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ORIGINAL ARTICLE

Outcomes of support rod usage in loop stoma formation

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Abstract
Aim Traditionally, support rods have been used when creating loop stomas in the hope of preventing retraction. However, their effectiveness has not been clearly established. This study aimed to investigate the rate of stoma rod usage and its impact on stoma retraction and complication rates.
Method A prospective cohort of 515 consecutive patients who underwent loop ileostomy/colostomy formation at a tertiary referral colorectal unit in Sydney, Australia were studied. Mortality and unplanned return to theatre rates were calculated. The primary outcome measure of interest was stoma retraction, occurring within 30 days of surgery. Secondary outcome measures included early stoma complications. The 10-year temporal trends for rod usage, stoma retraction, and complications were examined.
Results Mortality occurred in 23 patients (4.1 %) and unplanned return to theatre in 4 patients (0.8 %). Stoma retraction occurred in four patients (0.78 %), all without rods. However, the rate of retraction was similar, irrespective of whether rods were used ($P=0.12$). There was a significant decline in the use of rods during the study period ($P<0.001$) but this was not associated with an increase in stoma retraction rates. Early complications occurred in 94/432 patients (21.8 %) and were more likely to occur in patients with rods (64/223 versus 30/209 without rods, $P<0.001$).
Conclusions Stoma retraction is a rare complication and its incidence is not significantly affected by the use of support rods. Further, complications are common post-operatively, and the rate appears higher when rods are used. The routine use of rods warrants judicious application.
What does this paper add to the literature? It remains unclear whether support rods prevent stoma retraction. This study, the largest to date, confirms that stoma retraction is a rare complication and is not significantly affected by the use of rods. Consequently, routine rod usage cannot be recommended, particularly as it is associated with increased stoma complications.

Keywords Stoma · Support rods · Complications · Loop ileostomy · Loop colostomy

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Introduction

Preservation of gastrointestinal continuity is important for many patients undergoing colorectal surgery. Further, sphincter preservation and avoidance of a permanent stoma has been proposed as a quality indicator of rectal cancer care [1]. However, the creation of a permanent or temporary abdominal stoma may still be necessary as part of the treatment of both benign and malignant colorectal conditions in the elective and emergency setting. Complications following stoma creation can affect up to half of patients [2] and may be minor,

requiring only additional stomal therapy input, or can be serious, leading to reoperation(s) and significant morbidity.

Retraction is a significant complication of stoma creation [3] that is associated with difficulties maintaining an adequate pouch seal around the stoma and thus problems containing effluent [4]. However, in more extreme cases, it may cause complete mucocutaneous separation that can lead to subcutaneous, subfascial or peritoneal contamination and sepsis requiring emergency surgery and stoma revision [5]. Stoma retraction occurs in 0 to 40 % of cases [6–8] and may be related to too much tension on the stoma, resulting in stoma ischemia and necrosis [9]. Additionally, patient factors such as high body mass index (BMI) [5, 10, 11], steroid use, malnutrition, [4, 5] diabetes and smoking [10] have also been implicated [12].

For some time, stoma support 'rods' or 'bridges' have been inserted under loop stomas at the time of creation with the intention of preventing retraction in the immediate postoperative period [13]. However, the effectiveness of rods in preventing retraction has not been clearly established, with some studies reporting increased complication rates with their usage [14, 15]. Whilst studies that have routinely employed the use of rods report low stoma retraction rates of 0 to 2 % [6, 7, 16, 17], they have involved only relatively small numbers of patients ($n < 83$), have focused on either loop colostomy or ileostomy formation in isolation and have been uncontrolled. To date, there has been only one prospective, controlled trial of rod usage, and this found no significant difference in stoma retraction rates with and without the use of support rods [11]. However, this study only involved 60 patients and was associated with a much higher overall retraction rate of 20 % than other studies. Therefore, the aim of this study was to investigate the rate of stoma rod use and its impact on stoma retraction and complication rates in a large, prospective series of patients undergoing loop ileostomy/colostomy formation in a tertiary referral colorectal unit.

Methods

An observational cohort study of consecutive patients who underwent loop stoma formation between January 2003 and May 2012 at a tertiary referral colorectal unit in Sydney, Australia was performed.

Study population

The study population was identified from a prospectively collected dedicated electronic stomal therapy database, which records detailed clinical information in a standardised manner. Consecutive patients older than 18 years undergoing loop ileostomy or colostomy formation were included in this study. Those undergoing end stoma formation were excluded. Rigid plastic MARLEN rods (Coloplast Pty Ltd., Australia) positioned under the stoma at skin level were used until the end of 2006, when supply was ceased in Australia. For the remainder of the study, rods were fashioned from a piece of soft, plastic surgical drainage tubing and positioned in the same manner. There was no enhanced recovery after surgery (ERAS) programme during the study period.

