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ARTICLE

Minor microbial alterations after faecal diversion do not affect the healing process of anus-near pressure injuries in patients with spinal cord injury - results of a matched case-control study

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STUDY DESIGN: Retrospective matched case-control study including patients with spinal cord injury who presented with an anus-near pressure injury. Two groups were formed based on the presence of a diverting stoma.
OBJECTIVES: To evaluate the primary microbial colonisation and secondary infection of anus-near pressure injuries depending on the presence of a pre-existing diverting stoma and to investigate the effect on the wound healing.
SETTING: University hospital with a spinal cord injury unit.
METHODS: A total of 120 patients who had undergone surgery of an anus-near decubitus stage 3 or 4 were included in a matched-pair cohort study. Matching was realised according to age, gender, body mass index and general condition.
RESULTS: The most common species in both groups was Staphylococcus spp.(45.0%). The only significantly different primary colonisation affected Escherichia coli, that was found in the stoma patients less often (18.3 and 43.3%, $p < 0.01$). A secondary microbial colonisation occurred in 15.8% and was equally distributed, except for Enterococcus spp. that was present in the stoma group only (6.7%, $p < 0.05$). The time to complete cure took longer in the stoma group (78.5 versus 57.0 days, $p < 0.05$) and was associated with a larger ulcer size (25 versus 16 cm^2, $p < 0.01$). After correction for the ulcers' size, there was no association to outcome parameters such as overall success, healing time or adverse events.
CONCLUSIONS: The presence of a diverting stoma alters the microbial flora of an anus-near decubitus slightly without impact on the healing process.

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INTRODUCTON

Despite preventative efforts and well-established clinical guidelines [1–3], patients with spinal cord injury (SCI) develop pressure injuries quite frequently [4]. Over 30% of SCI patients are affected during their initial hospitalisation [5]; the prevalence in the chronic stage of SCI varies between 15 and 60% [6, 7]. Pressure injuries, also referred to as decubitus, are one of the most common reasons for rehospitalisation [7, 8]. The subjects affected suffer from a decreased health-related quality of life and an increased risk of severe complications and mortality [8–10].

Infectious problems occur frequently and might deteriorate the course of the disease. Necrotising fasciitis, for instance, develops in up to 5% of cases and leads to sepsis and multiorgan failure in every fourth patient affected [11]. The ulcer's progression and, accordingly, the extent and the intensity of the treatment depend on the bacterial burden [12], the colonisation with certain species, such as anaerobes [13], and the presence of multiresistant germs [14] that are associated with a longer and more severe course of the disease and with a more complex and expensive treatment [15]. Half of the pressure injuries are located near the anus [9], therefore, the impaired defecation control in SCI patients [16] might facilitate ongoing contamination and secondary infection. Faecal diversion via a stoma is a common concept that is thought to improve the healing process by preventing the wound from becoming contaminated with faecal microbiota [17].

Nevertheless, it is unclear whether and how the colonisation or secondary infection pattern changes in the presence of a stoma and if these presumed alterations play a pivotal role in the healing process. Although there are some hints in bed-bound patients [17], our group recently could not confirm an improved outcome in stoma-treated SCI patients [18] and, even more remarkably, a high mortality of 15% was described after colostomy in a small cohort [19]. Hence, we aimed to investigate the microbial pattern regarding the primary (preoperative) colonisation, the secondary (postoperative) infection, the frequency of multiresistant microbiota, and the effect on ulcer healing in a retrospective, age-, gender- and general condition-matched case-control study.

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MATERIALS AND METHODS

Study population

A total of 60 patients with colostomy or ileostomy was included in 464 consecutive adult patients with longstanding (≥6 months) SCI with an anus-near decubitus stage 3 or 4, according to the European Pressure Ulcer Advisory Panel (EPUAP) and the National Pressure Ulcer Advisory Panel (NPUAP) [1] (Table S-1) requiring surgery. An age- (±3 years), gender-, body mass index (BMI)- (±4 kg/m2) and ASA score-matched group of SCI patients without a stoma served as a control in this retrospective cohort study in a 1:1 ratio (Fig. S-1 and Table S-2). The inclusion and exclusion criteria are detailed in Table S-3. All patients were treated in a specialised SCI unit (University Hospital Bergmannsheil, Bochum, Germany) between 2007 and 2017.

