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The role of alginate dressings in wound healing and quality of life after pilonidal sinus resection: A randomised controlled trial

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Abstract

In this trial, we evaluated the role of alginate dressings in the secondary intention wound healing and quality of life (QoL) after pilonidal sinus resection. The study was designed as a prospective randomised controlled trial (RCT). In the experimental group, alginate dressings with silver and high-G cellulose were introduced after elective pilonidal cyst excision, whereas in the control group, simple gauges were used. The primary end point was the difference in terms of the wound healing period. Blinding existed at the level of the investigator. Overall, 65 patients were included during the study period. Wound healing duration was comparable between the two groups ($P = .381$). No difference in postoperative pain scores or recovery outcomes was found. The experimental group was associated with reduced wound secretions at specific time end points. Similarly, no effect was identified, on overall Wound-QoL or SF-36 scores. Alginate dressings do not accelerate wound healing or improve QoL. Due to suboptimal sample size and several study limitations, further RCTs are required to confirm our findings.

KEYWORDS

alginate, cyst, dressings, pilonidal, quality

Key Messages

- pilonidal disease is among the most common benign pathologies of the sacrococcygeal region with a higher incidence in young males
- optimization of the wound bed was considered as a mean to shorten the required closure time and reduce the impact on the quality of life (QoL)
- in this randomised controlled trial, we evaluated the role of alginate dressings in the secondary intention wound healing and QoL after pilonidal sinus resection
- alginate dressings do not accelerate wound healing or improve QoL

1 | INTRODUCTION

1.1 | Rationale

Pilonidal disease (PD) is among the most common benign pathologies of the sacrococcygeal region.[1] It is estimated that PD affects almost 25 per 100 000 population, with a higher incidence in young males.[1,2] The distinct structural and pathophysiological characteristics of the natal cleft resulting in the ingrowth of hair follicles and the subsequent, foreign body, inflammatory process, known as PD.[1,2]

Although the treatment of acute suppurative PD flares is based on incision and drainage, the management of chronic PD is less straightforward.[3,4] En-bloc resection of the pilonidal cyst and sinuses complex, combined with secondary intention healing, minimises the long-term recurrence risk, at the cost of a prolonged healing period and a considerable sociopsychological burden.[5,6]

Therefore, optimization of the wound bed was considered as a mean to shorten the required closure time and reduce the impact on the quality of life (QoL).[7] Wound dressings are the most prominent among the various adjuncts that have been investigated.[8,9] Alginate dressings consist of unwoven fibres of a natural polysaccharide deriving from the calcium salts of marine algae[10] and are, notably, biocompatible and hydrophilic.[8,10] Additionally, the compounding of these dressings with ionic silver further augments their ability to constrain local bacterial colonisation.[11,12]

Alginate dressings have been evaluated in multiple wound settings.[13,14] However, the current literature provides scarce evidence regarding the superiority of alginates over conventional gauge dressings after PD resection.[15] Therefore, taking into consideration the impact of wound management on the QoL, and the considerable material cost,[15] the need to elucidate any clinical benefit becomes apparent.

1.2 | Objectives

Therefore, the aim of this trial was to compare alginate dressings with silver and high-G cellulose, over simple gauge dressings, in terms of wound healing and postoperative QoL, of patients submitted to elective PD excision.

2 | METHODS

2.1 | Design

This parallel randomised controlled trial (RCT) was conducted in the Surgical Department of the University Hospital of Larissa. Prior to the initiation of the trial, a local ethics committee approval (UHL 20667, 13/10/17-05-2018) and an RCT registry identifier (ClinicalTrials.gov: NCT03757572) was received. All eligible patients provided a signed informed consent. The report of the study outcomes, adhering to the guidelines, is outlined in the CONSORT statement.[16]

2.2 | Participants

All consecutive adults, referred to the outpatient coloproctology office of our department, with a Stage I-IV[17] pilonidal sinus and an American Society of Anesthesiologists (ASA) score ≤IV were screened for inclusion. The following exclusion criteria were considered: (a) perianal abscess, (b) paediatric population, (c) age ≥80 years, and (d) patient's refusal to participate.

