# Ostomy continence devices: a systematic review of the literature and meta-analysis

Justin Dourado<sup>1</sup> | Zoe Garoufalia<sup>1</sup> | Sameh Hany Emile<sup>1,2</sup> | Anjelli Wignakumar<sup>1</sup> |  
 Pauline Aeschbacher<sup>3,4</sup> | Peter Rogers<sup>1</sup> | Zachary Delgado<sup>1</sup> | Matthew Greer<sup>1</sup> |  
 Steven D. Wexner<sup>1</sup>

<sup>1</sup>Ellen Leifer Shulman and Steven Shulman  
 Digestive Disease Center, Cleveland Clinic  
 Florida, Weston, Florida, USA

<sup>2</sup>Colorectal Surgery Unit, General Surgery  
 Department, Mansoura University  
 Hospitals, Mansoura, Egypt

<sup>3</sup>Department of General Surgery and  
 Bariatric and Metabolic Institute,  
 Cleveland Clinic Florida, Weston, Florida,  
 USA

<sup>4</sup>Department for Visceral Surgery and  
 Medicine, Bern University Hospital,  
 University of Bern, Bern, Switzerland

### Correspondence

Steven D. Wexner, Ellen Leifer Shulman  
 and Steven Shulman Digestive Disease  
 Center, Cleveland Clinic Florida, 2950  
 Cleveland Clinic Blvd, Weston, FL 33331,  
 USA.

Email: [wexners@ccf.org](mailto:wexners@ccf.org)

### Abstract

**Aim:** Colostomy complication rates range widely from 10% to 70%. The psychological burden on patients, leading to lifestyle changes and decreased quality of life (QoL), is one of the largest factors. The aim of this work was to assess the history and efficacy of ostomy continence devices in improving continence and QoL.

**Method:** In this PRISMA-compliant systematic review and meta-analysis, we searched PubMed, Scopus, Google Scholar and [clinicaltrials.gov](https://clinicaltrials.gov) for studies on continence devices for all ostomies up to April 2023. Primary outcomes were continence and improvement in QoL. Secondary outcomes were leakage, patient's device preference and complications. Risk of Bias 2 and the revised tool to assess risk of bias in non-randomized studies of interventions (ROBINS-1) were used to assess risk of bias. Certainty of evidence was graded using GRADE.

**Results:** Twenty-two studies assessed devices from 1978 to 2022. The two main types identified were ball-valve devices and plug systems. Conseal and Vitala were the two main devices with significant evidence allowing for pooled analyses. Conseal, the only currently marketed device, had a pooled rate of continence of 67.4%, QoL improvement was 74.9%, patient preference over a traditional appliance was 69.1%, leakage was 10.1% and complications was 13.7%. Since 2011, five studies have investigated experimental devices on both human and animal models.

**Conclusion:** Ostomy continence has been a long-standing goal without a consistently reliable solution. We propose that selective and short-term usage of continence devices may lead to improved continence and QoL in ostomy patients. Further research is needed to develop a reliable daily device for ostomy continence. Future investigation should include the needs of ileostomates.

### KEYWORDS

colostomy, meta-analysis, ostomy continence devices, systematic review

This is an open access article under the terms of the [Creative Commons Attribution](https://creativecommons.org/licenses/by/4.0/) License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2024 The Authors. *Colorectal Disease* published by John Wiley & Sons Ltd on behalf of Association of Coloproctology of Great Britain and Ireland.

## INTRODUCTION

An ostomy is a surgically created opening from an internal hollow organ to the outside of the body. The term 'ostomy' is often used interchangeably with the term 'stoma' [1, 2]. Ostomies are formed by exteriorizing the bowel to the abdominal wall for a variety of gastrointestinal pathologies including colorectal cancer and inflammatory bowel disease. The reported prevalence of individuals in the United States living with an ostomy ranges from 725 000 to 1 000 000. It is estimated that approximately 100 000–150 000 ostomy surgeries are performed each year [3–5]. Ostomies, while often necessary and lifesaving, are unfortunately associated with a multitude of complications, with complication rates ranging from 10% to 70% [6–8]. Common complications include peristomal skin complications, hernias, high-output ostomies, ostomy necrosis and ostomy stenosis [9]. Additionally, one of the most prominent complications of ostomy creation is the large psychological burden that ostomies place on patients. Patients often live in fear of leakage, flatus and embarrassment from their device and its function. Because of these fears, patients often make significant changes to their daily lives, including limiting their public and social activities [2, 10].

Although ostomy-related complications are relatively common, they can be mitigated through various strategies. One of the most common ostomy complications, skin irritation around the ostomy site [6, 11], can be addressed through a variety of products including bacterial and antifungal creams as well as skin protectants [12]. Furthermore, limiting the changing of the ostomy appliance to every 3–7 days can help prevent skin breakdown [13].

Loss of continence, or the ability to control passage of a bowel movement, places a large psychological burden on patients. Surgeons have attempted to devise surgical solutions to this problem, starting with continent ileostomy, which was first described by Kock in 1969 [14]. This procedure remains viable in select patients for whom ileoanal pouch surgery is not an option or has failed, although it has been noted to have numerous problems that necessitate repeat surgical revisions [15]. There have also been efforts to develop external devices that would allow for control of flatus and stool expulsion, referred to as 'colostomy continence' [16]. The first device, described in 1953, was a 'valvular colostomy plug' [17]. There was a gap in the literature for over 20 years before the next study on ostomy continence devices was published. The aim of the present study was to conduct a systematic review of the literature on the history, evolution and outcomes of ostomy continence devices.

## METHOD

### Registration and reporting

The protocol has been prospectively registered in the PROSPERO register of systematic reviews (CRD42023448348) and is reported according to the PRISMA 2020 guidelines [18]. There was no deviation from the registered protocol when reporting this systematic review.