Data collection and clinical variables

Comprehensive demographic, clinical and operative parameters were collected from all subjects by three experienced stomal therapy nurses (STN), according to unit protocol. All patients were examined prior to and following discharge by one of the STNs, allowing evaluation up to 30 days from surgery. Full database record review was performed for all patients meeting the inclusion criteria, and the relevant clinical and outcome data were extracted. Variables recorded included, but were not limited to, (i) patient age and gender; (ii) type of procedure (planned/emergency); (iii) indication for surgery, stratified into cancer, inflammatory bowel disease, diverticular disease, functional disorders (intractable incontinence/constipation), complex perianal sepsis, intra-abdominal sepsis (perforation/anastomotic leakage) and others (e.g. stoma resiting/refashioning, radiation proctitis, familial adenomatous polyposis); (iv) stoma type (ileostomy/colostomy) and (v) whether a supporting rod was used.

Outcome measures

Mortality and unplanned return to theatre rates were calculated. The primary outcome measure of interest was stoma retraction rate. For the purpose of the study, stoma retraction was explicitly defined when the mucosa was 5 mm or greater below the skin level for at least 50 % of the circumference, occurring within 30 days of surgery. Secondary outcome measures comprised other early (within 30 days) stoma complications which included (i) necrosis (mucosa/full-thickness), (ii) parastomal abscess, (iii) mucocutaneous separation, (iv) peristomal ulceration and (v) leakage causing irritant dermatitis. The 10-year temporal trends for rod usage, stoma retraction and other complications were examined.

Statistical analysis

Descriptive statistics assessing characteristics and outcomes of patients overall and by support rod usage were calculated. Association between rod usage and study outcomes were examined using two-tailed independent *t* tests and Mann-Whitney *U* tests for parametric and non-parametric data, respectively. Contingencies were analysed using Pearson's chi-square test

and Fisher's exact test, as appropriate. The test for trend in stoma rod use was performed using the Cochrane-Armitage test for trend in linear proportions. All analyses were conducted using Statistical Package for the Social Sciences (SPSS) v19 (IBM SPSS Statistics, Armonk, NY, USA), and a P value less than 0.05 was considered statistically significant.

Results

Overall, 515 patients underwent formation of a loop stoma during the study period of which 471 (91.4 %) were loop ileostomies, 38 (7.4 %) loop colostomies and 6 (1.2 %) transverse loop colostomies. Demographic, clinical characteristics and operative details are shown in Table 1. The majority of the patients were men, and the mean age of patients was 62.1 years. Most stomas were fashioned for cancer ($n=369$, 71.7 %), and the vast majority of procedures ($n=446$, 86.6 %) were performed in the elective setting, with all such patients receiving pre-operative education and stoma siting/marking by STNs.

Of the 515 stomas, 260 (50.5 %) were fashioned with support rods positioned at the level of the skin, leaving 255 (49.5 %) that were fashioned without a rod for comparison. The rate of rod usage was similar in patients undergoing planned and emergency stoma formation ($P=0.58$) and irrespective of gender ($P=0.93$). By contrast, rate of rod usage varied according to indication for surgery ($P=0.01$). When used, rods were left in for a median of 3.5 (range 3–12) days. Overall mean length of stay was 15.6 days (range 3–112), being similar irrespective of rod usage (rod, 15.0 days versus no rod, 16.2 days, $P=0.36$).

All 515 patients were assessed as in-patients by the STN. Post-discharge follow-up within 30 days of surgery was performed in 432 patients (83.9 %). Post-discharge follow-up was not possible in the remaining 83 patients due to inpatient death ($n=21$), death prior to scheduled follow-up ($n=2$), referral to another STN service ($n=47$), discharged to residential aged care facility precluding hospital follow-up ($n=10$). A further three patients were not followed up due to: stoma closed prior to discharge ($n=1$), returned overseas ($n=1$) and declined follow-up as this patient had a stoma previously ($n=1$).

Outcomes

Death occurred within 30 days in 23 patients (4.1 %), 16 patients (69.6 %) with rods and 7 patients without rods (30.4 %) ($P=0.06$). Unplanned return to theatre was necessary in four patients (0.8 %), all of whom underwent loop ileostomy formation and two (50 %) involving the use of support rods. Reasons for return to theatre included stoma stenosis, post-operative haemorrhage, midline wound dehiscence and suspected anastomotic leak from an ileal J-pouch ($n=1$ for each indication).