2.3 | Interventions

All patients underwent an elective pilonidal sinus excision under local anaesthesia on a day-care basis. The patient was placed in the prone position and the pilonidal sinuses were exposed by adhesive tapes. Prior to the initiation of the procedure, antibiotic chemoprophylaxis was administered. After hair clipping, the surgical field was disinfected by a 10% povidone-iodine solution and drapes were placed. Local anaesthesia was achieved through pericystic infiltration of a 10 mL 2% lidocaine solution. Resection and haemostasis were performed with the use of scalpel and diathermy, respectively. A secondary intention wound healing approach was implemented in all cases, and simple gauges were used for wound coverage during the first 24 hours.[3]

Perioperative care was standardised for all patients. The patients were discharged on the basis of the Clinical Discharge Criteria.[18] Postoperative follow-up enclosed regular outpatient visits for dressing changes and wound evaluation.

In the experimental group, a highly absorbent, nonwoven, alginate dressing with an ionic silver complex and high-G cellulose (3 × 45 cm) was applied to the wound after the first postoperative day. Hydrocolloid foam dressings with a perimetric adhesive layer were, also, applied. On the contrary, in the control group, simple gauge and adhesive dressings were used for wound coverage.

2.4 | Outcomes

The primary outcome of our study was the difference in terms of wound healing time between the experimental and the control group. Secondary end points included operation

and wound-related outcomes. The overall material costs were, also, compared. QoL evaluation was based on the QoL with chronic wounds (Wound-QoL)[19] and the SF-36 questionnaire[20] at one- (1 month) and three-time (1, 2, and 3 weeks postoperatively) end points, respectively.

2.5 | Randomisation and blinding

Randomisation was performed by a specialised software on a 1:1 ratio. The masking of the group allocation was based on the introduction of sealed opaque envelopes. Blinding existed at the level of the investigator, responsible for data recording.

2.6 | Statistical analysis

Sample size estimation was based on the primary end point. Considering a 5% decrease in the healing duration of the alginate dressings group, with a 5% alpha and 90% power, the total sample size was estimated at 178 patients.[21]

A per-protocol analysis was performed. All data underwent a Shapiro-Wilk normality test (Tables S1 and S2). Categorical and continuous variables were compared by a Pearson chi-square test and an independent samples *t*-test, correspondingly. In the case of non-normal data, the latter comparisons were completed by a Mann-Whitney test. Time-to-event analysis of certain outcomes