Clinical data acquisition

Clinical data, such as BMI, smoking habits, alcohol consumption, comorbidities, previous ulcer surgery and medication, were collected from the electronic database at admission. Laboratory parameters were studied before the pressure injury's surgery and at discharge.

Definition of ulcer characteristics and staging of disability

The anus-near localisation was defined as any ulcer that spread out with at least a substantial surface within the following anatomical structures: the connecting line between both posterior superior iliacal spines (e.g. the cranial margin), the connecting lines between the two ischial tuberosities and the dorsal perineal area (e.g. the ventrocaudal margin), and the connecting line between the posterior superior iliacal spines and the ischial tuberosities (e.g. the lateral margins). The severity level of the ulcers was classified according to the EPUAP, NPUAP and PPPIA (Table S-1) [1]. The healing was evaluated based on the clinical charts. If the detailed description of the achievement of the complete wound healing time was not available, the time of discharge was defined as the end point of wound healing as implemented in routine practice. Preterm discharge before complete wound healing was documented accordingly.

Microbial characterisation

Smears were taken from the deep wound ground during initial surgery and repeated on demand, for instance, in the case of delayed wound healing or signs of secondary infection. Microbial germs that are not part of the local skin microbiota or amounts over the upper limit values are classified as primary colonisation. Microbial colonisation that has not been described in the initial probe was classified as a secondary infection. Ulcers in which only one germ species was found were rated as a monoculture. Bacteria were distinguished as Gram-positive and -negative and were assigned to their superordinated species (e.g. Staphylococcus spp., Enterococcus spp.). Anaerobic bacteria and fungi were characterised separately.

Microbial testing routine

All microbial tests were performed at the microbial laboratory of the University Hospital Bergmannsheil Bochum with reagents and technical devices from bioMérieux, Nürtingen, Germany. Inoculated chocolate agar and MacConkey agar were incubated at 37 °C for 48 h to identify the germ species of blood agar plates. Growth media for anaerobic bacteria and fungi was incubated at the same temperature for five days. Enrichment broths were used. Growth media for multiresistant Staphylococcus aureus and enterococcus were used routinely. Identification of the cultured germs was realised by the microbial identification and antibiotic susceptibility testing system VITEK (bioMérieux, Nürtingen, Germany).

Surgical standard procedure

Surgical procedures, including the mechanical wound debridement with removal of coatings and necrotic tissue, were realised under general anaesthesia, as described previously [18].

Objectives

The primary objective was to evaluate the microbial colonisation of an anus-near pressure injury stage 3 and 4 depending on the presence of a stoma. Secondary objectives were the detection of multi-resistant bacteria, the frequency and the character of a secondary infection, and the impact on wound healing (days of hospital and intensive care stay, condition at discharge) on complications and mortality. General risk factors (e.g. active smoking, alcohol consumption) as well as SCI- and ulcer-related factors (e.g. length, size, severity) were analysed regarding possible effects on primary and secondary objectives.

Statistics

Statistical analysis was performed using SPSS for Windows, version 25.0 (SPSS Inc, USA). The arithmetic mean and standard deviation or median and interquartile range (IQR) were used for metric variables. Categorial and nominal data were indicated as absolute and relative frequencies. Interference statistics were realised using paired *t*-test, Fisher's exact test, Mann-Whitney *U* test, chi-squared ($\chi 2$) test and analysis of variance (ANOVA). A *p*-value < 0.05 was regarded as significant. Regression analysis (multinominal, binary logistic, linear regression) was performed on potentially biasing values that were tested with Cramer's V, Eta coefficient and/or Spearman and Pearson. Thus, correction concerning the pressure injury's size, white blood cell and haemoglobin value, presence of a stoma, and all germ species tested as an effect on the duration of healing was calculated. Additional risk factors on the endpoints, such as alcohol and nicotine consumption, were calculated. We tested the associations of different starting points (size of the pressure injury, previous operations and, above all, the presence of a stoma) with the colonisation of different bacterial species and analysed the association with clinical outcome parameters (duration of hospital stay, complications, recurrence). Missing data were mentioned explicitly.

