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Improvement of the patient early mobilization protocol after oral and maxillofacial free flap reconstruction surgery

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ABSTRACT

Objective: There is lack of standardized management and mobilization strategies after oral and maxillofacial reconstruction surgery. We used prospective randomized controlled trials to explore improvements in postoperative mobilization protocol in such patients.

Methods: A total of 149 patients were randomly divided into tracheotomy control group A (38 cases) and test group A (37 cases), nontracheotomy control group B (38 cases) and test group B (36 cases). Test group patients sat up in bed on the 2nd day after surgery and performed off-bed activity on the 3rd day, whereas control group patients sat up in bed on the 4th day postoperatively and performed off-bed activity on the 6th day. Objective evaluation included free flap success rate, postoperative complications, sleep time, and catheter removal time, among other parameters. Subjective evaluation included postoperative pain and comfort evaluation.

Results: The success rate of free flaps was 97.3% in test group A and 100% in the other groups. In terms of mean sleep time, 4.6 ± 1.0 h in test group A, which was longer than 4.1 ± 1.0 h in control group A ($P = 0.034$); 5.7 ± 1.4 h in test group B, which was longer than 4.9 ± 1.7 h in control group B ($P = 0.026$). Early activity makes catheter removal time (tracheal incision, nasogastric tube, urethral catheter) shorter and gets higher comfort evaluation scores in both test groups versus control groups ($P < 0.05$).

Conclusions: The early mobilization protocol for patients undergoing free flap reconstruction was safe, and can effectively improve sleep, shorten the catheter indwelling time, and increase the patient's comfort level.

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1. Introduction

Vascular free flaps for large defects after head and neck ablative surgery is the gold standard treatment (Yeung et al., 2013). With maturity and development of microsurgery technology and surgical materials, the success rate of surgery has exceeded 95–98% (Mao et al., 2016; Zhou et al., 2017). Certain studies have revealed that excessive postoperative exercise and incorrect head posture can cause anastomosed blood vessels to pull, kink, or become compressed, resulting in venous pedicle obstruction (Lamp, 2013; Chao and Lamp, 2014; Hoffman et al., 2012; Bui et al., 2007). Therefore, postoperative control of head activity is one of the methods to prevent failure of free flaps (Yeung et al., 2013; Lamp, 2013; Chao and Lamp, 2014; Bui et al., 2007). However, the available literature on the postoperative head activity protocol and postoperative mobilization protocol for such patients remains limited.

Flap compromise that requires urgent re-exploration is both expensive and complex, and can be devastating for both patients and surgeons. Although there is insufficient literature to support or to refute the influence of postoperative mobility on the survival of free flaps, many reconstructive microsurgeons are reluctant to adopt early mobilization protocols (Yeung et al., 2013). Moreover, certain studies have emphasized the importance of the patient's head and neck position after surgery (Liu et al., 2011; Hu and Li, 2012) but have not carefully considered the patient's comfort and bed-related complications (Han, 2016). Given that the reported flap failure rates are <5%, it is unclear whether this cautious approach to early mobilization is warranted. In the present prospective randomized controlled trial, we aimed to improve the postoperative mobilization protocol in patients who have undergone oral and maxillofacial reconstruction surgery, and sought to provide a basis for further development of postoperative management strategies for such patients.

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2. Materials and methods

2.1. Patients

This was a prospective randomized controlled trial, and the study protocol was approved by the hospital ethics committee (No. PKUSSIRB-201839157). From September 2018 to April 2019, patients who underwent free flap surgery at the Oral and Maxillofacial Surgery Department, Peking University School and Hospital of Stomatology, were selected. Patients volunteered to participate in the study and provided signed informed consent.

Inclusion criteria were as follows: (1) patients who had undergone vascularized free flap reconstruction for head and neck defect; (2) surgery performed by a single surgical team, with a consistent postoperative medication plan; (3) patients who had stayed in the resuscitation room for the night of the surgery and returned to the ward on the next morning; during their stay in the resuscitation room, patients were maintained in a sedated condition and in the supine position; and (4) patients had no history of free flap reconstruction. Exclusion criteria were as follows: (1) patients who had received radiation therapy for the head and neck; (2) patients with anastomotic vasospasm during surgery; and (3) patients who had undergone surgical exploration during stay in the resuscitation room.

