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Published in:
Journal of Tissue Viability

DOI:
[10.1016/j.jtv.2020.08.004](https://doi.org/10.1016/j.jtv.2020.08.004)

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Document Version
Publisher's PDF, also known as Version of record

Publication date:
2020

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Braafhart, M., de Laat, H. E. W., Wagner, T., van de Burgt, E., Hummelink, S., & Ulrich, D. J. O. (2020). Surgical reconstruction of pressure ulcers in spinal cord injury individuals: A single- or two-stage approach? *Journal of Tissue Viability*, 29(4), 319-323. [JTV 393]. <https://doi.org/10.1016/j.jtv.2020.08.004>

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Surgical reconstruction of pressure ulcers in spinal cord injury individuals: A single- or two-stage approach?

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ARTICLE INFO

Keywords:

Pressure ulcers
SCI individuals
Surgical reconstruction
Stage reconstruction
Two-stage reconstruction

ABSTRACT

Introduction: There are two surgical approaches to reconstruct a pressure ulcer (PU): one-stage reconstruction or two-stage reconstruction. One stage reconstruction consists of surgical debridement and flap reconstruction during one operation. Two-stage surgery consist of a surgical debridement and a final reconstruction in two different sessions, with approximately six weeks between both sessions.

Objective: The aim of this study was to compare the results of single stage surgery and two-stage surgery on the PU recurrence rate and other important post operative complications.

Method: A retrospective, comparative study in Spinal Cord Injured (SCI) individuals with a single- or two stage surgical reconstruction between 2005 and 2016 was designed. A total of 81 records were included for analysis.

Results: The primary outcome, the difference in occurrence of a recurrent PU in the reconstructed area (33.3% versus 31.6%), is not statistically significant between one-and two-stages reconstruction. Also, the mean duration to develop a recurrent PU between both surgical reconstructions is not statistically significant.

Other surgical complications in the reconstructed area like wound hematoma, hemorrhage, seroma or (partial) flap failure did not differ significantly between both groups, apart and in total.

We calculated the additional costs in case of a two-stage approach compared with a single-stage reconstruction at EUR 16,362.

Conclusions: There are no statistical significant differences in PU recurrence rate or other post operative complications between SCI patients who have undergone one- or two stage PU reconstructive surgery.

The most obvious choice for a one-stage approach in case of PU reconstructive surgery has great positive implications for the patient, family, health care providers and the health care system.

1. Introduction

Pressure ulcers (PUs) classified into four grades of increasing severity [1] are one of the most common secondary complications in spinal cord injury (SCI) individuals due to both sensory and motor constraints [2–4] with a prevalence and incidence of all categories between 30% and 49% [3,5–8] and 13% and 25% [8,9] respectively. In contrast to the general population, the severity of PU is high with up to 56% of the PU classified as category IV [8].

PU's in wheelchair bound patients are often localized in the sacral-, ischial- and trochanteric areas. Most of these PUs can be treated non-surgically by intensifying preventive measures focused on the paraplegic patient, wound treatment by cleansing, debridement and the

application of wound dressings and life style interventions [1]. However, in individuals with category III or IV PU that are not closing by conservative treatment, surgical treatment should be necessary as appropriate to the individual's condition and goals of care [1].

The surgical procedure for reconstructive PU-surgery exists of a comprehensive ulcer excision, bone necrosectomy, excision of bursae (if indicated) and finally the reconstruction. This reconstruction usually involves transposition of a cutaneous, myocutaneous or fasciocutaneous flap. The choice of type of flap depends on the localization, extent and previous surgeries in the same area of the PU [10–12].

In order to surgically treat a PU, two approaches have are available: single-stage reconstruction or two-stage reconstruction.

Single-stage reconstruction consists of surgical debridement and flap

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<https://doi.org/10.1016/j.jtv.2020.08.004>

Received 2 July 2019; Received in revised form 27 April 2020; Accepted 4 August 2020

Available online 14 August 2020

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reconstruction during one operation. Two-stage surgery consists of a surgical debridement and a final reconstruction in two different sessions, with approximately six weeks between both sessions. In this period the patient is admitted to a nursing home or rehabilitation center [13].

