Prospective Trial of Near-Infrared Spectroscopy for Continuous Noninvasive Monitoring of Free Fibular Flaps

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Introduction: Some free flaps develop postoperative vessel thrombosis, which influences the flap survival rate. Early discovery and identification of vascular crisis are critical to the success rate of flap salvage. The primary aims of this study were to determine the features of postoperative blood supply changes in fibular flaps with normal and abnormal blood flow, using near-infrared spectroscopy (NIRS), to monitor oxygenation and blood flow, and to characterize the probable risk factors for vascular crisis.
Methods: Sixty-three consecutive patients undergoing reconstruction of unilateral mandibular defects with free fibular flaps at the Peking University School of Stomatology were included. Patients were divided into 2 groups, A (n = 38) and B (n = 25); fibular flaps in group A underwent continuous NIRS monitoring from immediately postoperatively until 7 days postoperatively (approximately 150 hours), whereas fibular flaps and opposite mandibles in group B underwent intermittent monitoring: once every 4 hours during the first 24 hours postoperatively and once every 12 hours from 24 to 168 hours postoperatively.
Results: Six fibular flaps developed vascular thromboses: 4 were venous thromboses and 2 were arterial thromboses; 5 were rescued after exploration. Of 6 regional oxygen saturation (rSO_2) values in the continuous monitoring group, 4 showed no significant differences at any time point compared with the intermittent monitoring group ($P > 0.05$). The rSO_2 of the fibular flap was significantly different from that in the opposite mandible in the first 36 hours postoperatively ($P < 0.05$). This difference decreased over time. During the initial period of venous thrombosis, rSO_2, deoxyhemoglobin, and oxygenated hemoglobin all rose slightly, then showed simultaneous rapid reduction. However, the magnitude of reduction was smaller for deoxyhemoglobin than for oxygenated hemoglobin.
Conclusions: Near-infrared spectroscopy can be used for noninvasive and reliable assessment of oxygenation and blood flow in free flaps through continuous, real-time monitoring. It is also portable, inexpensive, and simple to operate. In addition, the detection depth of NIRS is up to 2.0 cm, so it can be used to monitor buried flaps with depths <2.0 cm.

Key Words: Near-infrared spectroscopy (NIRS), Regional tissue oxygen saturation (rSO_2), fibular flap, buried flap, continuous monitoring

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The free fibular flap was first used for tibia repair in 1975 and has become increasingly popular among head and neck surgeons.[1] Thus far, the free fibular flap approach has been the preferred option for maxilla and mandible repair and reconstruction because of its ability to provide up to 25 cm of uniform bone and adequate soft tissue. However, vascular crisis is a serious postoperative complication that can threaten flap survival. The incidence of vascular crisis is approximately 2% to 11%,[2–4] and the salvage rate is lower than 50% because of partial or total necrosis caused by ischemia lasting more than 5 hours.[5] Therefore, early discovery and diagnosis of vascular crisis are of critical importance for flap salvage, influencing the success rate of the free fibular flap approach.[6]

Currently, surgical observation remains the most prevalent method for the discovery and diagnosis of vascular crisis in clinical practice. This method is highly dependent on the observer's individual experience and good awareness of the intraoperative situation. Moreover, buried flaps without skin islands cannot be observed. Therefore, skin islands of free fibular flaps are used as an important observation window to monitor the postoperative blood supply to the flap, as well as for soft tissue repair and tension-free wound closure. Skin islands are used in clinical practice to repair soft tissue and are later removed after stabilization of the blood supply to the flap. There are various techniques and methods used to monitor the postoperative blood supply to free flaps, most of which are limited to the exposed superficial soft tissue flap; therefore, monitoring deep-seated and buried flaps remains a difficult problem. However, the characteristics and predictors of changes in the postoperative blood supply of free fibular flaps during vascular crisis have not yet been determined. It is of great clinical value to find an objective, effective, noninvasive, and continuous method to monitor the blood supply to free fibular flaps.