### What does this paper add to the literature?

Our study is the first systematic review of ostomy continence devices and includes the only quantitative pooled data comparing the outcomes of these devices. Additionally, we propose that selective usage of these devices, rather than continuous use, could lead to improved quality of life and continence in patients with ostomies.

### Search strategy

A systematic search of PubMed, Scopus and Google Scholar was undertaken by two investigators (ZD, ZG) for all available studies on continence devices for all ostomies up to April 2023. The investigators used the following syntax combination of keywords and Boolean operators 'AND' and 'OR' in the literature search: (device OR plug OR appliance) AND (stoma OR ostomy OR ileostomy). Additionally, [clinicaltrials.gov](https://clinicaltrials.gov) was searched for any ongoing trials.

Conference abstracts without a full text were evaluated for their content, and if the abstract contained sufficient information for this review, the study was included. After exclusion of duplicate reports, a stepwise filtration of all remaining articles was undertaken, firstly by title and abstract followed by full-text review of each article by two authors (SE, JD) to confirm eligibility for inclusion and extract relevant data for the systematic review and meta-analysis. The process of literature review and article selection was under the supervision of the senior author (SDW).

### Assessment of risk of bias and certainty of evidence

Three authors (PR, PA, AW) independently assessed the risk of bias in the studies using the revised tool to assess the risk of bias in non-randomized studies of interventions (ROBINS-1) for cohort studies [19] and the risk of bias in randomized trials (RoB 2) for randomized trials [20]. The certainty of the evidence was graded with the GRADE approach as very low, low, moderate, or high [21]. Publication bias was assessed if 10 or more studies met the inclusion criteria.

### Data extraction and study outcomes

Three authors (PR, PA, AW) collected data including publication details (authors, year, location, journal), type of study, number of subjects and the reported outcomes, which included adjuncts used, completeness of continence, episodes of leakage, wearable time range and complications of the device, and patient perception of the device. Data collection was verified by a fourth author (JD). The primary outcomes were continence and improvement in quality of life (QoL) and the secondary outcomes were leakage rate, patient preference for the device and complications.

## Data synthesis

A meta-analysis was conducted using the open-source, cross-platform software for advanced meta-analysis, openMeta [Analyst]<sup>™</sup> version 12.11.14. A proportional meta-analysis was conducted to assess the weighted mean rates and 95% confidence interval (CI) of continence, patient preference, leakage, QoL and complications. Statistical heterogeneity was assessed using the inconsistency ( $I^2$ ) statistic (low if  $I^2 < 25\%$ , moderate if  $I^2 = 25\% - 75\%$ , high if  $I^2 > 75\%$ ). A fixed-effect meta-analysis was used if  $I^2 < 25\%$  and a random-effect analysis was used if  $I^2 \geq 25\%$ . In case of moderate or high heterogeneity a leave-one-out sensitivity analysis was performed to assess for the source of heterogeneity.

## RESULTS

After screening 9754 articles and abstracts, 22 articles and abstracts were ultimately included (Figure 1). There were 21 studies that were classified as a cohort or case series and one prospective randomized study. Thirteen studies were single-centre and nine were multicentric (Table 1, Figure 2). There were no ongoing clinical trials registered. Other findings from the papers included were outside the scope of this systematic review and therefore excluded.

Ostomy continence devices were broadly classified as historical devices, currently available devices and those devices under development in animal models. Overall, the articles were divided into two groups according to the type of continence device: ball-valve devices and plug-based devices. Within the plug devices there were two main products that were studied in the literature, the Conseal (Coloplast S.p.A., Bologna, Italy) colostomy plug system and the Vitala<sup>™</sup> Continence Control Device (CCD) (Convatech, London, UK).

### Ball-valve devices

The first description in the literature of a device for colostomy continence was by Wulff in 1953 [17]. Subsequently, Heilblum and Cordoba investigated an implantable silastic balloon that created a valve effect in six patients [22]. Five patients achieved continence and none of the patients experienced ischaemia of their ostomy. However, one device was removed because of infection.

The method shifted to external devices. In 1983, Pemberton et al. evaluated a balloon-based occlusion device with a valve and found that occlusion of 5–8 h was well tolerated by four patients who achieved continence without impairing intestinal function [23]. Similarly, a study by Hadidi [24] in 2006 described a continence device that was used in 18 children ranging from 6 months