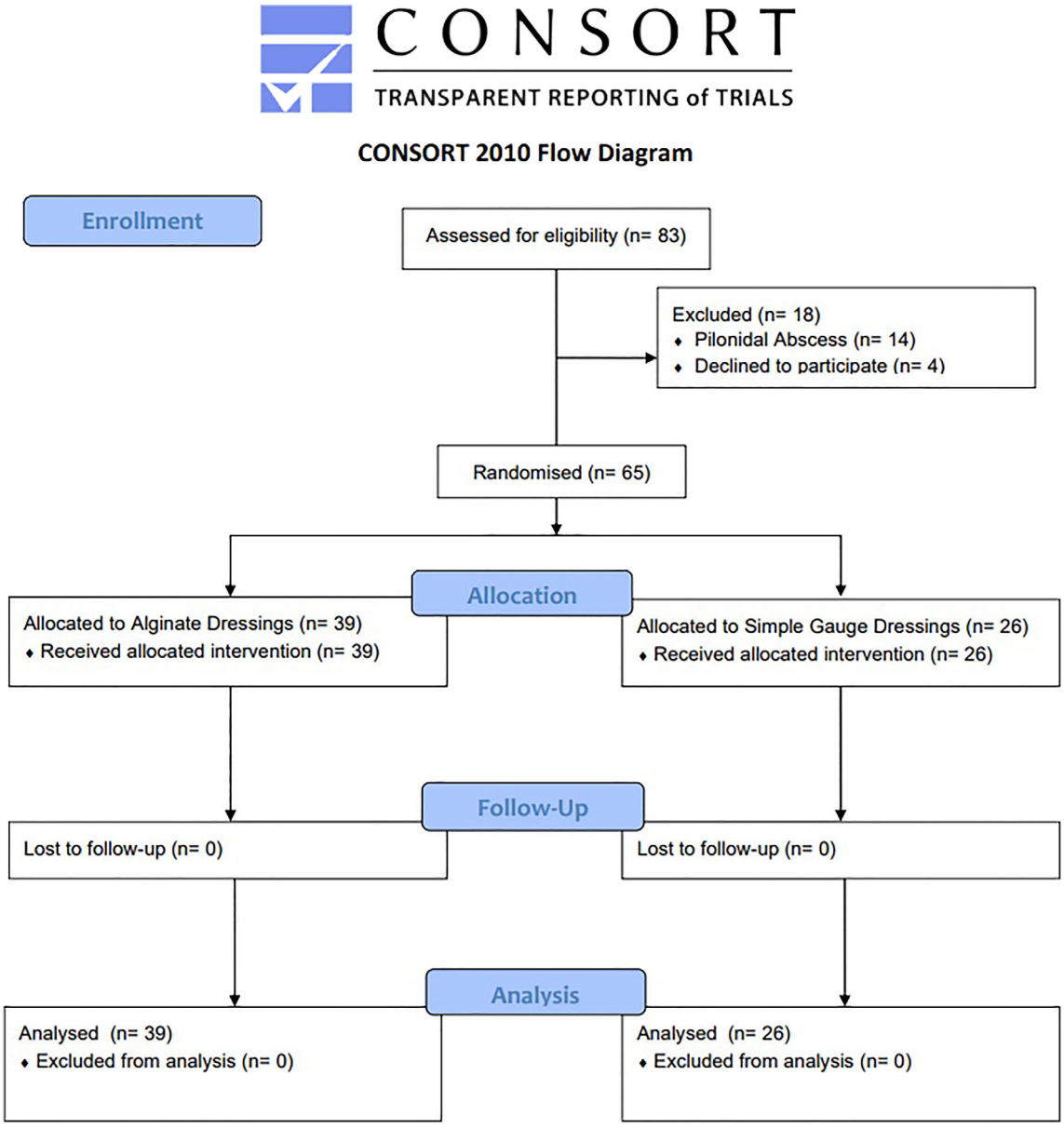

FIGURE 1 Consort study flow diagram

was performed by plotting the respective Kaplan-Meier curves. A Mantel-Cox log-rank test was used for the comparison of the two study groups. Material costs were estimated by the multiplication of the number of changes and the per change cost.

Association analysis of the primary outcome and the baseline demographics was based on a non-normal approach. Between-group differences were examined via the Kruskal-Wallis test followed by the Mann-Whitney test for pairwise comparisons. Correlation between continuous variables was estimated by the Spearmans Rank-Order Correlation test.

Continuous and categorical variables were presented as mean (SD) and N (percentage), respectively. Non-normal data were reported as median (interquartile range). Statistical significance was considered at the level of $P < .05$. All analyses were performed in the IBM SPSS Statistics v23 software.

3 | RESULTS

Due to the COVID-19 pandemic,[22] all elective case operations in our institution were suspended, thus minimising the enrollment potential of this trial. Due to the inability to reach the estimated sample size, the study committee convened and concluded the early termination of the trial protocol. Overall, 83 patients were evaluated during the 2018-2021 period (Figure 1), and 65 patients were, ultimately, considered eligible.

Table 1 summarises the characteristics of the included patients. Besides gender, base demographics were comparable between the two study subgroups. Furthermore, the operation duration and the length of hospitalisation were similar between the experimental and the control group.

Regarding the primary outcome, patients receiving alginate dressings displayed a shorter healing period (47 vs 60 days), compared with the control group; this difference, though, did not achieve statistical significance ($P = .381$). The comparability of the two groups was, also, noted in the wound healing (Figure 2) survival analysis (log-rank test $P = .496$). There was no significant association of the primary outcome with the baseline demographics (Tables S1 and S2).