Overall, stoma retraction occurred in only four patients (0.78 %), of which one was a loop ileostomy (protection of anastomosis following surgery for rectal cancer) and three were loop sigmoid colostomies (one each for pseudo obstruction, faecal incontinence and obstructing rectal cancer). All

Table 1 Demographic, clinical and operative characteristics of patients

	Rod ($n=260$)	No rod ($n=255$)	Total ($n=515$)
Male	154 (59.2 %)	150 (58.8 %)	304 (59.0 %)
Female	106 (40.8 %)	105 (41.2 %)	211 (41.0 %)
Age (mean, SD) years	59.7 (16.0)	64.6 (14.4)	62.1(15.4)
Indication for surgery*			
Cancer	173 (66.5 %)	196 (76.9 %)	369 (71.7 %)
IBD	25 (9.6 %)	8 (3.1 %)	32 (6.2 %)
Diverticular disease	24 (9.2 %)	16 (6.3 %)	40 (7.8 %)
Functional disorders	0 (0 %)	5 (2.0 %)	5 (1.0 %)
Perianal sepsis	9 (3.5 %)	5 (2.0 %)	14 (2.7 %)
Abdominal sepsis	16 (6.2 %)	10 (3.9 %)	26 (5.0 %)
Other	14 (5.4 %)	15 (5.9 %)	29 (5.6 %)
Type of procedure†			
Planned	223 (85.8 %)	223 (87.5 %)	446 (86.6 %)
Emergency	37 (14.2 %)	32 (12.5 %)	69 (13.4 %)

Values represent actual numbers (percentage)

SD standard deviation

*$P=0.01$

† $P=0.58$

four cases of retraction occurred in patients who underwent elective procedures requiring stoma formation without the use of a rod (1.6 %). However, given the small numbers, there was no difference in rate of retraction, irrespective of whether rods were used following stoma formation ($P=0.12$). The BMI of these four patients in whom stoma retraction occurred was increased (BMI 37) in one patient (indication: cancer), normal in one patient (indication: functional disorder—faecal incontinence) and decreased (BMI 17 and 18) in two patients (indication: one for pseudo-obstruction, the other for a partially obstructing cancer). All four of these patients were managed conservatively with additional input from the STN.

The frequency of rod usage in stoma patients over the study period is shown in Fig. 1. There was a significant decrease in use of rods from 91.4 % ($n=53/58$) of cases in 2003 to 10 % ($n=2/18$) in 2012 ($Z=13.47$; P trend <0.001), with a sharp decline between 2006 and 2007 (coinciding with the withdrawal of the MARLEN rod from the Australian market). Despite the change in rod use, the rate of retraction remained unchanged during this time with only one case of retraction in each of the years 2003, 2004, 2007 and 2008 and none in the latter years. A number needed to treat (NNT) calculation demonstrated that 63.7 rods needed to be used to prevent one case of stoma retraction.

Early stomal complications within 30 days of surgery are shown in Table 2. Overall, such complications occurred in 94 of the 432 patients followed up (21.8 %), the most common of which was peristomal skin irritation (leak irritant dermatitis), which occurred in 54 patients (12.5 %). There was a significant decrease in the rate of complications during the study period from 32.8 % ($n=19/58$) in 2003 to 25 % (5/20) in 2012 ($Z=-2.62$; P trend = 0.009).

Overall, patients with rods were more likely to suffer complications (28.7 %), compared to those without rods inserted (14.4 %) ($P<0.001$). Specifically, peristomal skin irritation (leak irritant dermatitis) occurred more commonly in patients with rods ($n=37/223$, 16.6 %) compared to those without rods ($n=17/209$, 8.1 %) $P=0.009$. However, the rates of mucocutaneous separation, peristomal abscess, peristomal ulceration and necrosis of the stomal mucosa were all similar ($P>0.05$), irrespective of rod usage.