Research or any other form of consideration of the differences in postoperative outcomes between single-stage surgery and two-stage reconstructive surgery of pressure ulcers is scarce and inconsistent. Based on an analysis of patient outcomes Jordan [13] advocates that a period between the debridement and the final reconstruction in a staged approach may result in a more solid base to ensure consolidation of the flap due to a more appropriate prepared wound bed. A two stage approach allows identification of wounds with potential to heal when managed conservatively [14]. Moreover, severely infected pressure ulcers can be treated by antiseptic agents between the stages. This approach is thought to reduce the risk of wound infection [15], flap failure or bleeding and consequently reduce risk of PU recurrence in a later phase [14].

Foster [16], on the other hand, concludes on the basis of the only comparative retrospective study that a reconstruction can be reliably performed in a single stage-approach and that flap selection and short- and long term sequence of flap use are the only significant predictors of successful pressure ulcer coverage. Healing rates were similar for single-staged or multiple staged reconstructions. Also the cases where infection was the reason for wound disruption were equally divided in the single- and multiples stage groups.

Proponents of the single-stage approach are not convinced of the idea that short term post-operative complications (dehiscence, infection) and long term outcomes (PU recurrence) are prevented by a two-stage procedure. Proper muscle choice to fill the space, targeted treatment of infection and experience are necessary conditions to perform the operation in single-stage. Consequently, only one episode of anesthesia is needed and a four to six weeks shorter admission time suffice, resulting in a more rapid start of rehabilitation and faster return to normal life and social reintegration [17].

A unique situation in the research hospital arose six years ago when a new staff switched from the usual two-stage approach to a one-stage approach. This difference in treatment in one hospital makes it possible to compare the results of both approaches. Therefore, the aim of this study is to compare the results of single-stage surgery and two-stage surgery on the PU recurrence rate and other important post-operative complications.

2. Materials and methods

2.1. Study design

A retrospective, comparative, cohort study of SCI individuals who underwent a single- or two-stage surgical reconstruction of PU between 2005 and 2016 was designed. The study was performed at the department of plastic surgery in a university hospital and a collaborating center for rehabilitation medicine in the Netherlands. Inclusion criteria were adult patients of any age and sex with sacral, ischial, or trochanteric pressure ulcers that required flap reconstruction between 2005 and 2016. Patients with pressure ulcers managed conservatively or that required wound debridement and/or primary closure without flap coverage were excluded. The Institutional Review Board approved the study protocol.

2.2. Surgical procedures

During the initial surgical debridement, unhealthy skin edge of the ulcer was marked, followed by excision of the ulcer and shaving of the prominent underlying bone to the healthy bleeding level. Samples of the soft tissues and bone were sent for bacteriological examination. If osteomyelitis was suspected, a biopsy from the deep bone was taken.

In case of a two-stage reconstruction, hemostasis was achieved by a

minimum of coagulation and tamponation with saline soaked gauzes.

During a single-stage procedure or after four to six weeks (4.9 ± 2.1) in case of two-stage procedure a flap was designed and harvested depending on localization, extent and severity of the PU. Skin closure in two layers was achieved without tension after the placement of one or two drains depending on flap design.

All procedures were randomly performed by one of five experienced senior consultant plastic surgeons, under general anesthesia and antibiotic prophylaxis.

2.3. Post-operative care

In case of a two-stage reconstruction, the patient was transferred to the collaborative rehabilitation center the day after the surgical debridement. Permanent bed rest on an air mattress was prescribed until the final reconstruction. The wound was treated three times daily with antiseptic soaked gauzes (sodium hypochlorite) or negative pressure wound therapy in this period. After formation of a sufficient granulation base in the opinion of the consulting surgeon, the patient was transferred to the study hospital for the a final reconstruction. During the research period, negative pressure therapy increasingly became the preferred treatment between the two procedures. Approximately two-thirds of the patients (67%) were treated with negative pressure therapy; one-third (33%) with antiseptic gauze [18].