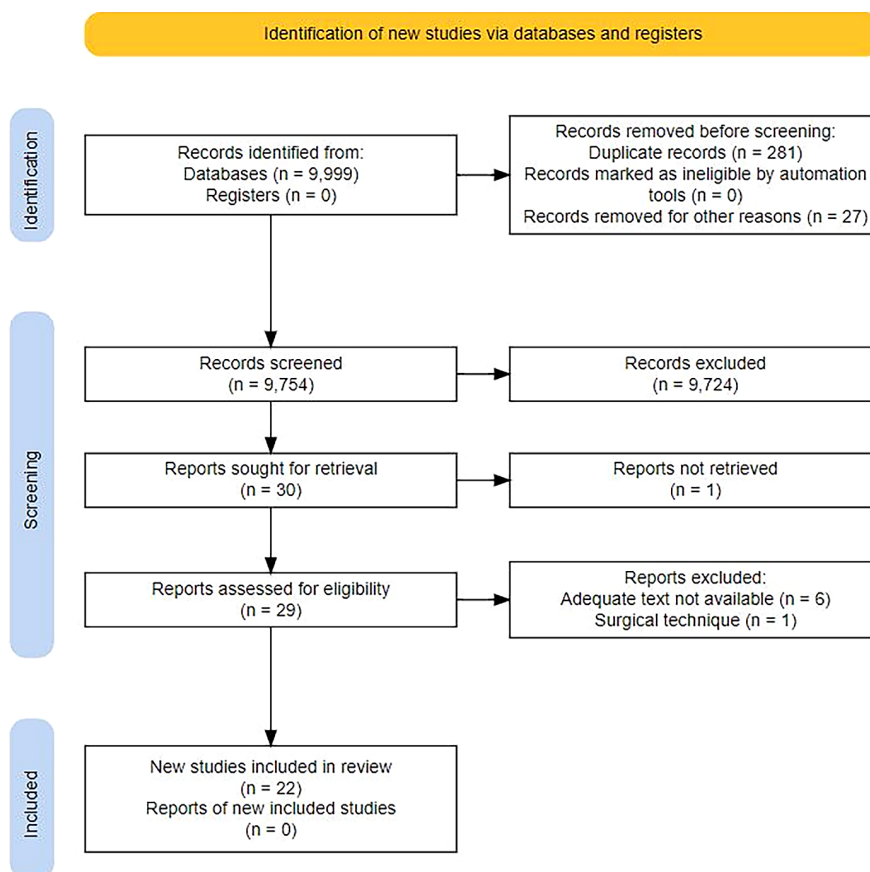
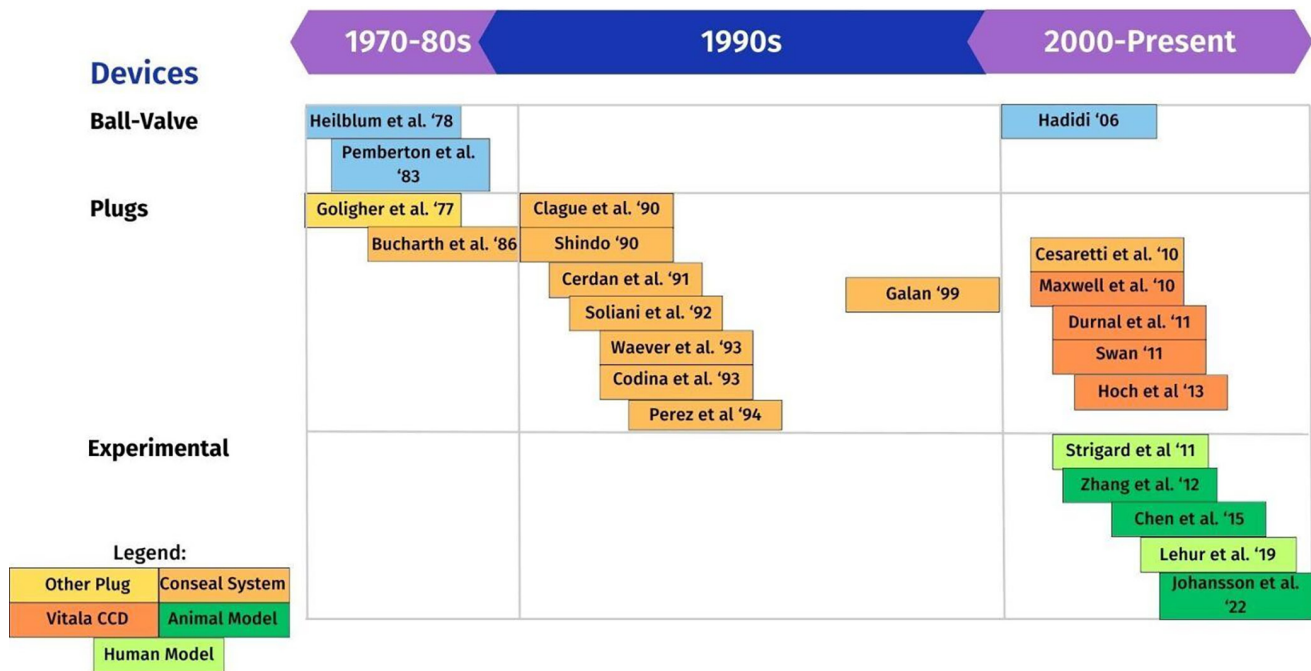


FIGURE 1 PRISMA search flowchart.



# EVOLUTION OF CONTINENCE DEVICES



**FIGURE 2** Evolution of continence devices. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

to 8 years of age, with good results in continence without adverse events. Patients self-inflated a ball with air which acted as a ball-valve at the anorectal junction or an external appliance when used in a colostomy. This study, however, was not exclusive to ostomy patients.

## Plug devices

As with ball-valve devices, there was an initial interest in implantable devices with plug systems. Goligher et al. described their treatment of 22 patients with an implantable magnetic ostomy device which utilized a plug system [25]. Of the 13 patients they assessed, only three (23.1%) achieved improvements in continence.

## The Conseal device

The first of the widely utilized plug systems to enter the market, the Conseal, was investigated in nine studies encompassing 426 patients [26–34]. Proportional meta-analysis showed that the Conseal device was associated with a 67.4% (95% CI 0.305–1.044,  $I^2=97.3\%$ ) rate of continence and 69.1% (95% CI 0.530–0.851,  $I^2=88.5\%$ ) of patients preferred the device to traditional pouching (Figure 3). Leave-one-out analyses of continence were performed, and when the study by Soliani et al. [31] was excluded the pooled continence rate increased from 67.4% to 83.6%. Leave-one-out analysis of device preference

revealed no significant change in the preference rates when each study was excluded as the rates ranged from 66.3% to 76.6%.