RESULTS

A total of 60 stoma-treated patients with faecal diversion (FDG) and 60 matched controls (CG) (median age 52 years (IQR 43; 65), 26 females (21.7%), median BMI 26.0 kg/m^2 (IQR 22.3; 29.3), ASA classification: 21 (35%) grade 2, 39 (65%) grade 3) were included (Table S-2). Basic demographic and SCI characteristics were distributed similarly (Table 1 and S-4). Comorbidities (Table S-5), medication (Table S-6) and laboratory parameters (Table S-7) differed only slightly: for instance, the FDG presented lower haemoglobin values at admission (10.9 vs. 12.1 g/dl, $p < 0.01$) and tendentially at discharge (11.3 vs. 12.1 g/dl, $p = 0.05$).

Ulcer characteristics

Approximately half of the patients in both groups had undergone previous ulcer-related surgery. Although the severity was equally distributed between both groups (grade 3 in 51.7 vs. 55.0% and grade 4 in 48.3 vs. 45.0%, respectively) the extent was slightly larger in the FDG (25.0 (6.0; 80.0) vs. 16.0 (4.5; 35.0) cm^2, $p < 0.01$, Fig. S-2). The current ulcer's size was not specified in 21 cases (FDG 51 vs. CG 48).

Stoma characteristics

The stomata were constructed as end-colostomy in 24 and as loop-ileostomy in 14 cases (Table 1 and S-2). The remaining cases were not specified. The median time between stoma construction and current ulcer treatment amounted to 40 months (IQR 2.9; 178.8).

Microbial colonisation and secondary infections

Virtually all patients (97.5%) presented a primary microbial colonisation (Tables 2 and 3). Gram-positive germs were most common in both groups (FDG = 43 (71.7%) and CG = 38 (63.3%), $p = 0.33$), and Gram-negative colonisation was detected in 40 (66.7%) and 43 (71.1%) patients, respectively ($p = 0.55$). The abundance of bacterial species did not differ: monocultures were documented in 24 (FDG, 40.0%) vs. 23 (CG, 38.3%), and polymicrobial colonisation with more than three species were detected in 4 (6.7%) and 3 patients (5.0%), respectively.

Almost half of the wounds were colonised with Staphylococcus spp. (FDG = 26 (43.3%) vs. CG = 28 (46.7 %), $p = 0.71$). Streptococcus spp. were less frequent with 12 (FDG, 20%) and 8 (CG, 13.3%, $p = 0.36$) verified germs (Fig. 1). A remarkable difference was detected with respect to E. coli spp.: 11 (18.3%) cases were found in the FDG compared to 26 in the CG (43.3 %; $p < 0.01$).

Table 1. Basic demographic characteristics.

	Faecal diversion group $n = 60$	Control group $n = 60$	p-value[a]
	Number (%) or Median (IQR)[a]		
Gender [female]	13 (21.7)	13 (21.7)	1.00
Age [years]	51.5 (43.3; 64.8)	52.5 (43.0; 65.8)	0.99
Body mass index [kg/m²]	26.0 (22.0; 29.3)	26.0 (22.5; 29.2)	0.37
Grade of decubitus			0.71
Grade 3	33 (55.0)	31 (51.7)	
Grade 4	27 (45.0)	29 (48.3)	
Size of pressure injury	25 (6;80)**	16 (4.5;35)	0.001
Comorbidities	58 (96.7)	57 (95.0)	0.65
Smoking habit			0.09
Active smoker	17 (33.3)	10 (18.9)	
Non-smoker	34 (66.7)	43 (81.8)	
Alcohol consumption	5 (10.0)	8 (15.4)	0.42
ASA classification[b]			
Grade 1	0 (0)	(0)	
Grade 2	21 (35.0)	21 (35.0)	1.00
Grade 3	39 (65.0)	39 (65.0)	1.00
Grade 4	0 (0)	0 (0)	
Grade 5	0 (0)	0 (0)	
Admission to surgery time [days]	70 (28.5; 125)	75 (35; 183)	0.62
Previous surgical pressure injury procedures	35 (58.3)	30 (50.0)	0.36
End-colostomy	24 (40.0)	-	
Loop-ileostomy	14 (23.3)	-	
Time between stoma surgery and current pressure injury [months]	39.9 (2.9; 178.8)	-	-
Adverse event during stoma surgery	3 (5.0)		-

ASA American Society of Anesthesia, *ASIA* American Spinal Injury Association, *SCI* spinal cord injury.
[a]as appropriate, [b]regardless SCI.
**$p < 0.01$.