The principle of near-infrared spectroscopy (NIRS) is based on the modified Lambert-Beer Law, which states that near-infrared light (700–1000 nm) can penetrate skin, muscle, and bone at various depths[7] and can also be absorbed by chromophore molecules. The most important absorbers in biological tissue are oxygenated hemoglobin (HbO_2) and deoxyhemoglobin (Hb). The near-infrared absorption properties of HbO_2 and Hb are distinct, so they absorb different wavelengths of light to varying degrees. In human tissue, scattering of near-infrared light is greater than light absorption; therefore, photons passing through human tissue follow a curved banana-shaped path, and emergent light can be detected using reflected infrared sensors. By introducing 2 wavelengths of light from a dual-wavelength light source and using at least 2 detectors placed at specific distances from the light source, the absolute value of regional oxygen saturation (rSO_2) can be calculated. A third-generation NIRS oximeter (TSAH-100; Fig. 1), developed based on these principles by the Department of Biomedical Engineering at the Tsinghua University School of Medicine, was used in this study.

The TSAH-100 sensor is composed of a dual-wavelength near-infrared light source and 2 detectors. The emitted wavelengths are 760 and 850 nm, and the 2 detectors are 3.0 cm and 4.0 cm, respectively, from the source (Fig. 2). The detection depth of the TSAH-100 is half the distance between the emitter and detector; therefore, the detection depth of the sensor is 1.5 to 2.0 cm, which is sufficient for monitoring transplanted fibula bone.

Three parameters can be measured by the TSAH-100: blood oxygen saturation (rSO_2), HbO_2 concentration, and Hb concentration. According to the analysis method used by the TSAH-100, rSO_2 is recorded as an absolute value, and HbO_2 and Hb are recorded as relative values. Oxygenated hemoglobin serves as a visual indicator of the oxygenation of local tissue, whereas Hb serves as a visual indicator of dynamic variation in blood flow volume.

The main aims of this prospective study were to determine the features of postoperative changes in blood supply to transplanted free fibular flaps including normal and abnormal blood flow and to

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FIGURE 1. Near-infrared spectroscopy oximeter: TSAH-100.

characterize the potential for using NIRS for monitoring deep tissue or buried flaps.

MATERIALS AND METHODS

Patients

In total, 63 consecutive patients were included in this study. All were referred for mandible reconstruction with a free fibular flap between September 2009 and February 2012 at the department of Oral and Maxillofacial Surgery, Stomatological Hospital of Peking University, China.

The inclusion criteria for the study were as follows: (1) unilateral mandibular defect reconstruction was performed with a free fibular flap and linear fibula bone segment more than 5 cm in length; (2) the lateral mandible was covered by an adipose layer less than 1.0 cm in thickness; and (3) a skin island was used, regardless of its position, and the skin was intact and free of any ulceration or surgical incision.

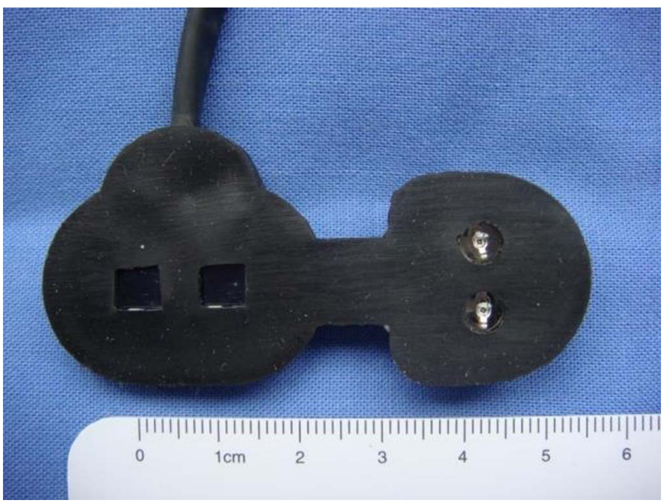

FIGURE 2. The TSAH-100 sensor is composed of a dual-wavelength near-infrared light source and 2 detectors, with distances of 3.0 and 4.0 cm, respectively, between the source and the detector.