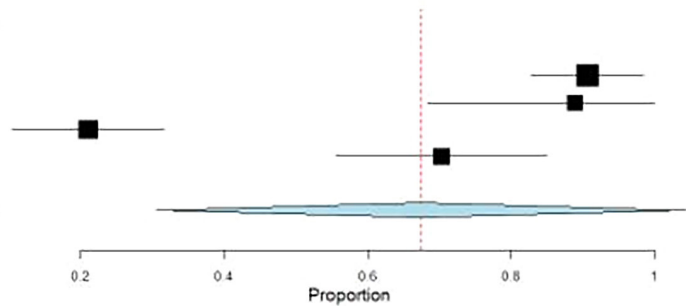
The weighted mean rate of leakage was 10.1% (95% CI 0.052–0.150,  $I^2=0\%$ ), of QoL improvement 73.9% (95% CI 0.459–1.018,  $I^2=61\%$ ) and of complications 13.7% (95% CI 0.047–0.227,  $I^2=92.03\%$ ) (Figures 3 and 4). Leave-one-out analyses of QoL showed that when the study by Down and Leaper was excluded the QoL improvement increased to 85% [27]. Leave-one-out analyses showed high heterogeneity, in that when the studies by Bucharth et al. [26] and Codina Cazador et al. [33] were left out the complication rate increased to 19.4% and 19.3%, respectively. Conversely, when the study by Clague and Heald [28] was excluded the complication rate dropped to 6.1%. Finally, the average wear time cited in the above studies ranged from 8 to 16.5 h [26, 28, 33].

## The Vitala™ CCD

The other device that was widely studied was the Vitala™ CCD. Four studies encompassing 271 patients were identified in the literature [16, 35, 36]. Two studies had quantitative data for analysis [16, 37]. The Vitala CCD was associated with a 69.3% (95% CI 0.605–0.782,  $I^2=0\%$ ) preference when compared with traditional ostomy appliances. Additionally, the pooled rate of leakage was 3.8% (95% CI 0.002–0.075,  $I^2=0\%$ ) and of complications was 34.1% (95% CI –0.099 to 0.780,  $I^2=96.48\%$ ). The two studies had individual complication rates of 11.5% [16] and 56.4% [37], which accounts for this high

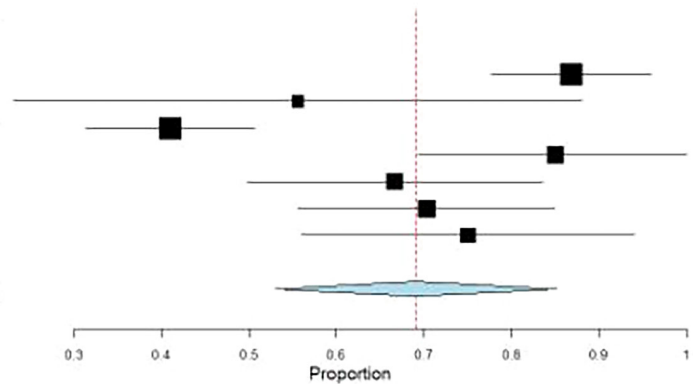
## Continance

Studies	Estimate (95% C.I.)	Ev/Trt
Burcharch 1986	0.906 (0.827, 0.984)	48/53
Down 1984	0.889 (0.684, 1.000)	8/9
Soliani 1992	0.211 (0.105, 0.316)	12/57
Codina 1993	0.703 (0.555, 0.850)	26/37
<b>Overall (I<sup>2</sup>=97.3 %, P&lt; 0.001)</b>	<b>0.674 (0.305, 1.044)</b>	<b>94/156</b>



## Device Preference

Studies	Estimate (95% C.I.)	Ev/Trt
Burcharch 1986	0.868 (0.777, 0.959)	46/53
Down 1984	0.556 (0.231, 0.880)	5/9
Clague 1990	0.410 (0.314, 0.506)	41/100
Cerdan 1991	0.850 (0.694, 1.000)	17/20
Waever 1993	0.667 (0.498, 0.835)	20/30
Codina 1993	0.703 (0.555, 0.850)	26/37
Picon 1994	0.750 (0.560, 0.940)	15/20
<b>Overall (I<sup>2</sup>=88.5 %, P&lt; 0.001)</b>	<b>0.691 (0.530, 0.851)</b>	<b>170/269</b>



## Device QoL

Studies	Estimate (95% C.I.)	Ev/Trt
Down 1984	0.556 (0.231, 0.880)	5/9
Cerdan 1991	0.850 (0.694, 1.000)	17/20
<b>Overall (I<sup>2</sup>=61 %, P=0.109)</b>	<b>0.739 (0.459, 1.018)</b>	<b>22/29</b>

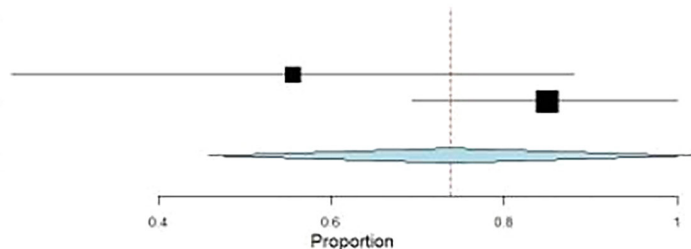


FIGURE 3 Conesal device efficacy.

heterogeneity. Finally, the average wear time of the device in these studies ranged from 6.8 to 11h [35, 36]. A comparison of the outcomes of the Vitala™ and Conesal devices is summarized in Table 2.