2.2. Study design

Once the surgical procedure was determined, patients were assigned to 2 groups according to whether or not tracheotomy was performed. Patients with tracheotomy were randomly divided into test group A and control group A according to the random number table method. Similarly, nontracheotomy patients were also divided into two groups: test group B and control group B.

2.2.1. Control groups

In the control groups, according to the normal postoperative management plan, i.e., from the first to the third day after surgery, the bedside was raised 15°–45°, the patient lay flat without the pillow, and 1-kg sandbags were placed on both sides of the head; on the fourth day, a pillow was placed under the head and patient could sit up; and off-bed activity was allowed on the sixth day.

2.2.2. Test groups

In the test groups, patients performed off-bed activities during initial 3 days after surgery with the assistance of a nurse. On the first day after surgery, the bedside was raised 30°–45°, and a pillow was placed under the head of nontracheotomy patients; on the second day, patients sat up in bed for 4 h in total (the first time, the patient was asked to keep sitting for 10 min, and if he or she did not feel uncomfortable, this time was increased to 30 min the second time and then to 1 h the third time. However, if the patient could not manage sitting alone for 10 min the first time, the goal of the second attempt remained 10 min until he or she achieved the same). Subsequently, on the third day, patients were instructed to perform off-bed activities and to mobilize 30 m for 3 times (at the first time, the patient was asked to sit out of bed and walk for 5 m; if he or she could finish it, he or she could try 10 m the second time, and then 15 m the third time. However, if the patient could not finish walking for 5 m the first time, the goal of the second attempt remained 5 m until the same was achieved).

All patients were informed that head and neck activities, particularly axial rotation of the head and neck, should be minimized for 1 week after surgery. All patients sat up in bed, sat outside of the bed, and performed off-bed activity for the first time under the guidance of a nurse.

2.3. Outcome measures

2.3.1. Blood circulation of free flap

Regular monitoring of free flaps, 1 time/hour for 3 days after surgery and 1 time/2 h on fourth and fifth day after surgery, was performed. If a circulatory disorder was suspected, the team doctor was promptly contacted.

2.3.2. Sleep time

The “Sleepace Rest On” intelligent sleep monitoring device was used to monitor and record sleep time from 20:00 to 8:00 from the first to the fifth day after surgery.

2.3.3. Postoperative complications

Postoperative complications included pressure sores, delirium, deep venous thrombosis of the lower extremities, pulmonary infection, or wound infection, as evaluated by the team doctor.

2.3.4. Other objective data

Other objective data collected included the following: (1) removal time of the catheter, including tracheotomy incision, urethral catheter, nasogastric tube, and negative pressure drainage tube; (2) total number of postoperative suction sessions by nurses; (3) first defecation time after surgery; and (4) length of stay and total hospitalization expenses.

2.3.5. Subjective evaluation

Subjective evaluation included (1) wound pain, based on a visual analogue scale (VAS), scored from 0 to 10 points; the higher the score, the higher the pain degree, which was evaluated daily from the first to the fifth day after surgery; (2) comfort: since there is no scale for comfort evaluation, specifically for perioperative oral and maxillofacial surgery, this study referred to the Kolcaba comfort status scale (General Comfort Questionnaire [GCQ]) (Kolcaba, 1994), which has good internal consistency and has been widely used for comfort evaluation (Lamino et al., 2014; Yu et al., 2017). Based on opinion of oral and maxillofacial surgery experts, we revised the scale (Appendix 1), with a Cronbach's α of 0.866, including 4 dimensions: physiology (shoulder neck stiffness, headache, gastrointestinal tract, sleep, nasogastric tube, ureter, and wound), psychology (anxiety fear, craving for disease knowledge, and empathy), society (friends and family care and belonging), and environment (room layout and wardmate), i.e., a total of 14 items. The 1–4 Likert scale scoring method was used, with a total score of 14–56 points (the higher the score, the more comfortable the patient was). These were evaluated on the third and fifth day after surgery.

2.4. Statistical analysis

Pre-experiment statistical analysis was performed on 10 patients, and sleep time was used as the outcome index within 5 days. The sample size was estimated using two independent-sample mean estimation formulas. Among these, α was set at 0.05, β was set at 0.1, and a two-sided test was conducted, by table lookups $t\alpha/2 = 1.96$, $t\beta = 1.282$. According to the preliminary test, $\sigma = 0.945$, $\delta = 0.79$, $N1 = N2 = 2^*[(t\alpha/2 + t\beta)\sigma/\delta]2 \approx 30$. Considering the 20% shedding rate, at least 36 patients per group were required.

