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Donor-site morbidity after harvesting of radial forearm free flaps—comparison of vacuum-assisted closure with conventional wound care: A randomized controlled trial

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ABSTRACT

Introduction: Radial forearm free flaps (RFFF) are often used to replace tissue removed in head and neck surgery. In recent years, many attempts have been made to reduce donor-site morbidity and to prevent common complications such as infection, skin-graft necrosis, tendon exposure and subsequent impairment of hand function. One promising option is the use of vacuum-assisted-closure wound therapy (VAC). The objective of this study was to evaluate the effectiveness of VAC compared with a conventional bolster dressing (CBD).

Material and methods: A randomized controlled trial was enrolled. Our study was prospective in design and included patients with a skin-grafted forearm defect after harvesting of RFFF. Patients who met the inclusion criteria were randomly assigned into two study arms. The predictor variable was the type of wound therapy (VAC therapy compared with CBD) and the outcome variables were (1) the size of the wound area, (2) wrist movement and (3) grip strength. Outcome variables were assessed 12 days, three weeks and eight weeks after surgery.

Results: Fifty patients (33 males, mean age 61.7 years [SD 15.5]; 17 females, mean age 54.7 years [SD 10.5]) were included consecutively in the study. Patients in the VAC group experienced a faster post-surgical reduction of wound area and had better wrist movement; nonetheless, the differences between the VAC group and CBD group did not reach statistical significance. In contrast, the recovery of post-surgical grip strength was significantly faster in the VAC group.

Conclusions: Our study failed to prove that VAC therapy is significantly superior to CBD for all the variable studied. Because VAC therapy has some positive effects, however, we recommend further development of this negative-pressure wound treatment, rather than the termination of its use.

1. Introduction

The technique of using radial forearm free flaps (RFFF) for the reconstruction of defects in head and neck surgery was introduced in 1981 (Yang et al., 1997). The first use of this method, for the treatment of intraoral defects, was published by Soutar and McGregor (1986). The use of forearm flaps for maxillofacial reconstruction is currently the most frequently performed method of microvascular tissue transfer worldwide (Evans et al., 1994; Hölzle et al., 2008; Jeremić and Nikolić, 2015).

Although the procedure is safe, quick and easy to perform, complications can occur. These include wound infections, skin necrosis of the transplanted skin graft used to cover the forearm defect and extensive scarring. Even when RFFF harvesting is practised routinely, wound complications and local late sequelae are quite often observed (Chio and Agrawal, 2010; Clark et al., 2019). It is reported that typical donor-site complications, such as partial or total loss of the skin graft with tendon exposure, develop

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in 30–50% of RFFF cases (Bardsley et al., 1990; Swanson et al., 1990; Avery, 2010).

The unwanted sequelae of radial-forearm-flap harvesting inconvenience patients because they result in pain and an extended healing time. A delayed healing process can result in temporary or permanent impairment of the function of the affected hand. For this reason, several operation techniques and postoperative treatment methods have been studied to minimise the risk of wound complications or potential wound-related damage to the hand (Fenton and Roberts, 1985; Ho et al., 2006; Avery et al., 2012), especially to minimise the size of the forearm defect, because this substantially affects the morbidity of the resulting donor-site (Moazzam and Gordon, 2003).

One promising adjunctive option for improving the outcome of RFFF defect closures is vacuum-assisted closure (VAC), which uses sub-atmospheric pressure for the treatment of chronic and difficult wounds (Argenta and Morykwas, 1997). Several studies have described how, soon after its introduction, this new technique was used for the postsurgical management of donor-site defects after RFFF, yielding favourable results (Greer et al., 1999; Avery et al., 2000; Vidrine et al., 2005; Andrews et al., 2006; Ray et al., 2018). Currently, controlled trials are missing on that topic.

The objective of this study was to examine whether the use of VAC therapy improves the postoperative healing process and reduces functional restriction of the skin-grafted donor site compared with the conventional bolster dressing treatment.

2. Material and methods

2.1. Study design and patient recruitment

The study was designed as a prospective randomised clinical trial. We included patients who required harvesting of a fasciocutaneous forearm graft for orofacial cancer reconstruction and who had adequate arterial perfusion of the designated hand (positive Allen test, Müller-Richter et al., 2008). Exclusion criteria were age <18 years, and patients under legal care. All patients who met the inclusion criteria were included in the study and randomly allocated to either the VAC interventional group or control group. Informed consent was obtained from all participants, including for the use of their photographs. The institutional review board approved the project (approval registration no. 088-11-07032011), and the study complied fully with the recommendations of the Declaration of Helsinki.