Similarly, the use of the alginate dressings did not facilitate the return to everyday activities (Table 2). This was highlighted in both the individual, per week, comparisons, and the respective survival analysis (Figures S1 and S2, log-rank test $P = .913$). Additionally, pain scores, alongside daily analgesics consumption, were not affected by the type of the applied dressing. Although the, per week, wound care visits were comparable, the alginate dressings group displayed significantly lower rates of additional wound care requirements, due to trauma secretions, during the 3rd to 6th postoperative week period. There was no difference in terms of wound complications and recurrence risk ($P = 1$, Figures S1 and S2, log-rank test $P = .610$). However, total material costs were, considerably, increased when alginate dressings were introduced (411.74 vs 139 € $P < .001$).

In terms of wound-related QoL (Table 3), alginate dressings resulted in significantly improved scores in the Wound-QoL Body Subscale at 3 weeks (1.2 vs 1.6 $P = .023$). Nonetheless, this superiority was not confirmed in the rest time end points of this or the other subscales. Likewise, the study group allocation did not have an impact on SF-36 measurements. Finally, treatment satisfaction ($P = .873$) and acceptance ($P = .694$), alongside overall satisfaction ($P = .519$) levels, did not vary among the two groups.

4 | DISCUSSION

4.1 | Summary of evidence

PD is a significant part of the workload in an outpatient anorectal department.[1] Despite the high prevalence of the disease, though, the optimal treatment approach is still elusive.[23-25] Although complex reconstructive and minimal invasive techniques have been introduced, radical resection is, still, the most frequently performed operation.[23] The main drawback of this technique, though, is the prolonged healing period, which consequently impacts overall QoL.[26] As a result, various modalities, including negative pressure treatment and bioactive dressings, have been used as a mean for promoting healing after PD resection.[23,24]

Alginates are ionic polymers deriving from marine seaweed.[27] Biocompatibility, wide availability, and non-toxicity are among the properties that rendered them a favourable candidate for targeted medical treatments.[27] They are composed of linked guluronate (G) and mannuronate (M) residues.[27] The divergences in the polymer block sequence, alongside the length of the G-block, regulate the physical properties of alginates.[27,28] It is estimated that over 200 variations are, currently, used for biomedical purposes.[27,28]

Secondary intention wound healing after PD excision is a time-demanding process, reaching the level of 2 months, in some cases.[29] Alginates preserve a moist local microenvironment and stimulate a local sustained release of growth factors, thus, accelerating the proliferation of epidermal cells in the wound cavity and promoting angiogenesis.[30] A recent trial by Sadati et al,[15]

TABLE 1 Patient characteristics

	Group			
	Alginate dressings	**Simple gauge dressings**	**Overall**	***P***
n	39	26		
Age, *y*[a]	24 (18)	28.5 (14)	26 (17)	.743
Weight, *kg*[a]	82 (31)	86 (21)	85 (25)	.198
Height, *m*[a]	1.76 (1.0)	1.79(1.1)	1.77 (1.1)	.451
BMI, kg/m^2	25.9 (3.94)	27.6(4.1)	26.6 (4.07)	.1
Gender				
Male	30 (76.9%)	26(100%)	56 (86.2%)	**.008**
Female	9 (23.1%)	0(0%)	9 (13.8%)	
Educational level				
Primary	3 (7.7%)	1(3.8%)	4 (6.2%)	.518
Lower secondary	3 (7.7%)	1(3.8%)	4 (6.2%)	
Higher secondary	10 (25.6%)	12(46.2%)	22 (33.8%)	
Tertiary	20 (51.3%)	10(38.5%)	30 (46.2%)	
Postgraduate	3 (7.7%)	2(7.7%)	5 (7.7%)	
Occupational status				
Housekeeping	1 (2.6%)	0(0%)	1 (1.5%)	.655
Unemployed	13 (33.3%)	7 (26.9%)	20 (30.8%)	
Occupied	21 (53.8%)	15 (57.7%)	36 (55.4%)	
Semioccupied	3 (7.7%)	4 (15.4%)	7 (10.8%)	
Retired	1 (2.6%)	0 (0%)	1 (1.5%)	
Smoking	17 (43.6%)	15 (57.7%)	32 (49.2%)	.265
Alcohol	16 (41%)	14 (53.8%)	30 (46.2%)	.310
Exercise				
No	14 (35.9%)	11 (42.3%)	25 (38.5%)	.603
>1 per week	25 (64.1%)	15 (57.7%)	40 (61.5%)	
Family history	12 (30.8%)	8 (30.8%)	30 (30.8%)	1
Sedentary lifestyle	19 (48.7%)	7 (26.9%)	26 (40%)	.079
Classification				
IA	5 (12.8%)	1 (3.8%)	6 (9.2%)	.224
IB	8 (20.5%)	5 (19.2%)	13 (20%)	
IIA	6 (15.4%)	6 (23.1%)	12 (18.5%)	
IIB	4 (10.3%)	7 (26.9%)	11 (16.9%)	
III	9 (23.1%)	6 (23.1%)	15 (23.1%)	
IV	7 (17.9%)	1 (3.8%)	8 (12.3%)	
Symptom duration, *mo*[a]	4 (22)	5.5 (17)	5 (22)	.657
Operation duration, *h*	24.7 (10.3)	25.8 (6.6)	25.2 (9)	.649
LOS, *h*	6.69 (4.33)	5.88 (2.6)	6.36 (3.7)	.398