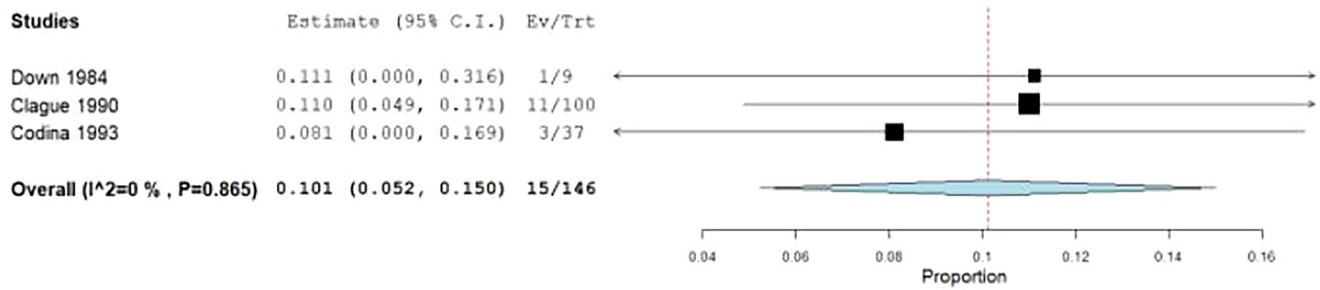
The effect of the Vitala CCD on improving QoL was supported by Swan [35] who combined two case studies with the above study by Durnal et al. [37] in a pooled analysis. Additionally, Hoch et al. [36] compared the Vitala CCD with traditional pouching over a 3-month period in 165 patients. Seventy patients (42%), with a mean age of 62.5 years and with 61.2% being male, used the CCD. It was established that Vitala™ users had a higher health-related QoL score when utilizing the EQ-5D ( $p=0.013$ ) and Stoma Appliance-specific Questionnaire ( $p=0.001$ ). No difference was found in the Stoma Quality of Life Scale. More Vitala users reported 'no problems' on all five EQ-5D domains ( $p=0.01$ ), and indicated that they enjoyed life most of the time ( $p=0.043$ ) when compared with those having a traditional ostomy.

## Experimental devices

### Devices under investigation in humans

There were two studies investigating new devices in human models. Strigård et al. tested a titanium transcutaneous implant evacuation system (TIES), which consisted of a titanium cylinder with a mesh and plastic cap [38], in four patients with inflammatory bowel disease who were having ostomy relocation or pouch excision. Two of the four patients needed minor corrective surgery. There were no device-related complications or safety concerns; however, only two patients were satisfied at 18 months, with one using an ostomy bag over the TIES for extra security. Additionally, Lehur et al. tested a two-piece appliance with a base plate and capsule cap that allowed patient-controlled release of a folded bag in the cap to collect stool [39]. Twenty-three patients completed the 2-week trial: 85.3% of appliance changes were

### Leakage



### Device Complications

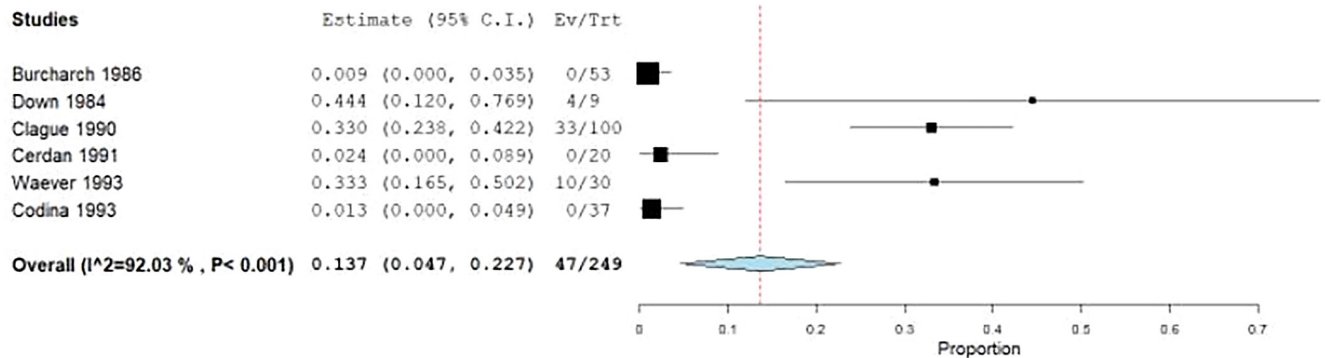


FIGURE 4 Conseal device safety.

TABLE 2 Descriptive comparison of Conseal versus the Vitala™ CCD.

Device	Complications	Continence	Device preference	Leakage	QoL	Wear time (h)
Conseal	0.137 (0.047–0.227)	0.674 (0.305–1.044)	0.691 (0.530–0.851)	0.101 (0.052–0.150)	0.739 (0.459–1.018)	8–16.5
Vitala™ CCD	0.341 (–0.099 to 0.780)	N/a	0.693 (0.605–0.782)	0.038 (0.002–0.075)	N/a	6.8–11

Note: All values except for wear time presented as a pooled rate (95% confidence interval).

Abbreviations: CCD, continence control device; QoL, quality of life.

associated with no leakage whereas there were 69 incidents of leakage; 58.6% of the cap removals associated with increased pressure were manual and 41.06% were spontaneous. Adverse events were recorded in 30% of patients, some of which resolved spontaneously. However, in 13.3% of cases there was skin and subcutaneous tissue reaction which required study discontinuation. There was no difference in QoL compared with normal pouching systems and 43% said they would be willing to use it in the future.

### Devices under development in animal models

Three studies addressed the development of additional continence devices in animal models. Zhang et al. developed an experimental model in miniature Tibetan pigs with the application of different sizes of silicone closure devices (3.0, 3.5 and 4.0cm) [40]. They found that

an occlusion diameter of 0.5–1 cm larger than the colostomy diameter has the best balance of occlusion while limiting infection, ischaemia and necrosis of the ostomy. The second study, by Chen et al., reviewed the efficacy of a pressure-sensing colostomy plug in reduction of faecal leakage in nine miniature Tibetan pigs [41]. They were divided into 5, 10 or 15 mmHg pressure-sensing settings. This device attempts to allow real-time feedback to the user on the pressure within the ostomy as it relates to stool burden and the need for emptying. It was found that at 15 mmHg there was the highest sensitivity for detecting stool with no significant leakage after the first postoperative week. The final study, by Johansson et al., was specific to reservoir ileo- and urostomies and utilized a soft-tissue-anchored percutaneous port in a dog model [42]. Despite subcutaneous portion integration, the study was terminated due to adverse events related to the lack of implant-skin and implant-intestine integration. There were also issues of recurrent superficial infection surrounding the port.