SPSS 17.0 statistical software was used, and numerical variables were described by number (percentage) and mean ± standard deviation. Count data were measured using the Chi-squared test. Measurement data conforming to normal distribution were tested using the independent-sample t test, whereas samples not conforming to normal distribution were tested using the Wilcoxon

rank sum test, with $P < 0.05$ considered to be statistically significant.

3. Results

3.1. Patient characteristics

A total of 164 patients were enrolled in this study. However, 15 patients were excluded (including 8 cases with radiation therapy at the head and neck, 2 cases with anastomotic vasospasm during surgery, and 5 cases requiring emergent exploration during the patients' stay in the resuscitation room), and 149 patients eventually completed the study. Patient characteristics and treatment data for these patients are summarized in Table 1, which includes sex, age, and flap type of the patients. No significant differences were observed between the two groups of tracheotomy and non-tracheotomy patients.

3.2. Objective evaluation results

Results of objective index evaluation of patients are summarized in Table 2, which shows a flap success rate of 100% in control group A and 97.3% in test group A; in addition, the flap success rate was 100% in control group B and test group B, and no significant difference was noted among these groups.

Four patients underwent free flap exploration surgery after they returned to the ward, and only one patient experienced flap loss. In the case of flap failure, an anterior lateral femoral flap had been used to repair a defect of the tongue root. On the fifth day after surgery, exploration was performed due to abnormal flap color; compression of the venous vessel was detected, and the flap failed.

In addition, we plotted the average nighttime sleep time values (Fig. 1), which indicated that the sleep time of patients with tracheotomy was less than that of patients without tracheotomy. In addition, the average nighttime sleep time of patients in both test groups was longer than that of the corresponding control groups.

3.2.1. Other objective indicators

Evaluation of other objective indicators showed that removal time of the catheter (tracheotomy, nasogastric tube, and urethral catheter) of the test groups was shorter than that of the control groups ($P < 0.05$); the total number of suctions in test group A was less than that in control group A ($P < 0.05$); and the length of stay in test group B was shorter than that in control group B ($P < 0.05$).

3.2.2. Subjective evaluation results

Table 3 shows physiological and environmental dimensions and the total scores in comfort evaluation. Scores of both test groups were higher than those of the control groups ($P < 0.05$). Pain scores on the fourth day and the mean value of all 5 days were higher in control group B compared with test group B ($P < 0.05$).

4. Discussion

Microvascular free flap reconstruction has led to a new era in treatment of oral and maxillofacial cancer and is now well established as the standard of care in reconstruction of oral and maxillofacial defects. Several studies have mentioned that oral and maxillofacial free flap veins can easily become kinked or compressed with neck motion (Lamp, 2013; Chao and Lamp, 2014; Hoffman et al., 2012; Bui et al., 2007). Early studies have shown that 89.1–95.6% of flap compromise occurs within 3 days after surgery (Stephen et al., 1996; Devine et al., 2001). To reduce venous pedicle obstruction during this period due to head and neck activity, several studies have reported activity restrictions after flap surgery: one type of practice promotes patients staying in the intensive care unit for 1.2–3.5 days, wherein sedatives were used to relieve mechanical ventilation discomfort and to restrict head movements (Yeung et al., 2013; Marsh et al., 2009; Chen et al., 2018). Another technique involved patients returning directly to the general ward after awakening from anesthesia, and use of head braking (use of sandbags or special pillows on both sides of the head to limit head activity) for 3–7 days, followed by prolonged stay in bed for 5–7 days (Liu et al., 2011; Hu and Li, 2012). However, the specific time limit and the restricted activity scope for such patients varies considerably, depending on the country or institution.

Prolonged stay in bed can cause complications such as insomnia, pressure sores, delirium, deep vein thrombosis of lower extremities, pulmonary infection, and constipation (Han, 2016). Furthermore, results of a retrospective cohort study conducted by Yeung et al. (2013) revealed that patients undergoing such surgeries who had not been out of bed by postoperative day 4 were more than four times more likely to develop pneumonia. Moreover, although Coyle et al. (2016) encouraged such patients to sit up on the first day after surgery, only 7% of patients were actually mobilized on the first day after surgery. Dort et al. (2017) also recommended early mobilization within the first 24 h after surgery, but evidence from the related literature review to support this recommendation is inadequate. Thus, although experts generally encourage early postoperative mobilization, specific early mobilization protocols and related evidence remain insufficient.