2.2. Clinical examination and study procedure

The included patients underwent a standardised clinical examination in accordance with the study protocol. Local wound therapy started immediately after the forearm defect had been covered with the skin graft. Subjects allocated to the interventional group were treated over seven days with the VAC therapy, followed by conventional wound care. The control group comprised patients who received a standardised conventional bolster dressing (CBD) without the use of VAC. After being randomised, the patients' preoperative active wrist movement and hand grip strength were assessed and documented (T0). Follow-up measurements were taken after 12 days (T2), three weeks (T3) and eight weeks (T4). The same postsurgical examination schedule (except T0) was used to assess the size of the forearm defect after graft attachment (FDGA) including an additional assessment immediately after surgery (T1). To avoid bias from subjective evaluations, instruments containing patient self-assessment tools, such as the "Michigan Hand Outcomes Questionnaire" (Chung et al., 1999), were not used.

2.3. Operation technique

The fasciocutaneous RFFF were preferentially harvested from the forearm of the non-dominant hand. If the result of the Allen test was substantially worse for the non-dominant hand, however, then the other forearm was chosen for graft harvesting (6 cases). The flap comprised the anterior forearm skin, subcutaneous tissue, the fascia containing the radial artery, and the venae comitantes. Lateral and medial antebrachial cutaneous nerves were identified and preserved. The donor-site skin defect of the forearm was then covered using a full-thickness skin graft harvested from the groin.

2.4. Wound management

In the VAC group, a multi-layered wound dressing was applied to the arm defect. The dressing consisted of a first layer of Mepitel® (silicone mesh, Mölnlycke Health Care AB), followed by a second layer of polyurethane foam sponge of adequate size. This dressing was covered with an adhesive foil for airtight occlusion (Fig. 1), and a continuous negative pressure of 125 mmHg was applied for seven days as recommended by Andrews et al. (2006). To generate negative pressure, we used either of two commercially available vacuum devices (KCI Vac; KCI Medical products Wiesbaden, Germany or VivanoTec; Paul Hartmann AG, Heidenheim, Germany). The dressing was checked daily for tightness and, if it leaked, was left in place but was taped over with Tegaderm™ Film (3M Deutschland GmbH).

In the CBD group (Fig. 2a and b), a Redon suction drain was applied intraoperatively and left in place for 12 days. In addition, a Mepitel silicone mesh coated with Betaisodona® ointment (Mundipharma GmbH) was applied, and covered by a cotton compress. The forearm was immobilised by means of an elastic bandage.

After seven (VAC group) or 12 days (CBD group), wound treatment was changed to a Panthenol ointment combined with Povidone iodine gauze dressing, which was renewed and loosely bandaged every two days. In both the interventional and control groups, the sutures (EthilonTM, Ethicon®) were removed on the twelfth day after surgery.

2.5. Measurement of the wound area

The size of the FDGA area was measured immediately after attachment of the skin graft. For each patient, a ruler was fixed next to each wound edge, and this setting was photographed (Canon E0S

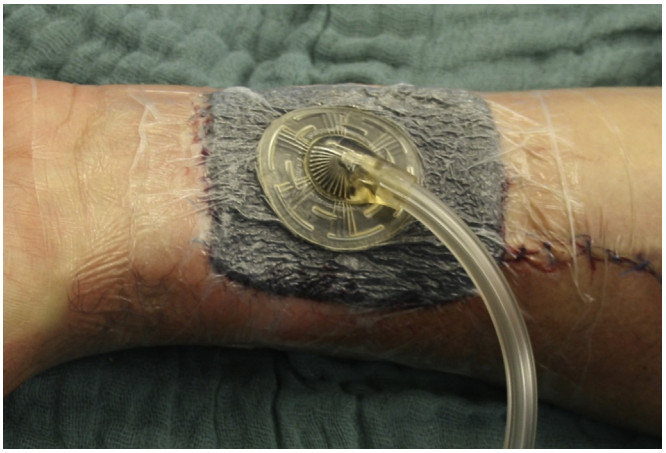

Fig. 1. Wound site immediately after attachment of the skin graft, application of the occlusive dressing and connection to the VAC device.