Colonisation with Klebsiella spp. differed tendentially with 7 (FDG 11.7%) vs. 2 (CG 3.3%) cases ($p = 0.08$). The colonisation with Pseudomonas spp., Proteus spp. and Enterococcus spp. was not distinguished (Table 3). Anaerobes were equally detected in both groups (FDG = 6, 10.0% and CG = 7, 11.7%). The presence of multiresistant was twice as high in the CG (FDG = 7 (11.7%) vs. CG = 14 (23.3%), $p = 0.09$). A detailed description is given in Figs. 1, 2, S-4 and S-5.

Nineteen patients experienced a secondary infection during ulcer treatment, equally distributed among both groups (FDG = 11 (18.3%) vs. CG = 8 (13.3%); Table 4). Gram-positive and -negative strains generally occurred similarly, but, in detail, there was a slight difference regarding Enterococcus spp. (FDG = 4 (6.7%), CG = 0; $p < 0.05$).

Length of hospital stay, adverse events and recurrence

Stoma-treated patients stayed 21 days longer in the hospital than the CG (78.0 (IQR 49.3; 113.0) vs. 56.5 (IQR 43.3; 90.5) days, $p < 0.05$). The vast majority were discharged with a cured ulcer. The remaining 9 patients aborted the treatment upon request and followed outpatient treatment (FDG = 2 (3.3%)) or died (FDG = 4 (6.7%) vs. CG = 3 (5%)). Hence, the mortality rate did not differ. Further adverse events are detailed in Table S-8, grouped by severity (Fig. S-3)

Taking only the patients with cured ulcers into account, the length of hospital stay needed a minor correction (FDG 78.5 vs. CG 57.0 days, $p < 0.05$; Table 2 and Fig. 3). The correlation between the presence of a stoma and the length of healing time is weak, but significant (Eta coefficient = 0.229, $p = 0.01$). Additionally, the healing time negatively correlated weakly with the decubitus' size ($p = 0.01$, Pearson = 0.252) and various other preoperative laboratory values (red and white blood cell count, platelets, and CRP; Table S-9). Partial correlation with adjustment for the parameters previously mentioned suggests that the presence of a stoma does not affect the ulcer's healing time ($p = 0.14$).

Risk factor analysis

The binary logistic regression revealed a significant effect for the grade of the decubitus to predict the colonisation with

Table 2. Outcome parameters.

	Faecal diversion group $n = 60$	Control group $n = 60$	p-value[a]
	Number (%) or Median (IQR)[a]		
Primary microbial colonisation	59 (98.3)	58 (96.7)	0.56
Microbial secondary infection	11 (18.3)	8 (13.6)	0.45
Length of hospital stay [days]	78.0 (49.3; 113.0)*	56.5 (43.3; 90.5)	0.01
Condition at time of discharge			0.33
Cured pressure injury	54 (90.0)	57 (95.0)	
Treatment aborted because of death	4 (6.7)	3 (5.0)	
Follow-up outpatient treatment needed	2 (3.3)	0 (0.0)	
Length of hospital stay (days) with complete cure	78.5 (50.0; 111.5)*	57.0 (45.0; 93.5)	0.02
Need for ICU stay	5 (8.3)	3 (5.0)	0.33
Adverse events during ulcer treatment			0.76
Grade 1	15 (25.0)	16 (26.7)	
Grade 2	3 (5.0)	8 (13.3)	
Grade 3	5 (8.3)	4 (6.7)	
Grade 4	4 (6.7)	3 (5.0)	
Healing disturbance	20 (33.3)	24 (40.0)	0.45
Adverse events during stoma surgery	3 (5.0)		
Stoma-associated adverse events	5 (8.3)		
Clostridioides difficile infection	2 (3.3)	1 (1.7)	0.56
Recurrence [within 3 months]	5 (8.3)	4 (6.7)	0.73
New pressure injury in the same region [within 3 months]	2 (3.3)	2 (3.3)	1.00