Recent retrospective surveys by Bui et al. (2007) and Chen et al. (2007) have found that 78.3–82.3% of pedicle thromboses occur within 24 h after surgery. Accordingly, in our mobilization protocol, we recommended that patients sit up in bed on the second day and participate in off-bed activity on the third day after surgery. We

Table 1
Summary of patient characteristics.

	Tracheotomy				Non-tracheotomy			
	Control A (n = 38) No. (%)	Test A (n = 37) No. (%)	*t/F*	*P*	Control B (n = 38) No. (%)	Test B (n = 36) No. (%)	*t/F*	*P*
Age (y)	50.9 ± 12.6	52.9 ± 12.6	−0.642	0.523	46.6 ± 15.9	51.9 ± 15.3	−1.375	0.169
Gender								
Male	25 (65.8)	22 (59.5)	0.321	0.571	20 (52.6)	22 (61.1)	0.542	0.462
Female	13 (34.2)	15 (40.5)			18 (47.4)	14 (38.9)		
Type of free flap								
RFFF	6 (15.8)	9 (24.3)	0.897	0.639	12 (30.3)	12 (32.0)	2.217	0.559
Fibula flap	14 (36.8)	13 (35.1)			10 (27.3)	14 (40.0)		
ALTF	18 (47.4)	15 (40.5)			11 (30.3)	6 (16.0)		
Iliac crest	0	0			5 (12.1)	4 (12.0)		

Note: ALTF, anterolateral thigh flap; RFFF, radial forearm free flap.

Table 2
Comparison of objective evaluation results in patients.

		Tracheotomy				Non-tracheotomy			
		Control A (n = 38) No. (%)	Test A (n = 37) No. (%)	t/F/Z	P	Control B (n = 38) No. (%)	Test B (n = 36) No. (%)	t/F/Z	P
Outcome	Normal	37 (97.4)	35 (94.6)	0.001	0.981	37 (97.2)	36 (100)	–	1.000
	Exploration	1 (2.6)	2 (5.4)			1 (2.8)	0		
	Flap lost	0	1 (2.7)			0	0		
Sleeping time (h)	D1	4.2 ± 1.4	4.5 ± 1.5	−0.810	0.421	4.9 ± 1.9	5.5 ± 1.7	−1.731	0.083
	D2	4.2 ± 1.9	4.6 ± 1.5	−0.802	0.425	4.9 ± 2.0	5.7 ± 1.3	−2.050	0.040*
	D3	3.9 ± 1.6	4.5 ± 1.2	−1.971	0.053	4.8 ± 2.1	5.7 ± 1.8	−2.001	0.049*
	D4	4.0 ± 1.3	4.6 ± 1.1	−2.467	0.014*	4.6 ± 2.2	5.7 ± 1.5	−2.391	0.019*
	D5	4.0 ± 1.3	4.6 ± 1.4	−2.113	0.038*	5.0 ± 2.1	5.9 ± 1.7	−1.975	0.048*
	Mean	4.1 ± 1.0	4.6 ± 1.0	−2.157	0.034*	4.9 ± 1.7	5.7 ± 1.4	−2.270	0.026*
Catheter removal time (d)	Tracheotomy	7.6 ± 2.1	6.1 ± 3.2	2.151	0.035*	–	–	–	–
	Urethral catheter	4.2 ± 1.1	3.2 ± 0.4	−5.157	<0.001*	3.9 ± 0.6	3.2 ± 0.4	−4.701	<0.001*
	Nasogastric tube	16.6 ± 4.9	13.2 ± 7.9	2.194	0.032*	12.1 ± 5.8	10.0 ± 6.7	−2.306	0.021*
	Drainage tube	7.1 ± 1.4	6.8 ± 2.0	−1.423	0.155	6.5 ± 1.9	5.7 ± 1.9	−1.713	0.087
Postoperative complications	Pulmonary infection	5 (13.2)	1 (2.7)	1.545	0.214	1 (2.6)	0	–	1.000
	Wound infection	4 (10.5)	3 (8.1)	–	1.000	5 (13.2)	3 (8.3)	0.086	0.769
	Delirium	1 (2.6)	0	–	1.000	0	0	–	1.000
	Total	10 (26.3)	4 (10.8)	2.968	0.085	6 (15.8)	3 (8.3)	0.391	0.532
Number of sputum aspirations		43.0 ± 18.4	32.5 ± 14.1	2.746	0.008*	4.3 ± 2.5	3.2 ± 2.4	1.701	0.094
First defecation day (d)		5.3 ± 1.4	4.9 ± 1.8	1.183	0.241	4.9 ± 1.8	4.1 ± 1.2	1.887	0.064
Length of stay (d)		16.0 ± 3.5	15.1 ± 2.3	−0.833	0.405	14.4 ± 2.3	13.3 ± 2.0	−2.099	0.036*
Total hospitalization expenses (k USD)		10.5 ± 1.8	10.4 ± 2.4	0.251	0.803	9.5 ± 1.9	9.3 ± 1.5	0.368	0.714