Note: Bold indicates significant *P*-value.
[a]Normality not confirmed.
Abbreviation: LOS, length of stay.

confirmed this clinical benefit. Moreover, in a multicenter RCT,[31] the local use of an alginate-based cream expedited the rate of re-epithelialization and complete wound healing. Although our experimental group displayed a shorter healing time, compared to conventional dressings, statistical significance was not confirmed.

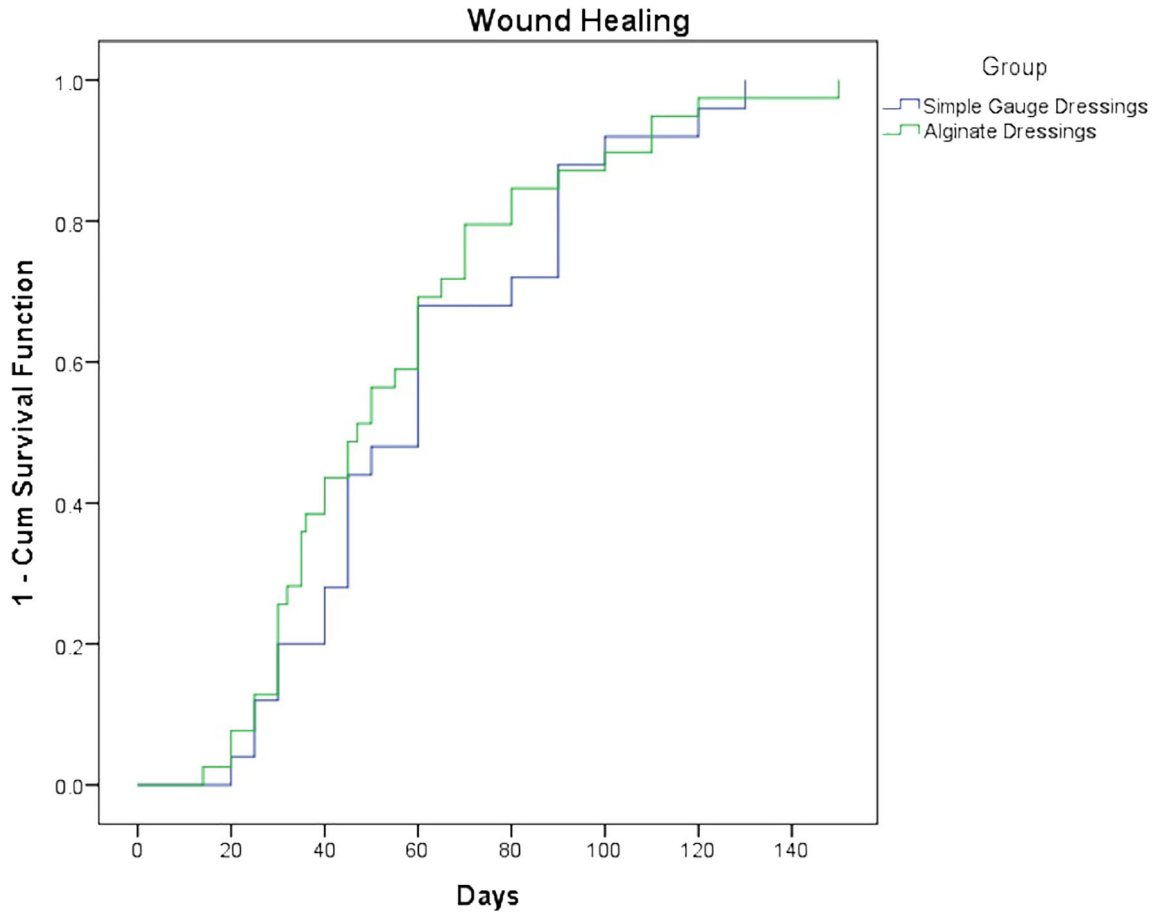

FIGURE 2 Healing Kaplan-Meier analysis (log-rank test $P = .496$)

Wound-related pain is a significant source of discomfort for the patient after PD surgery.[32] Theoretically, alginate dressings preserve the humidity of the wound cavity, thus deterring damage to the nerve endings.[33] This analgetic effect is further attributed to the modulation of the inflammatory cytokines expression and the subsequent downregulation of the pain signal transmission to higher processing centres.[34] In a literature review by Vermeulen et al,[35] a positive analgesic effect was highlighted. Nonetheless, the RCT by Ubbink et al,[36] failed to validate this analgesic advantage. Similarly, as both visual analogue scale measurements and analgesic requirements were comparable, our trial did not confirm any analgesic effect of alginate dressings.