[a]Chi^2 test or Mann-Whitney U test, as appropriate.
*$p < 0.05$.

multiresistant germs in general (OR = 2.7, CI = 1.1–6.6, $p = 0.03$). Smoking was determined as a relevant risk factor for secondary infections in the cohort of stoma-treated patients (OR = 8.7, CI 1.5–49.8, $p = 0.01$); these findings were not reproducible among the CG, which included only ten active smokers.

The binary logistic regression analysis considering the whole cohort showed that the presence of a stoma (OR = 2.9, CI 1.5–5.9, $p = 0.003$), monocultures (OR = 2.7, CI 1.1–6.6, $p = 0.02$) and multiresistant germs as primary colonisation (OR = 4.7, CI 1.0–21.3, $p = 0.05$) are associated with a reduced probability of E. coli spp. The other germ lines were associated with other parameters (Table S-10): the frequency of Streptococcus spp. decreased significantly with previous surgery (OR = 9.8, CI 4.2–22.7, $p < 0.001$) and colonisation with Staphylococcus spp. was identified to be associated with a decreased number of secondary infections (OR = 12.5, CI 4.3–34.6, $p < 0.001$). Wound-healing disturbances were not influenced by particular germ species. The verification of multiresistant germ lines was negatively associated with E. coli (OR = 17.5, CI 4.2–72.8, $p < 0.001$) and positively with Staphylococcus spp. (OR = 2.0, CI 1.1–3.5, $p = 0.01$). None of the species of the primary colonisation or secondary infection was associated with wound-healing disturbances or the length of the hospital stay.

Table 3. Primary microbial colonisation.

	Faecal diversion group $n = 60$	**Control group n = 60**	***p*-value[a]**
	Number (%) or median (IQR)[a]		
Monoculture	24 (40.0)	23 (38.3)	0.85
Bacterial species with > 1 species	36 (60.0)	37 (58.3)	0.85
Bacterial species with > 3 species	4 (6.7)	3 (5.0)	0.70
Multiresistant bacterial species	7 (11.7)	14 (23.3)	0.09
Candida species	2 (3.3)	1 (1.7)	0.56
Bacterial species			
Gram-positive	43 (71.7)	38 (63.3)	0.33
Gram-negative	40 (66.7)	43 (71.1)	0.55
Streptococcus spp.	12 (20.0)	8 (13.3)	0.36
Staphylococcus spp.	26 (43.3)	28 (46.7)	0.71
E. coli spp.	11 (18.3)	26 (43.3)**	0.003
Klebsiella spp.	7 (11.7)	2 (3.3)	0.08
Pseudomonas spp.	15 (25.0)	13 (21.7)	0.66
Anaerobier	6 (10.0)	7 (11.7)	0.77
Proteus spp.	14 (23.3)	13 (22.0)	0.87
Enterococcus spp.	15 (25.0)	10 (16.7)	0.26

[a]Statistics were realised by Chi^2 Test.
**$p < 0.01$.

DISCUSSION

The main result of this thoroughly matched retrospective cohort study of patients with SCI is that the presence of a stoma is associated with only minor changes of the microbial colonisation of anus-near pressure injuries. Though the main idea of the faecal diversion concept is to achieve a cleaner wound ground, the frequency of microbial colonisation, on the one hand, and of the variety of species isolated from the wound grounds, on the other hand, did not differ between the patients with faecal diversion and those relying on a supported natural defecation. Furthermore, as has been described previously, the main species [20] found in nearly every second ulcer was Staph. aureus. This finding was consistent in both groups similarly and underlines the importance of factors other than faecal contamination even in anus-related ulcers.