## Risk of bias and certainty of evidence

Bias analyses were completed using the ROBINS-1 and RoB 2 tools (Figures S1 and S2). Two studies had a low risk of bias, 11 studies had moderate risk of bias, eight had serious risk of bias and one did not have enough information to assess bias. Certainty of evidence was very low for all outcomes assessed (Tables S1 and S2).

## DISCUSSION

There have been no previous comprehensive reviews of ostomy continence devices. The present review found that, within the history of ostomy continence devices, two major devices were assessed in several studies that allowed pooling of their outcomes. The Conseal device, developed by Coloplast, was studied over a 24-year period between 1986 and 2010, followed by the Vitala™ CCD, developed by ConvaTec, between 2010 and 2013. The Conseal device is the only device currently available.

Our analysis found that after the advent of ball-valve devices, which did not have much success, the focus transitioned to plug-based devices. When comparing the pooled outcomes of the two main plug-based devices, the Conseal device showed an acceptably low rate of leakage and complications, with rates of continence, device preference and QoL improvement ranging from 67.4% to 73.9%. Additionally, the Conseal device had much fewer complications when compared with the Vitala CCD (13.7% vs. 34.1%). This analysis showed that, when properly used, the Conseal device could provide benefit to ostomy patients with an acceptable risk profile.

It has been shown that leakage is the criterion among ostomy patients that has the highest impact on QoL [43]. Worrying about leakage and changing lifestyle and reported wellbeing has been well documented in ostomy patients [44, 45]. Leakage is prevalent, in that the percentage of patients who report not having episodes of leakage with traditional appliances is <20% [45]. In traditional ostomy patients the Ostomy Life Study showed that 65% of ostomy patients experience leakage outside the baseplate at least once a year and 26% experience it at least monthly [46]. Additionally, they found that only 14% of patients had a leakage event less than once a year [46]. Our analysis showed that the Conseal device was able to reduce the leakage rate down to 10% while maintaining continence, which could represent an advantage.

Among patients with ostomies, a relationship has been shown between frequency of changing the appliance and increased skin complications [13]. It has also been shown that increased worry about leakage leads to more device usage [46]. These two facts, together with the fact that peristomal skin complications occur with an incidence of up to 43% [47], imply a need for a low-leakage device that improves patients' QoL. As previously stated, skin complications are limited with reduced leakage and when ostomy appliances are changed ideally every 3–7 days [13]. The combination of these factors makes the selection of patients who will benefit from

continence devices an important consideration that is likely to have led to their lack of widespread adoption.

The Conseal device showed a good combination of improved QoL and preference over a traditional appliance with wear times of 8–16.5 h, low leakage, and low rates of complications. The authors of this study suggest that continence devices, specifically the Conseal device, could be best utilized in patients with low-output ostomies on an as-needed basis for life events that require increased continence and discretion to improve QoL. However, the daily usage of this device is not recommended after our review, as frequent changes could increase skin complications.

Five experimental devices have been investigated since 2011 in both human and animal models. Both human models utilized an implantable baseplate and a plug system with two animal models using a plug system and one ball-valve system. None of these experimental devices reached optimal satisfaction or complication rates. This result further emphasizes that ostomy continence is relevant to patient care and QoL but a durable and reliable solution is not available.

The limitations of our study are the high heterogeneity, low certainty of evidence and the moderate to serious risk of bias in the included studies. As only one study was a randomized trial, the retrospective and descriptive nature of the studies included, in addition to the large time span over which they were performed, probably accounts for these limitations. To minimize the heterogeneity, leave-one-out analyses were performed. The increased continence after the exclusion of the study by Soliani [31] is probably because this study reported continence over a 48-h period rather than per device usage as reported in the other studies. This led the authors to conclude that the possible increase in continence is more pronounced with shorter wear and selective rather than continuous usage. The increased complications after the exclusion of the studies by Burcharth et al. [26] and Codina Cazador et al. [33] is probably because these studies reported no complications.

## CONCLUSION

Ostomy continence has been a long-standing goal without a reliable daily solution. We propose that the selective and short-term usage of continence devices could potentially lead to improved continence and QoL in patients with ostomies. Further research is needed to develop a reliable daily device for ostomy continence. In addition, continence for ileostomates also requires investigation.

## AUTHOR CONTRIBUTIONS

**Steven D. Wexner:** Conceptualization; project administration; supervision. **Justin Dourado:** Conceptualization; investigation; writing – original draft; methodology; validation; visualization; formal analysis; data curation. **Zoe Garoufalia:** Investigation; data curation; formal analysis; writing – review and editing. **Sameh Hany Emile:** Investigation; writing – review and editing; formal analysis; data curation. **Anjelli Wignakumar:** Investigation; writing – review and editing; formal



analysis; data curation. **Pauline Aeschbacher:** Investigation; writing – review and editing; formal analysis; data curation. **Peter Rogers:** Investigation; writing – review and editing; formal analysis; data curation. **Zachary Delgado:** Investigation; writing – review and editing; formal analysis; data curation. **Matthew Greer:** Investigation; writing – review and editing; formal analysis; data curation.

## FUNDING INFORMATION

None.

## CONFLICT OF INTEREST STATEMENT

Dr Wexner is a consultant for ARC/Corvus, Baxter, Becton, Dickinson and Co, GI Supply, Glaxo Smith Kline, ICON Clinical Research Ltd, Intuitive Surgical, Leading Biosciences/PalisadeBio, Livsmed, Medtronic, Olympus, OstomyCure, Stryker, Takeda, Virtual Ports, is a member of the Data Safety Monitoring Board of JSR/WCG/ACI (chair), Polypoid (chair) and Boomerang, and receives royalties from Intuitive Surgical Karl Storz Endoscopy America Inc., Medtronic and Unique Surgical Solutions, LLC.