Methods

All patients were randomly divided into groups A and B. The 38 patients in group A received continuous monitoring by NIRS (2 times/min), from immediately postoperatively until 7 days postoperatively (approximately 150 hours). The 25 patients in group B received intermittent NIRS monitoring of both the transferred fibular flap and the contralateral mandible; this was initiated immediately postoperatively and then performed every 4 hours for 24 hours postoperatively and every 12 hours from 24 to 168 hours postoperatively.

Statistical Analysis

Data are shown as the means ± standard deviations. SPSS software (version 19.0) was used to analyze the data. Paired *t* tests were used to compare groups A and B. All tests of were considered significant at the 5% level.

RESULTS

Patient Characteristics

A total of 63 patients were enrolled in the study, including 30 men and 33 women; the median age was 48 years (range, 17–78 years). Four patients in group A exhibited vascular embolization between 8 and 64 hours postoperatively; 3 of these patients had venous embolism, and 2 of which exhibited abnormal blood flow that was detected by TSAH-100. The remaining 1 patient developed arterial embolism that could not be rescued, and his TSAH-100 monitoring results showed no abnormality. In group B, 2 patients had vascular crisis; 1 patient had venous embolism, which was not detected, and the other one had arterial embolism, which was detected by TSAH-100. Five patients in the 2 groups encountered vascular crisis, which were rescued successfully except the arterial embolism in group A. A comparison of issues between group A and group B is shown in Table 1. The sensibility of NIRS was unpersuasive; meanwhile, the specificity of NIRS is high. In the remaining patients in groups A and B, 2 patients exhibited purple and swollen skin islands on the second and third days postoperatively, although TSAH-100 monitoring results showed normal blood supply and oxygen saturation. These 2 cases were identified as branch vascular embolization of the skin paddle during the salvage operation.

Continuous and Discontinuous Monitoring

A comparison of the rSO_2 values of healthy fibular flaps in groups A and B at the same time points (Table 2) showed no significant differences in the rSO_2 values measured by continuous and by intermittent monitoring methods at all postoperative time points. As shown in Figure 3, the oxygen saturation of the free fibular flap exhibited a slow upward trend from immediately postoperatively to 70 hours postoperatively; the range of oxygen saturation was relatively large within 80 hours postoperatively, but gradually became smaller after 80 hours postoperatively.

Free Fibular Flaps and Contralateral Normal Mandibles

A comparison of rSO_2 values in free fibular flaps and contralateral mandibles at each time point (Table 3) showed significant differences

TABLE 1. Comparison of False-Positive rate, False-Negative Rate, Accuracy, Sensibility, and Specificity Between Groups A (Continuous Monitoring) and B (Intermittent Monitoring)

	False-Positive Rate, %	False-Negative Rate, %	Accuracy, %	Sensibility, %	Specificity, %
Group A	0	5.3	94.7	50	100
Group B	0	4.0	96	50	100

TABLE 2. Comparison of Changes in Oxygen Saturation (rSO_2) of Free Fibular Flaps Between Groups A (Continuous Monitoring) and B (Intermittent Monitoring) at Each Detected Time Point

Postoperative Time, h	rSO_2 of Continuous Monitoring, %	rSO_2 of Intermittent Monitoring, %	*P*
0	62.2 ± 3.4	60.3 ± 4.5	0.901
4	60.0 ± 4.2	58.9 ± 3.9	1.000
8	59.1 ± 5.2	60.1 ± 4.1	0.798
12	58.5 ± 3.7	58.6 ± 4.6	0.102
16	61.7 ± 4.5	62.4 ± 4.2	0.316
20	58.3 ± 4.1	59.7 ± 3.1	0.687
24	62.9 ± 3.5	63.5 ± 3.7	0.068
36	60.5 ± 5.3	61.3 ± 5.2	0.203
48	63.4 ± 2.8	60.7 ± 5.1	0.072
60	60.3 ± 3.4	64.6 ± 4.3	0.135
72	65.4 ± 4.3	62.3 ± 3.8	0.872
84	64.1 ± 4.6	65.8 ± 3.2	0.752
96	62.2 ± 3.1	61.7 ± 4.5	0.236
108	63.4 ± 3.4	64.8 ± 4.3	0.673
120	60.9 ± 5.4	62.2 ± 4.2	0.635
132	62.7 ± 3.8	63.4 ± 3.8	0.324
144	60.2 ± 5.7	62.3 ± 3.1	0.412
156	61.2 ± 4.0	62.9 ± 2.7	0.097
168	63.7 ± 3.2	63.2 ± 4.6	0.254