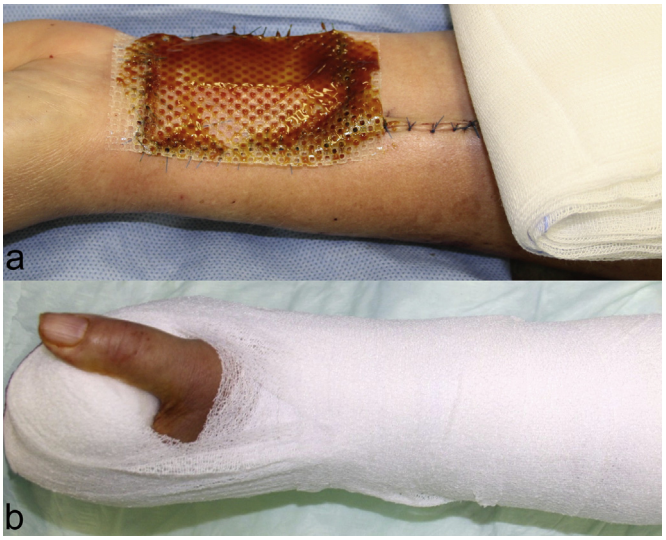

Fig. 2. Wound site immediately after attachment of the skin graft, application of the conventional dressing (a: Mepitel® silicone mesh coated with Betaisodona® ointment, b: Complete bolster dressing).

1000D, resolution 3888 × 2592 pixels). The FDGA area was set in ratio with a pixel-based rectangle of defined measurement using the software packages ImageJ and GIMP (GNU Image Manipulation Program). The final planimetric value of the affected area was calculated by means of cross-multiplication. Follow-up measurements of the FDGA area were taken in accordance with the schedule described in subsection 2.2.

2.6. Measurement of the range of wrist motion

The angle of active wrist motion (flexion and extension) was measured by use of an alignment device. Patients were instructed to hold their arm and hand in a standardised pose. Follow-up photographs of this pose were taken in accordance with the schedule described in subsection 2.2. The angle in degrees between the forearm and hand axis was measured by use of the digital protractor function of the software ImageJ. To reduce the effect of individual bias, all images were evaluated by three different researchers. The mean value of these three measurements was then used for the analysis.

2.7. Measurement of grip strength

Grip strength was measured by use of a dynamometer, as recommended by Jaquet et al. (2012). In our study, we used the Hydraulic Hand Dynamometer SAEHAN Professional SH5001 (Glanford Electronics Ltd, Scunthorpe, UK). The grip strength of both hands was measured to enable a comparison of the donor-site forearm and the unaffected forearm. To avoid weariness bias, patients were instructed to alternate between the right and left hands. Five measurements were taken for each patient, and the mean value of these five measurements was used for the analysis.

2.8. Variables, data transformation and statistical analysis

Our predictor variable was the type of wound management (VAC vs. CBD). The outcome variables were the size of the covered wound area (FDGA), wrist mobility and grip strength in relation to the postoperative healing time.

All data were reviewed for accuracy and completeness before entry. The differences between the interventional group and control group were compared by means of the chi-squared test and t-test. For all analyses, $p < 0.05$ was considered to indicate statistical significance. All statistical procedures were performed by use of the software 'R' (version 3.5). Complete data are not shown but are available upon request.

3. Results

From 19 June 2012 until 14 April 2014 (22 months), the data of 50 patients who had been randomly allocated to receive either VAC therapy or CBD treatment were gathered and analysed. The study sample comprised 50 individuals: 33 males (median age 56 years; range 33–83) and 17 females (median age 61 years; range 45–76). The demographic and clinical details of the study population are listed in Table 1. Forty-one flaps were harvested from the left forearm and nine from the right forearm, depending on hand dominance or arterial perfusion as described in subsection 2.3. The VAC system was used for all patients in the interventional group for the scheduled seven days. Two patients of the VAC group dropped out: one male patient had a stroke and was referred to the neurology department; another male patient entered a postoperative alcoholism-related delirium and no longer tolerated the VAC device.