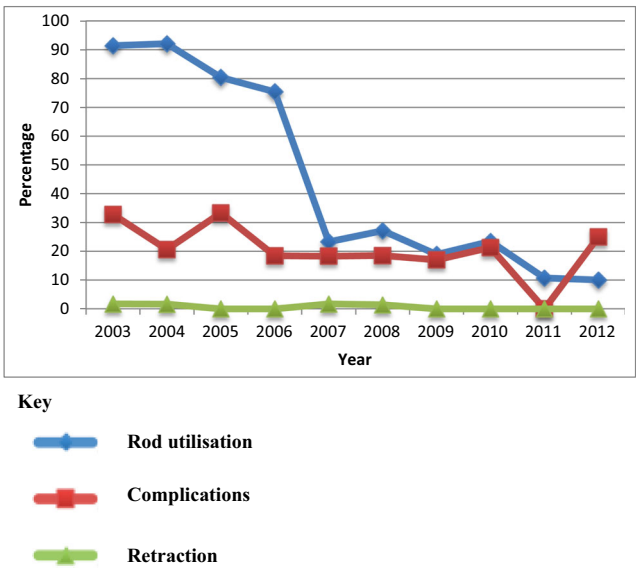

Fig. 1 Frequency of rods usage in loop stomas, rate of retraction and early complication rates during the study period 2003–2012. Despite a significant decrease in use of rods during the study period ($Z=13.47$; P trend <0.001), the rate of retraction remained unchanged

Discussion

This study is the largest prospective, observational study using explicitly defined outcome criteria of rod utilisation in loop stoma formation to date. It has shown that the inpatient mortality (4 %), unplanned return to theatre (0.8 %) and stoma retraction (0.78 %) rates were low. Further, it has demonstrated that the rate of stoma retraction was similar, irrespective of support rod utilisation and that despite a significant decrease in their utilisation, there was no increase in retraction rate during the study period. Moreover, the early stoma complication rate was 22 % and the use of support rods was associated with a significant increase in peristomal skin irritation; the rate of complications reduced significantly as stoma rod utilisation decreased.

This study reports low mortality and reoperation rates. Previous small studies (max $n=83$) have reported inpatient mortality rates of 0–1.2 % [12, 16, 17], and the higher inpatient mortality rate (4 %) observed in the current study is more in keeping with large population-based studies of outcomes following major colorectal surgery, which report 30-day mortality rates of 4.8 to 8.5 % [18, 19]. Similarly, low reoperation rates, ranging from 1.2 to 6.3 %, have been reported in previous studies [16, 17, 20] with reasons for return to theatre including stoma retraction, drainage of a peristomal abscess [16], bowel obstruction [20] and ileostomy retraction following rod removal [17]. The reoperation rate was slightly lower at 0.8 % in the present study and may simply reflect the fact that other studies involved smaller numbers of patients (max $n=83$).

Our overall rate of stoma retraction was very low at 0.8 % but similar to that of other studies reporting low rates of 0 to 1.4 % [6, 7, 15–17, 21, 22]. All apart from one of these studies [16] employed the routine use of a support rod [6, 7, 15, 17, 21, 22]. By contrast, other studies have reported higher retraction rates ranging from 5 to 26 % [11, 12, 23–25] and even as high as 40 % [8]. However, such studies analysed slightly different study populations to the present study, e.g. either only loop ileostomies [20] or end colostomies in addition to loop stomas [12] or did not explicitly state the type of the

Table 2 30-day complications in patients with loop stoma, according to rod usage

Complication	Rod ($n=223$)	No rod ($n=209$)	Total ($n=432$)
Peristomal skin irritation	37 (16.6 %)	17 (8.1 %)*	54 (12.5 %)
Mucocutaneous separation	20 (9.0 %)	10 (4.8 %)	30 (6.9 %)
Necrosis of stomal mucosa	5 (2.2 %)	2 (1.0 %)	7 (1.6 %)
Peristomal ulceration	4 (1.8 %)	2 (1.0 %)	6 (1.4 %)
Peristomal abscess	2 (0.9 %)	1 (0.5 %)	3 (0.7 %)
Total	64 (28.7 %)	30 (14.4 %)†	94 (21.8 %)

NB numbers do not add up to totals as some patients may have experienced more than one complication

*$P=0.009$

† $P<0.001$

stoma constructed [23], which may account for the observed differences. Furthermore, uniform criteria have not been established to diagnose stoma retraction, with some studies defining retraction when the lumen of the stoma is below skin level [8], whereas others have required the stoma to fall 0.5 cm or more below the skin surface [10, 11, 25] and thus variation in the definition used in different studies may have contributed to the differences in the published retraction rates.

Retraction can result from too much tension on the stoma leading to stoma ischemia and necrosis [9], such as can occur in the setting of inadequate mobilisation of the bowel [5, 26] or poor siting [27]. Over-aggressive post-operative fluid resuscitation [4] and the presence of high BMI [5, 10, 11] have also been implicated. Additionally, patient factors such as long-term steroid use, malnutrition [4, 5], diabetes and smoking [10] may result in poor wound healing and/or peristomal infection contributing to stenosis and retraction [12]. Unfortunately, such information was not routinely recorded during the entire study period so was unavailable for analysis. Further, the extremely low event rate of retraction would have precluded valid analysis and meaningful interpretation. That said, BMI was abnormal in two of the four patients in whom retraction occurred, being elevated in one and reduced in the other.