Alginate dressings are remarkably hydrophilic, with extensive water absorption capabilities.[27] More specifically, the potential of retaining 15-17 times their weight in saline has been highlighted in several biochemical studies.[30] This is considerably higher, compared with the respective 5-7 ratio of conventional gauges.[30] This allows a more effective control of wound exudate, thus enhancing wound healing.[37] Our cohort suggested that alginate dressings significantly lowered wound secretions during the 3rd to 6th week period, thus resulting in fewer additional wound change requirements. However, this did not translate to fewer total wound care visits. Similarly, current literature data suggest a markedly improvement in the wound care frequency, when alginates are employed.[38]

The promoting effect of alginate dressings in local cytokine expression and immunogenic response is, primarily, based on a high M-block ratio.[27,28] Additionally, coupling the polymers with ions such as zinc and silver further enhances the antimicrobial activity of the dressing.[27] In vitro studies showed that silver-containing dressings displayed antioxidant properties alongside an increased affinity for inflammation regulatory cytokines.[28] In an RCT by Beele et al,[11] the in vivo antimicrobial efficacy of silver alginate dressings in critically colonised wounds was highlighted. Similarly, Woo et al[12] reported a decrease in local inflammatory signs and acceleration of wound surface reduction, when silver alginates were applied. In our study, alginates failed to provide a significant reduction of the surgical site infection rates during the wound healing period.