The planimetric assessment of the FDGA area (T1) recorded an average size of 43.1 cm^2 (SD ± 17.2; range 23.7–91.6 cm^2). A slightly faster reduction in FDGA size, better wrist movement and a faster recovery of grip strength were observed for the patients in the VAC group than for the control group. For the outcome variables of wound size and wrist movement, however, the difference between the VAC group and the CBD group did not reach statistical significance. Comparison of the two groups (t-test) with regard to reduction in FDGA area yielded the following results: T2: $p = 0.68$, T3: $p = 0.693$, T4: $p = 0.197$ (Fig. 3). The difference between the two groups with regard to postsurgical wrist movement (extension) was (t-test): T2: $p = 0.291$, T3: $p = 0.441$ and T4: $p = 0.608$. The difference between the groups with regard to wrist movement in degrees (flexion) was (t-test): T2: $p = 0.856$, T3: $p = 0.844$ and T4: $p = 0.857$ (Fig. 4). With regard to grip strength, we found significant

Table 1
Demographic and clinical details of the study population.

	VAC group ($n = 25$)	CBD group ($n = 25$)	*p*-value
Males, number (%)	20 (80)	13 (52)	
Females, number (%)	5 (20)	12 (48)	
Age in years, mean (SD)	61.7 (15.5)	54.7 (10.5)	0.058[a]
Body mass index, mean (SD)	26.4 (3.8)	23.7 (4.8)	0.032[a]
Height in cm	173.1 (7.9)	169.4 (9.8)	0.155[a]
Weight in kg	79.3 (13.5)	67.9 (14.5)	0.005[a]
Flaps harvested, number (%)			
Right	3 (12)	6 (24)	0.461[b]
Left	22 (88)	19 (76)	
Handedness, number (%)			
Right	24 (96)	23 (92)	1.000[b]
Left	1 (4)	2 (8)	
Smoking status, number (%)			
Current smoker	9 (36)	14 (56)	
Former smoker	7 (28)	4 (16)	0.340[b]
Never smoked	9 (36)	7 (28)	
Alcohol consumption, number			
Never	3	6	
Occasionally	12	6	
> 60 g daily	5	6	

[a] Student's test.
[b] chi-squared test; VAC = vacuum-assisted-closure wound therapy, CBD = conventional bolster dressing.

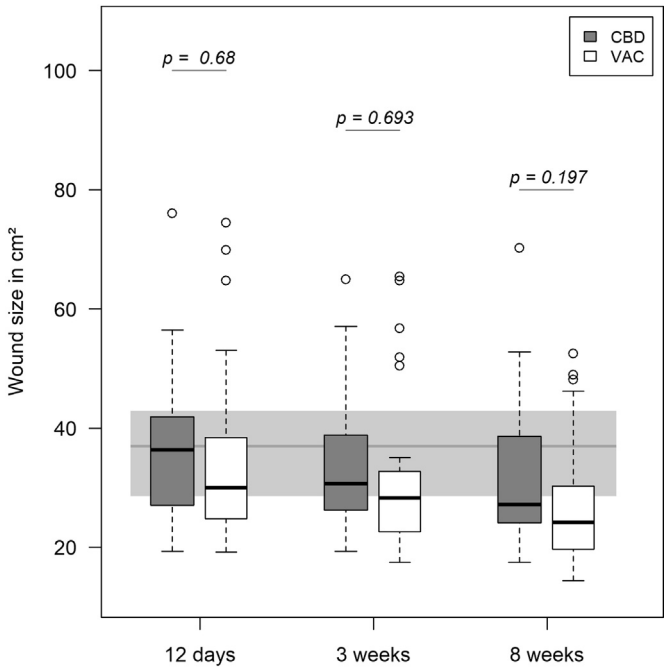

Fig. 3. Box-and-whisker plot depicting the reduction in size of the covered forearm defect (FDGA) at T2, T3 and T4 (t-test). Grey box: wound area immediately after attachment of the skin graft (T1).

differences between the VAC and CBD group. Comparison of the donor-site forearm and unaffected forearm (again, t-test) revealed that the grip strength of the operated arm among patients in the CBD group was significantly worse at T2 ($p = 3e\text{-}05$), T3 ($p < 0.0008$) and T4 ($p = 0.037$). This indicates that recovery of the donor-site arm was quite slow. The recovery of the patients in the VAC group was faster. At T2, the grip strength of the donor-site arm was still significantly lower than that of the unaffected arm ($p = 0.023$), but this difference was no longer detectable three weeks after surgery (T3: 0.089, T4: 0.354; Fig. 5).