TABLE 3. Comparison of Changes in Oxygen Saturation (rSO_2) Between Free Fibular Flaps and Contralateral Mandibles With Intermittent Monitoring

Postoperative Time, h	rSO_2 of Free Fibular Flap, %	rSO_2 of Contralateral Mandible, %	*P*
0	60.9 ± 4.2	63.9 ± 4.3	0.000
4	59.6 ± 3.4	65.4 ± 3.7	0.000
8	61.2 ± 4.7	64.7 ± 3.4	0.000
12	62.8 ± 4.5	65.1 ± 4.1	0.000
16	60.3 ± 3.7	65.6 ± 3.2	0.003
20	64.2 ± 3.3	65.9 ± 3.5	0.000
24	60.8 ± 3.0	64.3 ± 4.0	0.000
36	59.3 ± 4.9	64.1 ± 3.8	0.021
48	64.7 ± 5.5	66.9 ± 3.8	0.110
60	61.2 ± 4.2	65.6 ± 4.3	0.006
72	66.1 ± 3.8	67.3 ± 4.5	0.002
84	61.5 ± 4.1	66.1 ± 4.1	0.015
96	63.7 ± 4.4	67.8 ± 3.9	0.061
108	59.6 ± 3.7	65.7 ± 3.6	0.084
120	63.0 ± 4.9	65.4 ± 3.9	0.038
132	61.1 ± 3.5	65.9 ± 3.2	0.076
144	61.5 ± 5.2	65.0 ± 4.8	0.081
156	62.7 ± 3.9	64.8 ± 4.3	0.102
168	60.5 ± 3.1	64.3 ± 3.6	0.096

($P < 0.05$) within 36 hours postoperatively. The rSO_2 values also showed significant differences ($P < 0.05$) at several time points after 36 hours, but the overall difference moderately decreased with time. Figure 4 shows that the rSO_2 values of free fibular flaps were continuously lower than those of contralateral mandibles. Therefore, although the fibular flaps exhibited vascularization, the postoperative blood supply was not equivalent to that of normal mandibles. In addition, the rSO_2 values of free fibular flaps exhibited obvious fluctuations during revascularization after surgery, whereas those of the opposite mandible remained relatively stable.

Changes in Blood Flow of Patients With Venous Embolism in Group A

Three fibular flaps developed venous embolism in group A, one of which showed stable and favorable conditions within 11 hours postoperatively. The rSO_2 values varied from 58% to 61%, whereas Hb and HbO_2 remained stable. However, the rSO_2 values declined slowly after 11 hours postoperatively (Fig. 5); Hb and HbO_2 simultaneously showed a small decline. At 12 hours postoperatively, the rSO_2 value remained greater than 55%, the skin island stayed moist and soft, and no abnormalities were observed. However, rSO_2 decreased rapidly (to approximately