## DATA AVAILABILITY STATEMENT

By reasonable request to first author.

## ETHICS STATEMENT

No ethic committee approval was required for this kind of studies (Literature review).

## ORCID

Sameh Hany Emile  <https://orcid.org/0000-0001-7854-5244>

Steven D. Wexner  <https://orcid.org/0000-0001-8046-5753>

## TWITTER

Steven D. Wexner  SWexner

## REFERENCES

- Ambe PC, Kurz NR, Nitschke C, Odeh SF, Möslin G, Zirngibl H. Intestinal ostomy. *Dtsch Arztebl Int.* 2018;115:182–7. <https://doi.org/10.3238/arztebl.2018.0182>
- Ayaz-Alkaya S. Overview of psychosocial problems in individuals with stoma: a review of literature. *Int Wound J.* 2019;16:243–9. <https://doi.org/10.1111/iwj.13018>
- Gleba J, Miller LR, Peck BM, Burgess-Stocks J. United Ostomy Associations of America's Ostomy and Continent Diversion Patient Bill of Rights: an examination of best-in-practice care for ostomy patients. *J Wound Ostomy Continence Nurs.* 2022;49:462–8. <https://doi.org/10.1097/WON.0000000000000909>
- Sheetz KH, Waits SA, Krell RW, Morris AM, Englesbe MJ, Mullard A, et al. Complication rates of ostomy surgery are high and vary significantly between hospitals. *Dis Colon Rectum.* 2014;57:632–7.
- Krishnamurthy DM, Blatnik J, Mutch M. Stoma complications. *Clin Colon Rectal Surg.* 2017;30:193–200.
- Shabbir J, Britton DC. Stoma complications: a literature overview. *Colorectal Dis.* 2010;12:958–64.
- Robertson I, Leung E, Hughes D, Spiers M, Donnelly L, Mackenzie I, et al. Prospective analysis of stoma related complications. *Colorectal Dis.* 2005;7:279–85.
- Pearson R, Knight SR, Ng JCK, Robertson I, McKenzie C, Macdonald AM. Stoma-related complications following ostomy surgery in 3 acute care hospitals. *J Wound Ostomy Continence Nurs.* 2020;47:32–8.
- Babakhanlou R, Larkin K, Hita AG, Stroh J, Yeung SC. Stoma-related complications and emergencies. *Int J Emerg Med.* 2022;15:17. <https://doi.org/10.1186/s12245-022-00421-9>
- Davis JS, Svavarsdóttir MH, Pudlo M, Arena R, Lee Y, Jensen MK. Factors impairing quality of life for people with an ostomy. *Gastrointest Nurs.* 2011;9:14–8.
- Aboulian A. Ostomy complications in Crohn's disease. *Clin Colon Rectal Surg.* 2019;32:314–22.
- Metcalfe C. Managing moisture-associated skin damage in stoma care. *Br J Nurs.* 2018;27:6–14.
- Arumugam PJ, Bevan L, Macdonald L, Watkins AJ, Morgan AR, Beynon J, et al. A prospective audit of stomas-analysis of risk factors and complications and their management. *Colorectal Dis.* 2003;5:49–52.
- Kock NG. Intra-abdominal “reservoir” in patients with permanent ileostomy. Preliminary observations on a procedure resulting in fecal “continence” in five ileostomy patients. *Arch Surg.* 1969;99:223–31. <https://doi.org/10.1001/archsurg.1969.01340140095014>
- Nessar G, Wu JS. Evolution of continent ileostomy. *World J Gastroenterol.* 2012;18:3479–82. <https://doi.org/10.3748/wjg.v18.i27.3479>
- Maxwell TR, Taylor D, Durnal AM, Wills R, Kommala D, Wade S. Safety and efficacy of a novel continence device in colostomy patients. *Dis Colon Rectum.* 2010;53:1422–31. <https://doi.org/10.1007/DCR.0b013e3181e5e0c4>
- Wulff HB. Erfahrungen mit einem Ventilcolostomieverschluss [Experiences with a valvular colostomy plug]. *Chirurgie.* 1953;24:485–7.
- Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ.* 2021;372:n71. <https://doi.org/10.1136/bmj.n71>
- Sterne JAC, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomized studies of interventions. *BMJ.* 2016;355:i4919. <https://doi.org/10.1136/bmj.i4919>
- Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ.* 2019;366:l4898.
- Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol.* 2011;64:401–6.
- Heiblum M, Cordoba A. An artificial sphincter: a preliminary report. *Dis Colon Rectum.* 1978;21:562–6. <https://doi.org/10.1007/BF02586397>
- Pemberton JH, van Heerden JA, Beart RW Jr, Kelly KA, Phillips SF, Taylor BM. A continent ileostomy device. *Ann Surg.* 1983;197:618–26. <https://doi.org/10.1097/0000658-198305000-00016>
- Hadidi AT. An external device for faecal incontinence. *Eur J Pediatr Surg.* 2006;16:109–14. <https://doi.org/10.1055/s-2006-923994>
- Goligher JC, Lee PW, McMahon MJ, Pollard M. The Erlangen magnetic colostomy control device: technique of use and results in 22 patients. *Br J Surg.* 1977;64:501–7. <https://doi.org/10.1002/bjs.1800640715>
- Burcharth F, Ballan A, Kylberg F, Rasmussen SN. The colostomy plug: a new disposable device for a continent colostomy. *Lancet.* 1986;2:1062–3. [https://doi.org/10.1016/s0140-6736\(86\)90466-6](https://doi.org/10.1016/s0140-6736(86)90466-6)
- Down G, Leaper D. The Conseal continent colostomy appliance: Southmead Hospital experience. *Bristol Med Chir J.* 1989;104:59–60.