Focusing on typical faecal bacteria, we only found one remarkable difference: as expected, E. coli colonised the wounds of patients with natural defecation approximately twice as often (43.3 vs. 18.3 %; $p < 0.01$). On the other hand, when E. coli was absent, multiresistant germs occurred five times more often. Since multiresistant bacteria were more prevalent among the control group it might be reasonable that more frequent

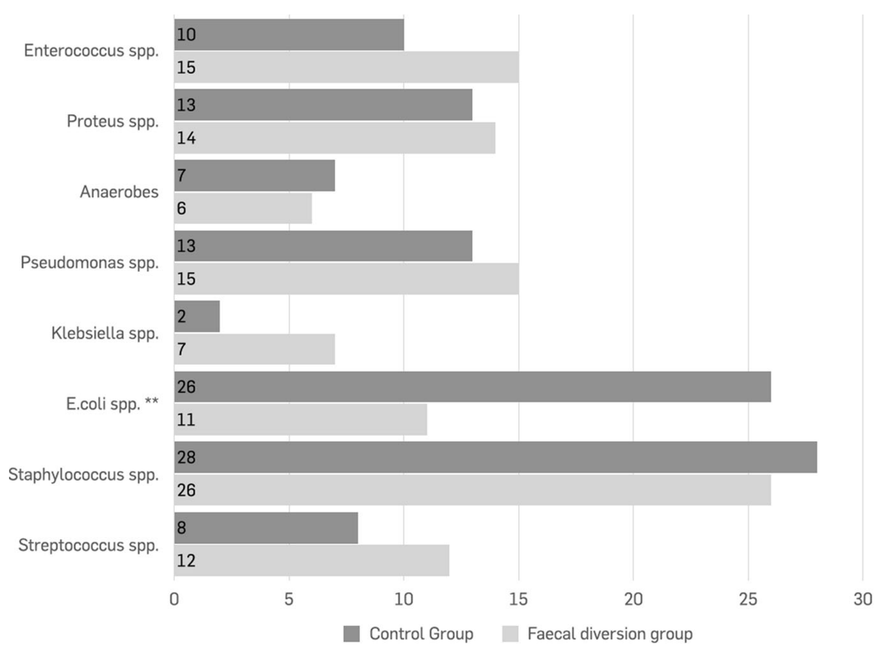

Fig. 1 Distribution of the primary bacterial colonisation. Diversity and variable proportions of bacterial species regarding the primary colonisation in the faecal diversion (FDG) and control group (CG) shown as a bar chart. A significant difference can be seen in E. coli spp. colonisation with 11 (18.3%) in the FDG vs. 26 (43.3%) in the CG. ($p < 0.01$). Statistics were realised by the Chi^2-test (**: significant with $p < 0.01$).

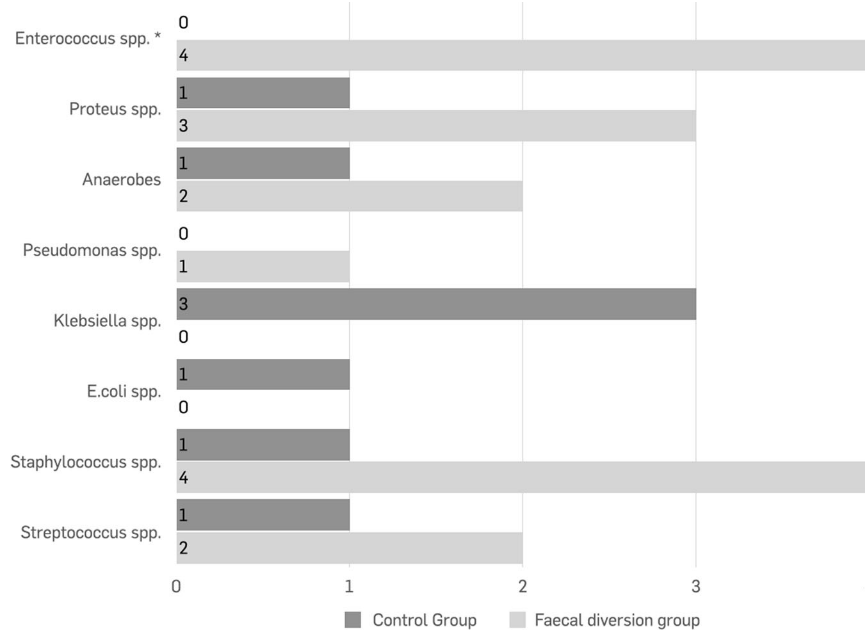

Fig. 2 Distribution of the primary bacterial colonisation infection. Diversity and variable proportions of bacterial species regarding the secondary infection in the FDG and CG shown as a bar chart. A significant difference is seen in Enterococcus spp. colonisation. No case was detected in the CG, but 4 (6.7%) in the FDG ($p < 0.01$). Statistics were realised by Chi^2-test (*: significant with $p < 0.05$).