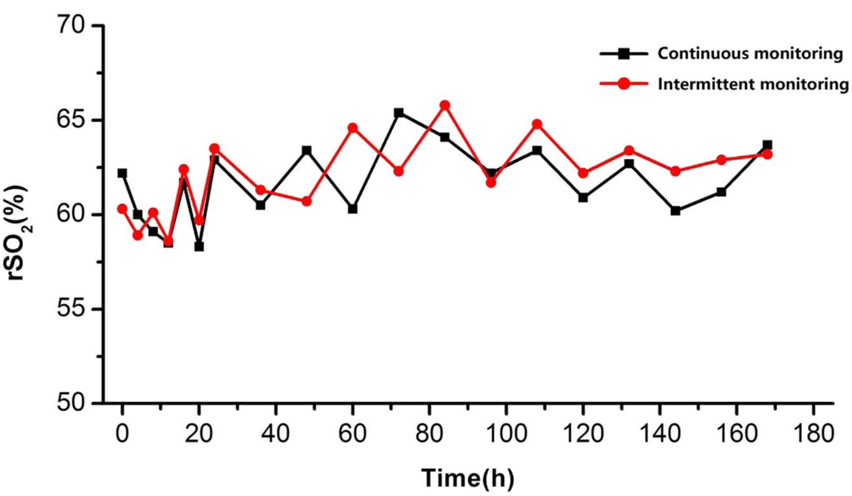

FIGURE 3. Changes in oxygen saturation (rSO_2) values of free fibular flaps between groups A (continuous monitoring) and B (intermittent monitoring) at each detected time point.

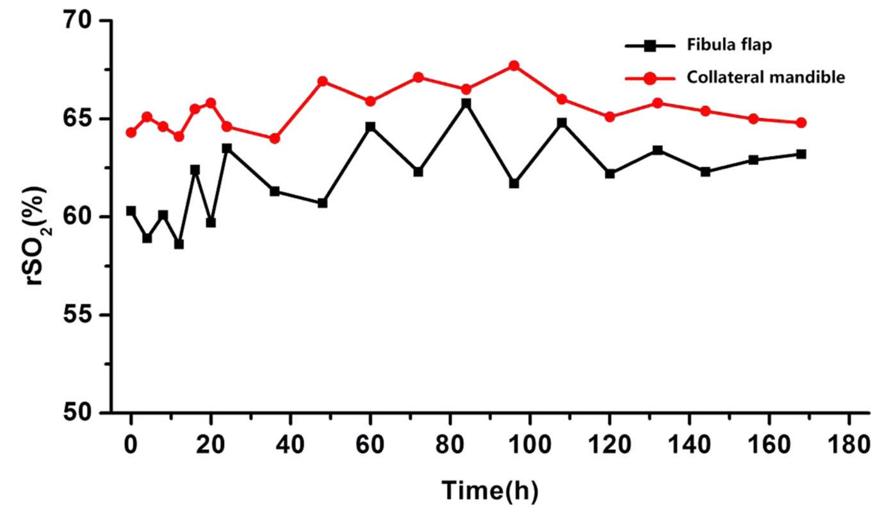

FIGURE 4. Changes in oxygen saturation (rSO_2) values between free fibular flaps and contralateral mandibles with intermittent monitoring.

50%) within the next 1 hours, and the skin island exhibited mild swelling and a purple color. Interestingly, when the 3 curves were magnified after 600 minutes, rSO_2, Hb, and HbO_2 all exhibited slight increases during the postoperative period from 725 to 735 minutes, followed by a sharp decline. However, the reduction in Hb was significantly lower than that in HbO_2, whereas rSO_2 continued to decrease (Fig. 6). Therefore, this flap underwent a successful salvage operation at 13 hours postoperatively.

Changes in Blood Flow in Patients With Vascular Embolism in Group B

Two fibular flaps developed vascular embolism in group B: 1 arterial embolism and 1 venous embolism. As shown in Figure 7, the rSO_2 values of the flap with arterial embolism displayed a decreasing trend that began at 8 hours postoperatively, then declined sharply, from 52% to 37%, at 24 hours postoperatively. In addition, the skin island was visually pale and wrinkled and showed no fresh bleeding in the needling test. Arterial embolism was diagnosed, and a salvage operation was performed immediately. The thrombus was removed, and the vessels were reanastomosed; however, the rSO_2 values remained between 52.2% and 55.7%, significantly lower than those of the contralateral mandible.