TABLE 2 Postoperative outcomes

	Group			
	Alginate dressings	**Simple gauge dressings**	**Overall**	***P***
n	39	26		
Wound healing, *d*[a]	47 (40)	60 (50)	50 (45)	.381
Return to everyday activities, *d*[a]	15 (15)	15 (22)	15 (15)	.711
Return to everyday activities				
1st wk	3 (7.7%)	4 (15.4%)	7 (10.8%)	.327
2nd wk	9 (23.1%)	6 (23.1%)	15 (23.1%)	1
3rd wk	9 (23.1%)	5 (19.2%)	14 (21.5%)	.712
4th wk	10 (25.6%)	4 (15.4%)	14 (21.5%)	.324
5th wk	2 (5.1%)	3 (11.5%)	5 (7.7%)	.342
6th wk	3 (7.7%)	0 (0%)	3 (4.6%)	.148
7th wk	2 (5.1%)	3 (11.5%)	5 (7.7%)	.342
VAS				
1st wk[a]	5 (3)	3.5 (6)	4 (4)	.377
2nd wk[a]	2 (5)	2 (4)	2 (5)	.65
3rd wk[a]	0 (4)	0 (2)	0 (3)	.927
4th wk[a]	0 (0)	0 (0)	0 (0)	.335
5th wk[a]	0 (0)	0 (0)	0 (0)	.361
6th wk[a]	0 (0)	0 (0)	0 (0)	.151
7th wk[a]	0 (0)	0 (0)	0 (0)	.151
Analgesics consumption, *pills per day*				
1st wk[a]	1 (1)	0 (1)	1 (1)	.382
2nd wk[a]	0 (0)	0 (1)	0 (0)	.082
3rd wk[a]	0 (0)	0 (0)	0 (0)	.338
4th wk[a]	0 (0)	0 (0)	0 (0)	1
5th wk[a]	0 (0)	0 (0)	0 (0)	1
6th wk[a]	0 (0)	0 (0)	0 (0)	1
7th wk[a]	0 (0)	0 (0)	0 (0)	1
Wound care visits, *visits per week*				
1st wk[a]	7 (0)	7 (0)	7 (0)	0.682
2nd wk[a]	7 (2)	7 (2)	7 (2)	.629
3rd wk[a]	5 (4)	4 (4)	4 (4)	.696
4th wk[a]	4 (2)	3 (1)	3 (2)	.67
5th wk[a]	3 (4)	2.5 (3)	3 (3)	.692
6th wk[a]	2 (3)	2 (3)	2 (3)	.872
7th wk[a]	2 (3)	1.5 (2)	2 (3)	.692
Trauma Secretions (*secretions leading to extra dressing care*)				
1st wk	22 (56.4%)	18 (69.2%)	40 (61.5%)	.298
2nd wk	17 (43.6%)	12 (46.2%)	29 (44.6%)	.839
3rd wk	8 (20.5%)	13 (50%)	21 (32.3%)	**.013**
4th wk	4 (10.3%)	10 (38.5%)	14 (21.5%)	**.007**
5th wk	1 (2.6%)	7 (26.9%)	8 (12.3%)	**.003**

TABLE 2 (Continued)

	Group			
	Alginate dressings	**Simple gauge dressings**	**Overall**	***P***
6th wk	1 (2.6%)	5 (19.2%)	6 (9.2%)	**.023**
7th wk	1 (2.6%)	4 (15.4%)	5 (7.7%)	.057
Wound complications				
Contamination	2 (5.1%)	3 (11.5%)	5 (7.7%)	.342
Erythema	2 (5.1%)	2 (7.7%)	4 (6.2%)	.673
Haematoma	0 (0%)	1 (3.8%)	1 (1.5%)	.217
Other	2 (5.1%)	1 (3.8%)	3 (4.6%)	.809
Recurrence	6 (15.4%)	4 (15.4%)	10 (15.4%)	1
Material costs, €	411.74 (177.1)	139 (55.4)	302.6 (194.8)	**<.001**

Note: Bold indicates significant *P*-value.
[a]Normality not confirmed.
Abbreviation: VAS, visual analogue scale.