Table 4. Secondary microbial infection.

	Faecal diversion group $n = 60$	Control group $n = 60$	*p*-value[a]
	Number (%) or Median (IQR)[a]		
Microbial secondary infection	11 (18.3)	8 (13.3)	0.45
Monoculture	7 (11.7)	5 (8.3)	0.54
Bacterial superinfection with ≥ 2 species	4 (6.7)	3 (5.0)	0.70
Multiresistant bacterial species	4 (6.7)	2 (3.3)	0.40
Candida species	1 (1.5)	0 (0)	0.32
Secondary infection: bacterial species			
Gram-positive	8 (13.3)	4 (6.7)	0.22
Gram-negative	7 (11.7)	5 (8.3)	0.54
Streptococcus spp.	2 (3.3)	1 (1.7)	0.56
Staphylococcus spp.	4 (6.7)	1 (1.7)	0.17
E. coli spp.	0 (0.0)	1 (1.7)	0.32
Klebsiella spp.	0 (0.0)	3 (5.0)	0.08
Pseudomonas spp.	1 (1.7)	0 (0.0)	0.32
Anaerobier	2 (3.3)	1 (1.7)	0.56
Proteus spp.	3 (5.0)	1 (1.7)	0.31
Enterococcus spp.	4 (6.7)*	0 (0.0)	0.04

[a]Statistics were realised by Chi^2 Test.
*$p < 0.05$.

antibiotic use in these patients and the resulting selection pressure on the colonising bacteria may have lead to these microbial changes [21]. Since we do not possess any such information, it might also be arguable that E. coli prevents the wound's colonisation competitively and by activation of the mucosal immune system [22].

A similar amount of 18.3 and 13.3% acquired a secondary infection during the ulcer's treatment and healing process; the only remarkable difference involves Enterococcus spp., which occurred more frequently in the faecal diversion group. A possible explanation might refer to the higher bacterial load in the stoma-treated patient's environment that might result from spreading faeces [23]. Hence, the bacteria might be transferred during stoma and wound care.

Some bacterial species, particularly Staph. aureus, Proteus spp. and Bacteroides spp., play a vital role because those infections increase the risk of complications and mortality in pressure injuries [24]. Our data suggest that the presence of a stoma does not prevent microbial colonisation or secondary infection and affects the microbial wound flora only slightly. More importantly, neither the faecal diversion nor the microbial spectrum was associated with the wound healing.

Despite diligent matching according to ASA classification, gender, age and BMI, there are some limitations to discuss. First of all, the patients with faecal diversion presented slightly larger ulcers and, consequently, probably needed longer for the healing process. Nevertheless, there were no associations to the bacterial colonisation or secondary infection. Secondly, though the reason for the previous stoma construction remained unclear, it was rarely constructed for the purpose of the current ulcer treatment and contained different types, such as loop ileostomy and end colostomy. It might be arguable that the time shift between stoma construction and ulcer treatment might have influenced the primary colonisation pattern, but it is not reasonable to affect the secondary colonisation or wound healing. The lack of any association on the outcome parameters confirms these fundamental considerations regarding the faecal diversion concept. Thirdly, the retrospective design resulted in a loss of certain information. The ASA classification, for instance, was only available at the time of inclusion, but not the stoma construction. Additionally, the indications for stoma construction remained uncertain; it might reasonably be possible that the severity of comorbidities, a lower overall physical performance or other clinical aspects could have influenced the decision in favour of the stoma. The matching process has adjusted these biasing factors