Variations in the rSO_2 values of the flap with venous embolism in group B are shown in Figure 8. The postoperative rSO_2 values of this flap were relatively stable, remaining above 57%, which was slightly lower than the values of the contralateral mandible. At 12 hours postoperatively, the skin island of the fibular flap exhibited purple ecchymosis with progressive expansion. However, no significant reductions in rSO_2 values were detected.

Changes in Blood Flow of Fibular Flaps With Skin Island Collateral Vessel Embolism in Group A

The skin islands of free fibular flaps in 2 patients exhibited ecchymosis on the second and third days postoperatively; however, these

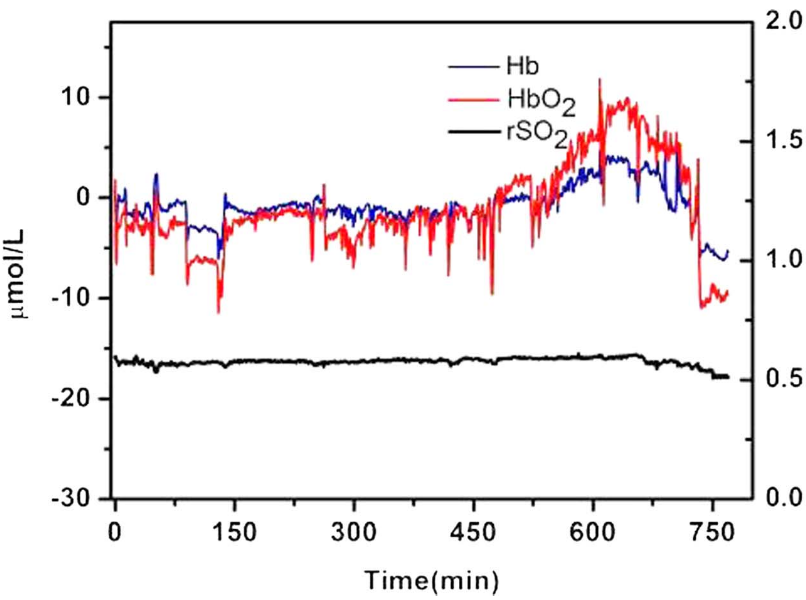

FIGURE 5. Panoramic view of changes in blood supply of the flap with venous embolism in group A.