Stoma support rods have been used in an attempt to prevent stoma retraction. However, their effectiveness has not been extensively investigated in the literature, with only one previous randomised, controlled trial that specifically addressed this issue [11]. In this small study of 60 patients, the retraction rate was similar [11], irrespective of whether a support rod was used, consistent with the findings of the present study. However, that study only included patients with loop ileostomy formation and the overall retraction rate was higher at 20 % [11]. Stoma retraction can also occur as a complication in the later post-operative period [9], requiring prolonged retention of stoma rods. However, there is no consistency in the literature regarding how long a rod should be left with subcutaneous rods typically being removed after 5–7 days [11, 13, 17, 28–30], although usage for 7 to 14 days [14, 15, 20, 22, 24, 31] or even up 3–4 weeks post-operatively has been reported [6, 21]. In our study, the duration of rod use was short being only 3.5 days.

In addition to being no observed difference in the rate of stoma retraction with rod usage in the current study, there was no increase in the rate of retraction despite a significant reduction in the utilisation of support rods when fashioning stomas during the study period. Whilst some surgeons continue to regularly use a support device when constructing loop stomas, this practice has been in decline amongst colorectal surgeons for some decades [13]. A sharp decline in stoma rod utilisation was noted in the present study between 2006 and 2007, which coincided with the withdrawal of MARLEN rods in Australia. However, they are still being sold in 20 countries across the UK and Europe. Indeed, the Hollister 'Loop Ostomy Bridges' are the only commercially available rods still available in Australia and only 60 were sold locally between January and August 2012 (Lamb, Hollister Pty Ltd Personal communication 08-08-2012).

Complications occur in up to half of patients following stoma formation [2] and the use of a support rod has been associated with increased complication rates in some studies [14, 15], consistent with the findings of the present study where the complication rate doubled from 14 to 28 % when rods were used. Specifically, there was a significantly higher rate of peristomal skin irritation of 17 versus 8 % when rods were used, which may be explained, at least in part, by the fact that rods may prevent the creation of an adequate seal and lead to effluent leakage and subsequent peristomal skin erosion and pain [30–32]. A study comparing skin level to subcutaneous rods reported skin irritation due to persistent effluent leakage in 70 % of cases when skin level bridges were used compared to 6 % when placed subcutaneously [30]. Notably, the decrease in stoma rod utilisation was mirrored by a significant decrease in the complication rate in the current study.

Other theoretical risks of rod usage may include pressure ulcers or cutaneous necrosis [13, 14, 24], peristomal sepsis [12, 15, 21], as a consequence of faecal contamination of the subcutaneous tissues as the rod passes through the mesentery, and even stoma necrosis [7, 20], although there was no increase in the occurrence of such complications in the current study.

This study is limited as the utilisation of rods was not randomised but was instead determined by surgeon preference and based on historical practice in our unit. Additionally, patients and observers were not blinded to rod usage, although this may have proved impractical in practice. Notably, the extremely low event means that a type II statistical error cannot be ruled out. However, the study was strengthened by the systematic and objective collection of data relating to stoma outcomes made prospectively by an expert team of three experienced STN. Further, all patients were examined in hospital and the vast majority (84 %) subsequently followed up in the Stomal Therapy Outpatient Clinic enabling accurate documentation of post-operative outcomes.

Conclusion

This study highlights that retraction is a rare complication and that rates are similar, irrespective of whether stoma support rods are used during their construction. Further, retraction rates did not increase as rod utilisation decreased. Moreover, stoma complications are common post-operatively, and the rate is higher when support rods are used. These findings, in conjunction with those from the other published prospective comparative trial, suggest that the routine use of rods in clinical practice is associated with inferior patient outcomes and of limited value that warrants judicious application in the future.

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Compliance with ethical standards This study was approved by the Sydney Local Health District Human Research Ethics Committee—Concord Repatriation General Hospital.

Conflicts of interests No conflicts of interest exist.

Authors' contributions
- Ian Whiteley developed the research question, collected data and maintained the stomal therapy database, applied to Human Research Ethics Committee for study approval, conducted the literature review and contributed to data analysis and writing/reviewing the final manuscript.
- Michael Russell conducted preliminary data analysis and review of final data, as well as reviewing the final manuscript.
- Assoc. Professor Natasha Nassar contributed to analysis of data, as well as writing and reviewing the final manuscript.
- Prof. Marc Gladman was involved in project conception/design and data interpretation, as well as writing and reviewing the final manuscript.

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