4. Discussion

The objective of this study was to examine the effect of VAC therapy on the healing process and on donor-site morbidity after RFFF harvesting. Particular issues of interest were the size of the wound area, the range of wrist movement and grip strength. In our study we compared the quite laborious and expensive VAC therapy with conventional dressing management without application of a vacuum device. We chose a full-thickness skin graft for defect closure of all studied patients in order to compensate the loss of the fascia. Split-thickness skin grafts might show faster healing, but provide a poor, thin and vulnerable skin cover. Another disadvantage is the creation of a further donor site with a prolonged wound healing (Sidebottom et al., 2000; Riecke et al., 2016).

Although wound consolidation was faster and donor-site morbidity was lower in the VAC group, our study failed to show significant differences between the VAC and CBD groups for all the variables assessed. The recovery of grip strength, however, was significantly faster in the VAC group.

The potential benefits and disadvantages of the use of vacuum devices for postsurgical wound therapy are often discussed in the literature. It is more time-consuming to apply, observe and maintain VAC devices than it is to use conventional dressing methods. In addition, the costs of vacuum therapy are about five times higher than those of conventional dressings (Koch et al., 2017). Despite this, VAC therapy is still sought after in poorer countries. Because commercial systems are not affordable there, self-made devices of doubtful quality are used instead (Peinemann and Sauerland, 2011). The postulated benefits of adjunctive VAC therapy are improved perfusion in the treated area, a lower incidence of infection, a reduction in pain, an accelerated healing process and faster patient recovery. These findings explain the worldwide use of VAP therapy for a wide range of indications, such as plastic and reconstructive surgery; abdominal and orthopaedic surgery; breast surgery; traumatology; burns; paediatric surgery and many others (Mouës et al., 2007; Li et al., 2019a; Li et al., 2019b; Kim et al., 2019; Matusiak et al., 2019; Javed et al., 2019; Khurram et al., 2019; Shen et al., 2019). The development of portable, lightweight and disposable VAC devices that can be used in an outpatient setting has resulted in a gradual reduction of treatment costs and has improved acceptance of VAC among patients and caregivers (Hurd et al., 2014). The extensive use of VAC since the introduction of more user-friendly devices in 1997 might suggest that VAC therapy has positive and reproducible effects; however, the data in the literature are by no means unequivocal. In 2011, a systematic review failed to provide evidence that VAC was superior (Peinemann and Sauerland, 2011). This result was mainly

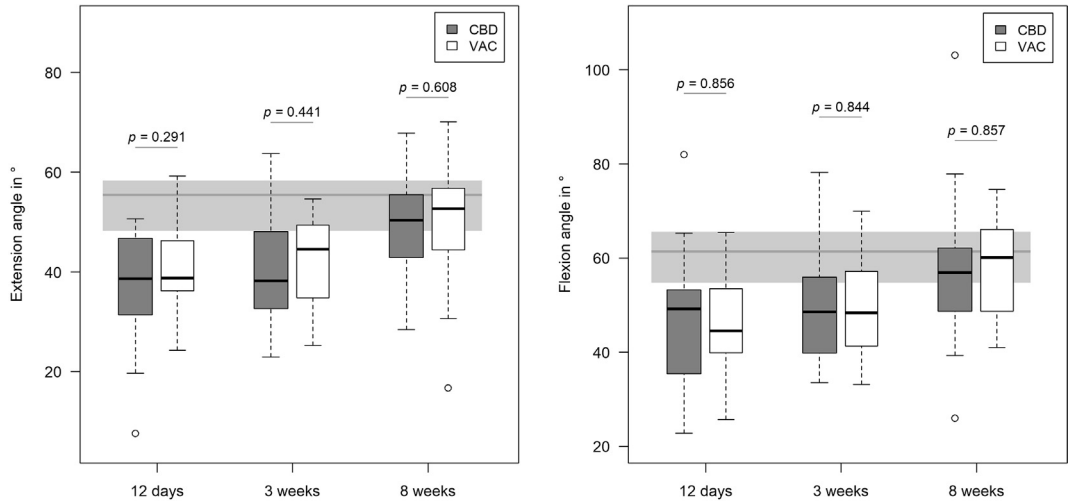

Fig. 4. Box-and-whisker plots depicting the range of motion after surgery (T2, T3, T4). Left: angle of extension. Right: angle of flexion (t-test). Grey box: range of motion before surgery (T0).