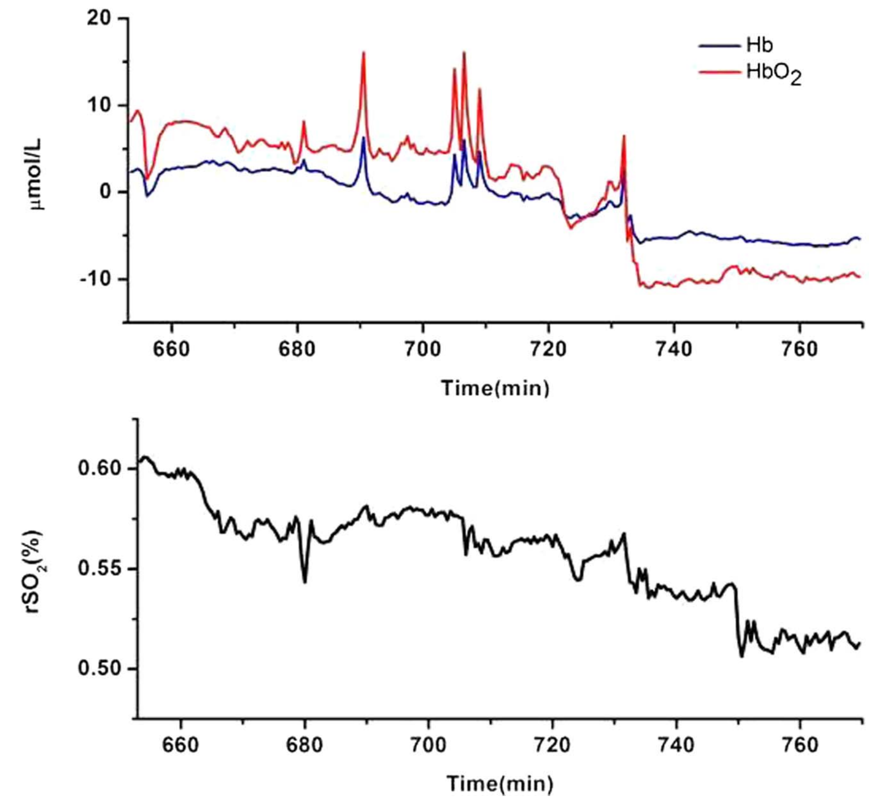

FIGURE 6. Magnified curve of rSO_2 from 620 to 800 minutes postoperatively in the flap with venous embolism in group A, depicted in Figure 5.

skin islands were dry without exudation and had soft texture (Fig. 9). Continuous monitoring revealed that the rSO_2 values remained above 62% (Fig. 10). Exploration confirmed that the fibula segment had good blood supply and that the skin island's perforation vessel was occluded. Therefore, the skin island was temporarily retained, then removed at 8 days postoperatively.

DISCUSSION

Free fibular flaps have been widely used in the reconstruction of soft and hard tissue defects of the head and neck area, particularly in the reconstruction of mandibular defects. To ensure the success of free flap transplantation, surgeons attach great importance to the postoperative

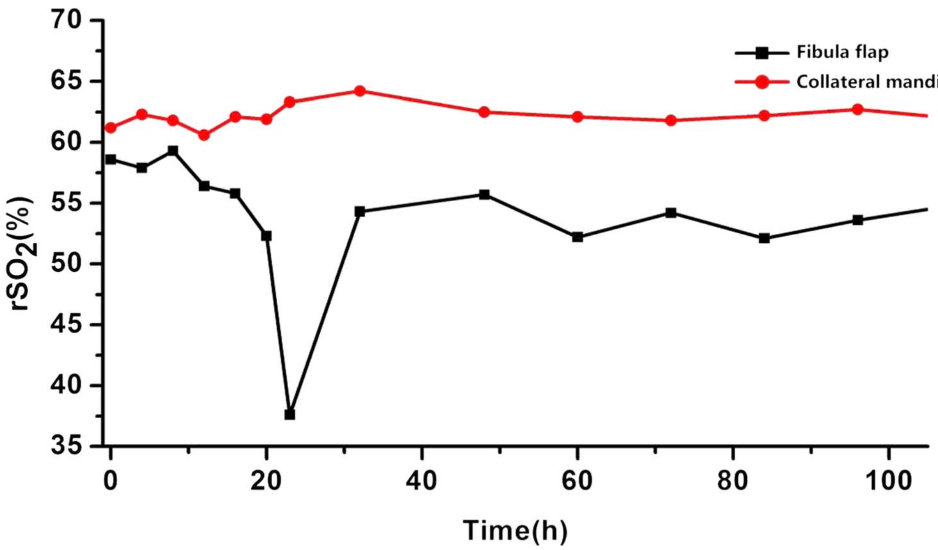

FIGURE 7. Changes in rSO_2 values of the flap with arterial embolism in group B.