Directly after the single-stage reconstruction or the second stage of two-stage approach patients were treated according to a postoperative protocol based on principles that are generally used and described in the literature [19–22]. The first week post-operatively patients were placed on an air fluidized bed, followed by five week bed rest on an air mattress avoiding or minimizing pressure on the flap by positioning. Drains were kept in place until the discharge was less than 30 ml per 24 h. The sutures or staples were removed 3 weeks after surgery. Sitting was gradually allowed after six weeks, starting with the first day two times 15 min to three times 3 h on the ninth day. All patients were educated on PU risk and instructed and trained on appropriate transfers depending on the level of paraplegia and abilities to prevent PU recurrence. Before discharge from rehabilitation center an occupational therapist assessed patient position and cushion pressure in the wheel chair. Moreover a nursing assessment on daily care at home (shower seat, mattress) was performed. Outpatient control visits were carried out after three weeks by a nurse practitioner, after three months by the rehabilitation physician. After this period, visits were undertaken regularly every year by a multidisciplinary team or earlier if necessary.

2.4. Outcome measures

Recurrence of pressure ulcer at the site of flap, defined as the appearance of skin break at the surgical site after patients had completed their postoperative mobilization protocol with intact skin [23].

Dehiscence was defined as any recorded break in the skin in reconstructed area, occurring at any point before or during the mobilization protocol. The occurrence of a significant dehiscence necessitating revision of the flap was noted as distinct from suture line dehiscences that healed without intervention [23].

For the purpose of the present investigation hemorrhage was defined as persistent visible blood loss in the reconstructed area necessitating surgical re-exploration or external pressure for longer than 2 h. Hematoma and seroma were defined as the development of a tender, tense and discolored swelling that raised the wound area or flap and from which in case of a hematoma clotted or collected blood and in case of a seroma clear serous fluid was expressed or aspirated.

2.5. Statistics

Categorical variables are displayed in absolute and relative frequencies. Averages, range and standard deviation are displayed for

continuous variables. Both Chi-squared or Fisher's exact test was used to analyze the difference in frequencies between single- and two-stages reconstruction. An independent *t*-test was used to test the difference between continuous (interval or ratio) variables.

An estimation of the costs difference between single-stage surgery and two-stage surgery was based on the cost per day in a nursing home/hospital [24] and the additional costs for extra ambulance transport and negative pressure therapy.

IBM SPSS Version 22 (IBM Corp., Armonk, N.Y.) was used for statistical analyses, and a value of $p < 0.05$ was considered statistically significant.

3. Results

Between 2005 and 2016 a total of 84 eligible patients, have undergone a single-stage ($n = 24$) or two-stage ($n = 57$) reconstruction of a grade IV PU in our hospital. Five incomplete medical records were excluded. A total of 79 records of 27 female (34.2%) and 52 (65.8%) male SCI individuals with a one- (2013–2016) or two-stages (2006–2012) reconstruction were included for analysis. The mean age of the patients was $55.7 (\pm 15.6)$ years. Forty-five (57.0%) of these patients had a traumatic paraplegia. Twenty paralysis (25.3%) were the result of congenital disorder, in all cases spina bifida. Twelve paralysis (15.2%) had a non-traumatic cause like syringomyelia or non-traumatic spinal cord hemorrhage. The distribution of these characteristics in both groups did not differ statistically significant as well as the BMI, types of co-morbidities, specific medication, smoking status and transfer performance, as shown in Table 1.

The most performed surgical procedure was a reconstruction with the gluteus maximus flap ($n = 42$; 51.9%), followed by the tensor fascia lata flap ($n = 10$; 12.3%) and the gluteal thigh flap ($n = 7$; 8.6%).

The primary outcome, the difference in occurrence of a recurrent PU in the reconstructed area (33.3% versus 31.6%), is not statistically significant between single- and two-stages reconstruction. Also, the mean duration to develop a recurrent PU between both surgical reconstructions is not statistically significant (Table 2).

Other surgical complications in the reconstructed area like wound hematoma, hemorrhage, seroma or (partial) flap failure did not differ significantly between both groups (Table 3). The total number of complications did not differ significantly as well.

The mean surgery time differed statistically significant between a single-stage approach (110.8 ± 75.5) minutes and a two-stage approach (146.9 ± 58.6) ($p = 0.041$; $df = 65$).

The mean length of stay in the rehabilitation center between the two surgical procedures in case of a two-stage approach was $34.7 (\pm 12.5)$ days with a minimum of 9 days and a maximum 59 days. We calculated the additional costs in case of a two-stage approach compared with a single-stage reconstruction at EUR 16,362 (Table 4).