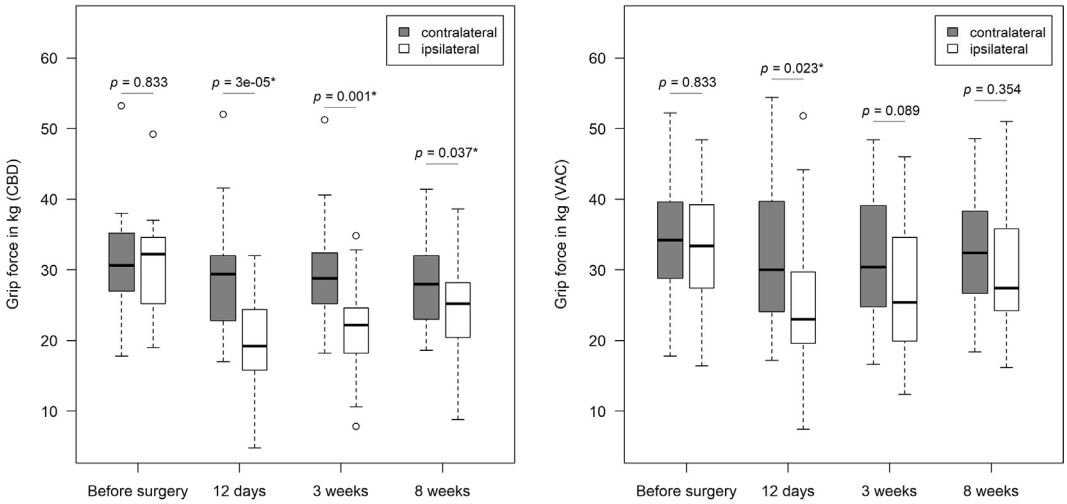

Fig. 5. Box-and-whisker plots depicting grip force before (T0) and after (T2, T3, T4) surgery. Left: conventional dressing. Right: vacuum-assisted dressing (t-test, * ≙ statistical significance).

due to the methodological heterogeneity of the studies included, however, not the ineffectiveness of the therapy itself. Moreover, the review included only one article that refers to forearm donor-site healing specifically (Chio and Agrawal, 2010). The authors of that review, which studied 54 patients after RFFF harvesting, found no difference in outcomes (wound complication rate and graft failure) between a VAC dressing and a static pressure dressing. A different study (Koch et al., 2017) surveyed 138 patients, comparing 55 patients who received conventional wound therapy with 83 patients who received a vacuum dressing. They found no differences between the two techniques with regard to wound complication rates. In contrast, a recent review in 2018 of 45 articles—comprising 404 negative-pressure wound therapy cases, of which 53% involved the forearm—found that most of the studies analysed had a positive outcome (Shine et al., 2019). Unfortunately, the evidence of the studies that refer to RFFF defect closure under VAC therapy is mostly of poor quality.

Our study only revealed a trend for accelerated reduction in FDGA size. We could not, however, prove that VAC is significantly superior to conventional wound management. These findings are in agreement with those of a recent study by Ray et al. (2018), which confirmed that VAC has a positive effect on graft healing but could not show significant differences compared with conventional dressing methods. Nevertheless, the patients in our VAC group still benefited from the therapy studied because their grip strength recovered significantly faster than that of the patients in the non-VAC group. These findings are in agreement with the results of a similar study by Clark et al. (2019), which found that only one outcome variable of function (flexion) was significantly better under VAC therapy, while other variables such as wound healing and graft complications were not affected.

Our study has several limitations. First, the sample size is quite small and males are slightly overrepresented. Second, we did not exclude or distinguish participants with risk factors such as cardiovascular diseases, smoking, diabetes mellitus or the use of steroid therapy; however, no relevant effect on wound healing after RFFF defect closure has been found for these conditions in previous studies (Koch et al., 2017; Clark et al., 2019). The process of wound healing can be affected by unknown factors and differs between individuals. Last, the digital assessment of photographs can be affected by small measurement errors that might slightly bias the results.

5. Conclusions

The effects of VAC therapy on wound healing after RFFF defect closure using a skin graft remain unclear. In our study we observed that VAC had a positive effect on reducing the size of the affected forearm area and on the mobility of the wrist compared with conventional dressing methods; however, the differences are not statistically significant. Nonetheless, the use of VAC therapy did result in a significantly faster recovery of grip strength. On the basis of the observed advantages of VAC therapy in many surgical applications and the availability of small and portable devices that are met with high acceptance among patients, we recommend further development and research of the negative-pressure wound treatment, rather than the termination of its use.

Ethical approval

Approved.

Financial disclosure

There was no grant support for this study.

Declaration of Competing Interest

The authors report full freedom of investigation and no potential conflicts of interest.

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