*$P < 0.05$.
Note: The exchange rate of RMB against the US dollar was considered according to the annual average exchange rate in 2018 (6.64:1).

found that the success rate of vascular free flaps in both the control and test groups was >97%, indicating that the mobilization protocol did not increase the risk of flap failure.

Preventive tracheotomy is performed in oral and maxillofacial surgery patients to prevent postoperative tissue swelling and organ shifting that may lead to upper respiratory obstruction. Tracheotomy is a major factor affecting sleep, comfort, and postoperative complications in patients undergoing head and neck reconstruction (Heffner and Hess, 2001; Wu, 2015), and these indices can serve as evaluation indicators for the present study as well. In order to avoid the important impact of tracheotomy, patients were divided into two categories based on whether or not tracheotomy was performed. This study showed that pulmonary infection was the main postoperative complication, particularly among patients undergoing tracheotomy (which accounted for 85.7% of those experiencing pulmonary infection), consistent with that noted in the literature (Lo et al., 2017; Lodders et al., 2015; Mcmahon et al., 2013; Dautremont et al., 2013; Yang et al., 2019). This study indicated that early postoperative mobilization can shorten the duration of tracheal incision and reduce the number of sputum suction sessions. One reason for this finding may be that early mobilization increases the number and intensity of active movements of the chest and abdominal muscles, strengthens the contraction ability of the diaphragm, and promotes more effective coughing and expectoration in patients. In addition, raising the bedside helps to open the throat and facilitates insertion of the suction tube, which consequently reduces the stimulation of the pharynx and trachea and is beneficial for complete sputum suction (Wang et al., 2019). Meanwhile, the study found that the incidence of pulmonary infection in patients undergoing tracheotomy in the test group (2.7%) was lower than that of patients in the control group (13.2%).

Time for extubation of the nasogastric tube and the urethral catheter was significantly shorter in test groups of both types than in the control groups, indicating that early mobilization can reduce symptoms of gastric retention and gastrointestinal discomfort. Early removal of catheters can reduce infection and reduce the impact of catheters on postoperative mobilization and psychological well-being of patients, which was in line with the

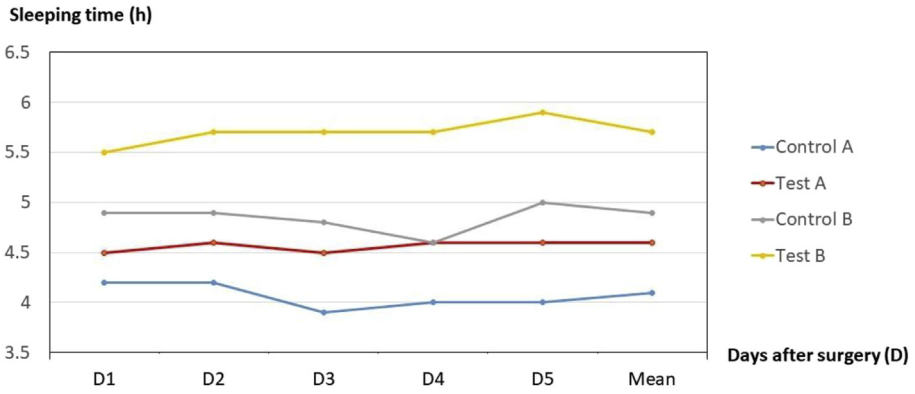

Fig. 1. Graph indicating the comparison of sleeping time; the average nighttime sleep time of the 2 test groups of patients was longer than that of the control groups ($P_A = 0.034$, $P_B = 0.026$).

Table 3
Comparison of subjective evaluation results in patients.