4. Discussion

In literature, no consensus has been reached on best practice concerning surgical treatment of pressure ulcers, with both single- and two-stage approaches being described. The results of this single-center retrospective study show no statistically significant difference in the number of recurrent pressure ulcers or other surgical complications between SCI individuals who underwent PU reconstructive surgery in single- or two-stages.

This finding refutes the superiority of a two-stage approach, which would lead to less short-term and long-term complications [13–15]. Therefore, the implications of this findings for practice are considerable. The most important gain of single-stage reconstruction in comparison to a two-stage approach, is reduction of length of stay in the rehabilitation center of approximately five weeks. This is advantageous for both the patient and the health care center. Patient admission is related to negative feelings like loneliness, homesickness, boredom are decreased.

Table 1

Patient characteristics.

	One-stage ($n = 24$)	Two-stages ($n = 55$)
Sex (female)	12 (50.0)	15 (27.3)
Age ($M \pm SD$)	57 ± 16.5	55.1 ± 15.3
Living situation		
Living alone	5 (20.8)	15 (27.3)
With family	10 (41.7)	17 (30.9)
Institutionalized	3 (12.5)	5 (9.1)
Unknown	6 (25.0)	18 (32.7)
BMI ($M \pm SD$)	26.6 ± 4.6	26.0 ± 7.1
Comorbidity		
Myocardial infarction		1 (1.8)
Peripheral vascular diseases		4 (7.3)
Pulmonary disorders	4 (16.7)	5 (9.1)
Cerebrovascular accident	3 (12.5)	1 (1.8)
Diabetes	2 (8.3)	9 (16.4)
No comorbidities	15 (39.0)	35 (63.6)
Medication		
Immunosuppressive agent	1 (4.2)	2 (3.6)
Cytostaticum		1 (1.8)
Smoking		
Smokes	1 (4.2)	8 (14.5)
Never smoked	5 (20.8)	9 (16.4)
Stopped smoking	5 (20.8)	7 (12.7)
Unknown	13 (54.1)	31 (56.3)
Paraplegia genesis		
Trauma	11 (45.8)	34 (61.8)
Congenital	8 (33.3)	12 (21.8)
Non-traumatic	3 (12.5)	9 (16.4)
Unknown	2 (8.3)	
Transfer performance		
Independent with aid	13 (54.1)	25 (45.5)
Patient lifter	4 (16.7)	7 (12.7)
Independent without aid	1 (4.2)	1 (1.8)
Dependent	1 (4.2)	
Unknown	6 (25.0)	22 (40.0)

Numbers are frequencies (%) or means $\pm$ standard deviation.

Table 2

Pressure ulcer recurrence in the reconstructed area.

	One-stage ($n = 24$)	Two-stages ($n = 55$)
Total of new PU	8 (33.3)	18 (32.7)
• $\leq$ Grade 2	1 (4.2)	
• Grade 3	3 (12.5)	3 (5.5)
• Grade 4	3 (12.5)	9 (16.4)
• Unknown	1 (4.2)	6 (11.0)
Time (days) to recurrence	709 ± 874	519 ± 489

Numbers are frequencies (%) or means $\pm$ standard deviation.

Table 3

Surgical complications in the reconstructed area.

	One-stage ($n = 24$)	Two-stages ($n = 55$)
Flap necrosis		4 (7.2)
Hemorrhage		1 (1.8)
Surgical site infection	1 (4.2)	2 (3.6)
Dehiscence	4 (16.7)	10 (18.2)
Seroma		4 (7.2)
Total of surgical complications	5 (20.8)	21 (38.2)

Numbers are frequencies (%).

Faster return to their own social environment is therefore beneficial. Also the burden of surgery or anesthesia related problems like anxiety, pain and nausea need to be endured only once, as a single operation suffices.

Another advantage of a single-stage approach is the reduction of the

Table 4

Additional costs in case of a two stage approach in Euro's.

Accommodation costs (rehabilitation center or nursing home x 35)	13,930
Accommodation costs hospital x 2	1270
Ambulance transport	350
Negative pressure therapy	812
Total additional costs	16,362

general risk that is part of every surgical intervention. Furthermore, there are always surgery related complications like infection and bleeding [25,26]. Although not statistically significant, less direct post-operative complications in the single-stage approach was found. This means that, in addition to the equivalence of the single-stage approach considering the PU recurrence rate, also the frequency of direct post-operative complications is reduced in case of a single-stage approach.