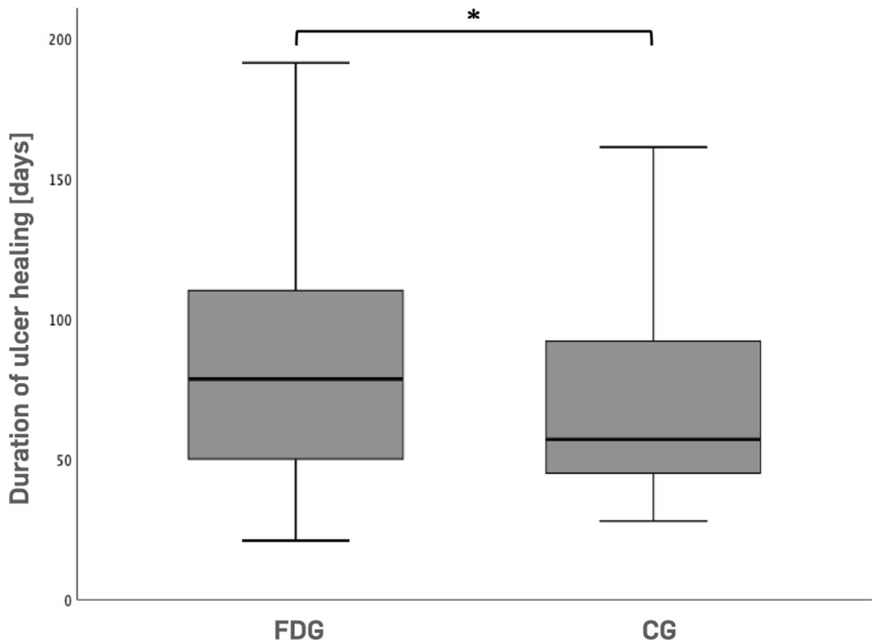

Fig. 3 Duration of ulcer healing. Duration of ulcer healing regarding the presence of a stoma: the length of healing (in days) of the FDG and the CG are shown as box plots, so that a comparison of the two groups is possible. These box plots include only patients who completed the treatment regularly and hence are labelled as successfully cured. Patients who died prematurely (FDG = 4 (6.7%) vs. CG = 3 (5%)) or discontinued treatment for other reasons (FDG = 2, 3.3%) are not reflected. The median duration varied significantly (*) from 75.5 days (IQR 50.0; 111.5) in the FDG to 57.0 days (IQR 45.0; 93.5) in the matched CG with supported natural defecation (Mann–Whitney-*U*-test, $p < 0.05$).

and resulted in mostly similar basic demographic characteristics; only a few differences occurred including a longer duration of SCI, more frequent smoking habits, divergent laboratory values and larger ulcer sizes. According to the regression analysis, these parameters interfered with the prolonged healing time in the faecal diverted patients, but did not change the bacterial flora. Additionally, the healing time that complies with the current literature [7] is not influenced by the presence of a stoma. Fifthly, the microbial identification was realised by culture techniques that might not detect all the different species within the complexity of a chronic wound [20]. Though the flora found in this cohort matches well to that described in literature [20], newer techniques, such as RNA-based fingerprints, might have detected a larger variety of germs [25].

CONCLUSION

Although the presence of a stoma is associated with less frequent colonisation of anus-near pressure injuries with E. coli, the overall microbial pattern shows only minor alterations. Future, preferably prospective studies with larger cohorts should validate the results and broaden the analysis by new laboratory methods. After correction for the ulcer's size, the stool deviation concept did not influence the treatment outcome parameters such as overall success, healing time or adverse events. Regarding the potential morbidity and psychological restrictions related to the stoma construction, we currently do not recommend it to be the standard strategy and it should, instead, be based on individual decision-making. A randomised controlled study, though hardly realisable, is mandatory to clarify the impact of the faecal diverting concept in the context of the treatment of anus-near pressure injuries.

DATA AVAILABILITY

Data for this study are available on reasonable request. Please contact the corresponding author for the research data.

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ETHICS APPROVAL

The study protocol was approved by the institutional review board of the Ruhr University Bochum [registry number 18-6351] on the basis of the ethical guidelines of the Declaration of Helsinki and its later revisions; informed consent was obtained from all patients before surgery. Informed consent was neither practicable nor necessary for this retrospective study and was exempted by the institutional review board.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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