TABLE 3 Quality of life and patient satisfaction

	Group			
	Alginate dressings	**Simple gauge dressings**	**Overall**	***P***
n	39	26		
Quality of life with chronic wounds (wound-QoL) Questionnaire Body Subscale				
1 wk	2.18 (0.78)	2.42 (1.03)	2.28 (0.89)	.295
2 wk[a]	1.6 (1)	2 (1.4)	1.6 (1.1)	.09
3 wk[a]	1.2 (0.6)	1.6 (0.9)	1.2 (0.8)	**.023**
Quality of life with chronic wounds (wound-QoL) Questionnaire Psyche Subscale				
1 wk[a]	1.8 (1)	1.8 (1.45)	1.8 (1.2)	.798
2 wk[a]	1.6 (1)	1.8 (1.05)	1.6 (0.9)	.925
3 wk[a]	1.4 (0.6)	1.5 (0.8)	1.2 (0.8)	.913
Quality of life with chronic wounds (wound-QoL) Questionnaire Everyday Life Subscale				
1 wk[a]	2.16 (1.83)	2.25 (1.62)	2.16 (1.58)	.712
2 wk[a]	1.6 (1.17)	1.83 (1.54)	1.66 (1.33)	.736
3 wk[a]	1.33 (1)	1.41 (0.87)	1.33 (0.92)	.6
Quality of life with chronic wounds (wound-QoL) Questionnaire Total Subscale				
1 wk	2.09 (0.68)	2.15 (0.8)	2.11 (1.24)	.775
2 wk[a]	1.58 (0.88)	1.7 (1.07)	1.7 (0.85)	.334
3 wk[a]	1.35 (0.53)	1.52 (0.71)	1.41 (0.62)	.2
Short Form 36 (SF-36) questionnaire				
Physical functioning[a]	80 (30)	80 (32.5)	80 (27.5)	.657
Physical role limitations[a]	50 (100)	37.5 (81.25)	50 (100)	.733
Emotional role limitations[a]	100 (66.67)	100 (75)	100 (66.6)	.838
Energy/fatigue	65 (19.7)	68.6 (20.8)	66.4 (20.1)	.477
Emotional well-being[a]	84 (20)	84 (18)	84 (20)	.925
Social functioning[a]	75 (37.5)	87.5 (50)	75 (37.5)	.327

(Continues)

TABLE 3 (Continued)

	Group			
	Alginate dressings	Simple gauge dressings	Overall	*P*
Pain[a]	77.5 (32.5)	77.5 (35)	77.5 (32.5)	.549
General health[a]	85 (20)	82.5 (21.25)	85 (17.5)	.43
Treatment satisfaction, *1-5 scale*[a]	2 (1)	1.5 (1)	2 (1)	.873
Treatment acceptance, *1-5 scale*[a]	2 (1)	2 (1)	2 (1)	.694
Overall satisfaction, *0-10 scale*[a]	9 (1)	8 (3)	9 (3)	.519

Note: Bold indicates significant *P*-value.
[a]Normality not confirmed.

Wound pain and the need for frequent wound changes due to trauma secretions have a detrimental impact on the patient well-being and psychosocial functioning.[26] Therefore, optimization of the microenvironment through the application of novel material would allow the enhancement of QoL parameters. The efficacy of alginates in improving the QoL of chronic wound patients is well established[39]; however, evidence regarding the effectiveness after pilonidal sinus resection is scarce. Throughout our study period, the Wound-QoL measurements gradually tended to normalisation. Despite a difference in the body subscale at 3 weeks postoperatively, pooled comparisons could not confirm any significant impact of the experimental group on QoL. This was, also, reflected in the scores of the generic, SF-36 questionnaire.

Regarding chronic wounds, total treatment costs derive from the summation of wound change requirements, morbidity, and material costs.[40] Therefore, it was suggested that the increased material cost of advanced wound dressings would be balanced by the reduction of complications and change frequency.[40] This was confirmed in the study of Meekul et al,[41] where the use of alginate dressings, instead of conventional gauges, did not affect the total costs of complex wound management. However, the recent trial of Sadati et al[15] reported that the substitution of gauges with alginate dressings almost doubled the total treatment expenses. These are in parallel with our findings, where the material costs in the experimental group were considerably higher compared with the control group. As no difference in terms of morbidity and change frequency was found, and although a cost-effective analysis was not performed, this finding is indicative of the cost correlation between the two comparators.

4.2 | Limitations

The present RCT displays several limitations. Due to the negative effect of the pandemic on the patient accrual rate, the trial was prematurely terminated. Therefore, the estimated analyses were severely underpowered, thus inhibiting the validity of our results. Moreover, bias should be expected from the inherent heterogeneity in base demographics and PD characteristics. The introduction of a longer follow-up period could have affected time-related end points, such as recurrence and complications. Finally, both the patient and the operating surgeon were not blinded to the allocation group, thus increasing the respective risk of bias.

4.3 | Conclusions

The present RCT could not confirm any wound healing benefit of alginate dressings, after pilonidal sinus resection. Moreover, no difference in postoperative pain scores or recovery outcomes was found. Despite these, a superiority of the experimental group, in terms of wound secretions, at specific time end points, was confirmed. Taking into consideration the several study limitations and the suboptimal sample size, further RCTs are required to validate our results.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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