Besides patient benefits, the findings as presented in this study are important for hospitals, rehabilitation centers and nursing homes with regard to the treatment costs and bed occupancy. A short hospital admission of two days for the surgical debridement is no longer necessary, as well as the subsequent interim admission period in a rehabilitation center or nursing home before the plastic surgical reconstruction. Moreover, only one instead of two transportations of the patient from the hospital to the rehabilitation center or nursing home by ambulance is required. This result confirms what earlier research has already indicated [13]. It also appears that the total operation time of a single-stage approach will take half an hour shorter than a two-stages reconstruction. A statistically significant decrease of half an hour of operation time will have positive impact on capacity and costs.

Although our study was not designed as a cost-effectiveness study, we calculated a cost saving of more than EUR 16,000 per treatment.

In this study, no statistically significant difference in the overall number of complications after a single- or two-stage approach was established, and occurred in a total of 26 patients (32%). The number of complications in similar patient groups varies between 0% [27] and 59% [28]. This variation can be explained by methodological differences, underreporting, type and complexity of reconstructions and differences in patient groups included. For our data extraction we had access to all and complete day-to-day registrations in patient records. It is unlikely that the assessment of complications is biased by underreporting [29].

Ultimately, the time between emergence of a recurrent pressure ulcer in single- and two-stage reconstruction did not differ significantly. This finding refutes the suggestion that a two-phased approach would protect the patient from an earlier recurrence of a new pressure ulcer due to wound infection, directly after a single-stage in the early post-operative phase [13,14]. Moreover, the favorable results with a two-stage reconstruction assumed in these studies were based on a noncomparative study design. The comparative nature of our design is unique and precisely the most striking difference with all other studies on this subject.

We found a pressure ulcer recurrence within two years after surgery of 33% (8/24) and 32% (18/57) in the one- and two-stage approach respectively. For SCI individuals is self-management post-operative very important. SCI individuals need supportive efforts from family, caregivers and medical disciplines. However, barriers like funding, physical constraints and secondary complications play a role. This increases the risk of complications and hence the occurrence of a recurrent pressure ulcer [30,31]. The recurrence rate in our study is an issue of serious concern, but in line with previous findings [23,32–34]. This finding seems to be in contrast to the extensive efforts by health care professionals to instruct patients how to prevent new pressure ulcers and by patients to incorporate these recommendations in their normal life by self-management programs. In a former study [35] we found that the vast majority of spinal cord injury patients do agree that the responsibility for the management of their own health conditions lies

within themselves. However, there is a gap between the intended and actual behavior to prevent pressure ulcers. Moreover, the extent of self management in spinal cord injured people is lower when compared to patients with other chronic diseases, e.g. diabetes mellitus. We discussed that patients with spinal cord injuries are less capable to manage their health condition as opposed to patients with other chronic diseases. A possible explanation for this difference are difficulties with emotional adjustment after a spinal cord injury occurred, that may result in depression, self-neglect behaviors and substance abuse. This underlines the importance of an early detection of potential self-management disorders and the development of a tailored self-management program for individuals with SCI and their caregivers preferably in the pre-operative phase [31,36].

Finally, some limitations due to the retrospective design of this study need to be discussed. The inclusion covers a period of 12 years. During the period that a single-stage reconstruction was preferred, there were, exceptionally, two-stage reconstruction performed in patients with infected and neglected pressure ulcers. These patients are also at risk of postoperative complications. As a result, a selection bias cannot fully be excluded, which is possible in a controlled prospective design [37].

In a retrospective study, data on additional therapies like lifestyle or nutrition are often subject to underreporting. Therefore, these variables are not included in this study. In a prospective design, however, these data can be collected systematically and their influence on the final outcome can be analyzed [37].

We are of the opinion that the above limitations do not affect the final conclusion of this study.

5. Conclusion

There are no statistically significant or clinical relevant differences in the number of recurrent pressure ulcers or other surgical complications in SCI individuals who underwent PU reconstructive surgery in a single- or two-stage approach. This also applies to the duration in which a recurrent pressure ulcer occurs.

Consequently, the most obvious choice for a single-stage approach in case of PU reconstructive surgery has great positive implications for the patient, family, health care providers and the health care system.

Declaration of competing interest

The authors declare that in connection with the submitted article there are no commercial associations that might pose a conflict of interest.

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