28. Clague MB, Heald RJ. Achievement of stomal continence in one-third of colostomies by use of a new disposable plug. *Surg Gynecol Obstet.* 1990;170:390–4. PMID: 2183370.
29. Cerdán FJ, Díez M, Campo J, Barbero MA, Balibrea J. Continent colostomy by means of a new one-piece disposable device. Preliminary report. *Dis Colon Rectum.* 1991;34:886–90. <https://doi.org/10.1007/BF02049702>
30. Cesaretti IU, Santos VL, Vianna LA. Qualidade de vida de pessoas colostomizadas com e sem uso de métodos de controle intestinal [Quality of life of the colostomized person with or without use of methods of bowel control]. *Rev Bras Enferm.* 2010;63:16–21. Portuguese. <https://doi.org/10.1590/s0034-71672010000100003>
31. Soliani P, Carbognani P, Piccolo P, Sabbagh R, Cudazzo E. Colostomy plug devices: a possible new approach to the problem of incontinence. *Dis Colon Rectum.* 1992;35:969–74. <https://doi.org/10.1007/BF02253500>
32. Waever E, Bülow S, Moesgaard FA. Kolostomiprop (Conseal systemet). Vurdering af tidlig postoperativ anvendelse [A colostomy plug (the Conseal system). Assessment of early postoperative use]. *Ugeskr Laeger.* 1993;155:797–9. Danish.
33. Codina Cazador A, Piñol M, Marti Rague J, Montane J, Noguera FM, Suñol J. Multicentre study of a continent colostomy plug. *Br J Surg.* 1993;80:930–2. <https://doi.org/10.1002/bjs.1800800748>
34. Picón Pérez G, Calpena Rico R, Candela Polo F, Compañ Rosique A, García García S, Meroño Carbajosa E, et al. Manejo de las colostomías mediante obturador: aspectos clínicos y evaluación de los pacientes [Management of colostomies with plug: clinical aspects and patient evaluation]. *Rev Esp Enferm Dig.* 1994;85:95–8. Spanish.
35. Swan E. Colostomy, management and quality of life for the patient. *Br J Nurs.* 2011;20(22):24–8. <https://doi.org/10.12968/bjon.2011.20.Sup11.S22>
36. Hoch J, Yang M, Yan S, van den Broek N, Xie J, Warusavitarne J. A health-related quality-of-life study comparing Vitala continence control device versus traditional pouch system only in patients with end colostomy. *Eur J Gastroenterol Hepatol.* 2013;25:739–47. <https://doi.org/10.1097/MEG.0b013e32835d5f3c>
37. Durnal AM, Maxwell TR, Kiran RP, Kommala D. International study of a continence device with 12-hour wear times. *Br J Nurs.* 2011;20:54–6–8–11. <https://doi.org/10.12968/bjon.2011.20.Sup9.S4>
38. Strigård K, Oresland T, Rutegård J, Gunnarsson U. Transcutaneous implant evacuation system: a new approach to continent stoma construction. *Colorectal Dis.* 2011;13:e379–e782. <https://doi.org/10.1111/j.1463-1318.2011.02739.x>
39. Lehur PA, Deguines JB, Montagliani L, Duffas JP, Bresler L, Mauvais F, et al. Innovative appliance for colostomy patients: an interventional prospective pilot study. *Tech Coloproctol.* 2019;23:853–9. <https://doi.org/10.1007/s10151-019-02059-x>
40. Zhang Q-a, Huang Z-h, Shi F-j, Chen F, Li J-g, Zou Z-w. Occlusion effect comparison of artificial silicone rubber closure devices with different diameters. *Chin J Tissue Eng Res.* 2012;16:1496–500.
41. Chen F, Li ZC, Li Q, Liang FX, Guo XB, Huang ZH. A novel, intelligent, pressure-sensing colostomy plug for reducing fecal leakage. *Artif Organs.* 2015;39:514–9. <https://doi.org/10.1111/aor.12412>
42. Johansson ML, Hultén L, Jonsson O, Ben Amara H, Thomsen P, Edwin B. Achieving stomal continence with an ileal pouch and a percutaneous implant. *J Mater Sci Mater Med.* 2022;33:7. <https://doi.org/10.1007/s10856-021-06633-4>
43. Hubbard G, Taylor C, Beeken B, Campbell A, Gracey J, Grimmett C, et al. Research priorities about stoma-related quality of life from the perspective of people with a stoma: a pilot survey. *Health Expect.* 2017;20:1421–7. <https://doi.org/10.1111/hex.12585>
44. Claessens I, Probert R, Tielemans C. The Ostomy Life Study the everyday challenges faced by people living with a stoma in a snapshot. *Gastrointest Nurs.* 2015;13:18–25. <https://doi.org/10.12968/gasn.2015.13.5.18>
45. Hedegaard C, Ajslev T, Zeeberg R, Hansen A. Leakage and peristomal skin complications influences user comfort and confidence and are associated with reduced quality of life in people with a stoma. *World Counc Enteros Ther J.* 2020;40:23–9. <https://doi.org/10.33235/wcet.40.4.23-29>
46. Jeppesen PB, Vestergaard M, Boisen EB, Ajslev TA. Impact of stoma leakage in everyday life: data from the Ostomy Life Study 2019. *Br J Nurs.* 2022;31:548–558. <https://doi.org/10.12968/bjon.2022.31.6.S48>
47. Steinhagen E, Colwell J, Cannon LM. Intestinal stomas—postoperative stoma care and peristomal skin complications. *Clin Colon Rectal Surg.* 2017;30:184–92.

## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**How to cite this article:** Dourado J, Garoufalia Z, Emile SH, Wignakumar A, Aeschbacher P, Rogers P, et al. Ostomy continence devices: a systematic review of the literature and meta-analysis. *Colorectal Dis.* 2024;00:1–10. <https://doi.org/10.1111/codi.16906>