		Tracheotomy				Non-tracheotomy			
		Control A (n = 38)	Test A (n = 37)	t/Z	*P*	Control B (n = 38)	Test B (n = 36)	t/Z	*P*
Wound pain score	D1	1.5 ± 1.5	1.1 ± 1.8	−1.644	0.100	1.7 ± 2.0	1.0 ± 1.7	−1.546	0.122
	D2	1.5 ± 1.7	1.1 ± 1.9	−1.41	0.159	1.6 ± 2.0	0.9 ± 1.2	−1.285	0.199
	D3	1.7 ± 1.7	1.2 ± 1.4	−0.951	0.342	1.6 ± 2.1	0.8 ± 1.1	−1.134	0.257
	D4	1.9 ± 1.7	1.4 ± 1.9	−1.844	0.065	2.3 ± 2.0	1.0 ± 1.6	−2.604	0.009*
	D5	1.9 ± 1.7	1.6 ± 2.0	−1.358	0.175	2.1 ± 2.1	1.2 ± 1.7	−1.562	0.118
	Mean	1.7 ± 1.4	1.2 ± 1.2	−1.437	0.151	1.9 ± 1.7	1.0 ± 1.1	−2.082	0.037*
Comfort score (D3)	Physiology	17.6 ± 3.8	20.7 ± 4.0	−0.755	0.002*	18.7 ± 3.3	20.7 ± 3.6	−2.149	0.036*
	Psychology	8.1 ± 1.4	8.4 ± 2.0	−0.225	0.822	8.7 ± 1.7	8.6 ± 2.2	−0.281	0.779
	Society	5.6 ± 1.0	6.2 ± 1.1	−2.443	0.015*	6.0 ± 1.0	6.3 ± 1.2	−1.06	0.289
	Environment	5.6 ± 1.2	6.8 ± 1.1	−3.787	<0.001*	6.0 ± 1.2	6.8 ± 1.2	−2.429	0.015*
	Total	37.0 ± 6.2	42.1 ± 6.2	−3.365	0.001*	39.4 ± 5.2	43.8 ± 6.2	−2.928	0.005*
Comfort score (D5)	Physiology	14.9 ± 4.3	17.2 ± 3.2	−2.546	0.013*	16.0 ± 2.7	19.4 ± 3.7	−3.902	<0.001*
	Psychology	8.1 ± 1.6	9.2 ± 1.9	−2.073	0.038*	8.9 ± 1.7	9.2 ± 2.2	−0.56	0.578
	Society	5.6 ± 0.9	6.4 ± 1.2	−2.747	0.006*	6.0 ± 1.0	6.3 ± 1.3	−0.801	0.423
	Environment	5.7 ± 1.1	7.0 ± 0.9	−4.803	<0.001*	6.3 ± 1.4	7.1 ± 1.1	−2.232	0.026*
	Total	34.3 ± 6.3	39.8 ± 5.3	−3.93	<0.001*	37.2 ± 4.6	42.0 ± 6.8	−3.013	0.004*

*$P < 0.05$.

recommendation of ERAS that extubation should be performed as early as possible (Coyle et al., 2016).

The mean values of postoperative sleep time and comfort evaluation of both test groups were better than those of the two control groups, which may be related to the increase in early postoperative mobilization. Previous studies have confirmed that prolonged stay in bed can decrease comfort (Han, 2016), whereas early mobilization can alleviate these issues and can promote better sleep (Coyle et al., 2016).

An advantage of the present study is that >600 cases undergo vascularized free flap transplantation at Peking University School and Hospital of Stomatology annually, with a success rate of 97% (Zhou et al., 2017). Thus, as our institute conducts the most number of procedures with one of the highest success rates worldwide, we believe that the performance represents the international frontier of such surgical procedures. This study also had certain limitations; the sample size was small and the study time was limited to hospital stay alone. Additional studies with larger samples and longer study duration are warranted to further explore postoperative management practices for such patients.

Conclusion

In patients who have undergone free flap reconstruction for oral and maxillofacial defects, sitting up on the 2nd day and off-bed activity on the 3rd day after surgery with the assistance of the nurse is recommended. This activity protocol does not affect the entire treatment process, does not increase postoperative complication rates, does not prolong hospital stay, and does not increase hospitalization costs, but can effectively improve sleep, shorten the catheter indwelling time, and significantly increase the patient's comfort level.

Ethical approval

Ethical approval obtained from Peking University School and Hospital of Stomatology Biomedical Institutional Review Board PKUSSIRB-201839157. Patient consent was not required.

Declaration of Competing Interest

There is no conflict of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.11.016.

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