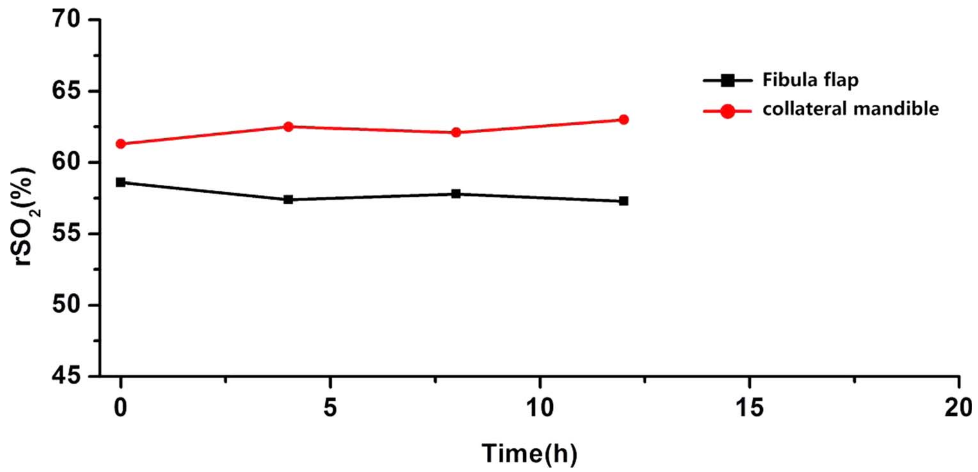

FIGURE 8. Changes in rSO_2 values of the flap with venous embolism in group B.

observation of free flap blood supply to identify vascular crisis and perform flap rescue at the appropriate time. Numerous techniques and methods have been introduced to monitor the blood supply of free transplanted tissue. However, none has been able to replace clinical observation to monitor the postoperative blood supply to free flaps.[8]

In this study, NIRS was used to monitor changes in blood flow. Until now, the warning value is discordant among studies.[9] The baseline of the postoperative free flap, which was described by several authors,[10–14] differed according to the type of flap, the patient, and the study; the actual values ranged from 40%–50% to 90%–100%. The inconsistency of rSO_2 values in studies was partly because of the various equipment used. The baseline of rSO_2 calculated by instrument was. Based on the results of previous studies, in a flap with no vascular compromise, the initial rSO_2 value would likely be no less than 40%. Thus, the absolute value of rSO_2 has little meaning for estimating whether a flap has developed vascular embolism. The Hb and HbO_2, which reflect the relative change in volume of blood flow, would more likely reveal real blood perfusion status. We observed that the rSO_2 values of free fibular flaps normally varied between 55% and 70%. We checked for ischemia when rSO_2 values were less than 55% and for proper function of the instrument's detector and the presence of visible light interference when rSO_2 values were greater than 70%. The postoperative rSO_2 values of the fibular flaps were consistently lower than those of the contralateral normal mandible, although the flaps were vascularized. However, the range of rSO_2 values in fibular flaps was relatively wide within 80 hours postoperatively; this gradually decreased and tended to become stable over time, consistent with the clinical observation that the incidence of vascular crisis was high within 3 days postoperatively.

The dynamics of continuous monitoring of venous embolism in free fibular flaps in group A was consistent with the results of animal experiments. When venous occlusion occurred, rSO_2, Hb, and HbO_2 exhibited small increases, mainly because of the continuous pumping of arterial blood and poor venous return, which increased the regional blood volume, thus causing higher Hb and HbO_2. As oxygen was slowly consumed by local tissue, HbO_2 was converted to Hb, so HbO_2 declined more rapidly than Hb. In addition, rSO_2 continued to decrease. However, the results of intermittent monitoring of free fibular flaps in group B were not satisfactory in that the rSO_2 values in flaps without venous embolism showed no abnormal signs. This may be due to the rapid process of venous embolization of the flap and delayed changes in blood perfusion not yet reflected in rSO_2 values. We discovered significant abnormal rSO_2 values of arterial blocked flaps in group B at 24 hours postoperatively but could not determine when the arterial embolism had begun to develop. Thus, there was no early warning for flap rescue. Hb and HbO_2 are known to reflect relative changes in blood flow within regional tissue; they are more sensitive than rSO_2, so it is important to observe these parameters for the detection of vascular crisis.

In this study, there were no significant differences between the results of continuous and those of intermittent monitoring of rSO_2 by TSAH-100; thus, the monitoring method can be selected based on clinical demand to improve the utilization rate of the instrument and serve more patients. However, more parameters were detected by continuous monitoring than by intermittent monitoring. By observing the changing trends and characteristics of the parameters before and after crises, more comprehensive information can be obtained regarding local tissue blood supply, which is helpful for the early detection of abnormal blood perfusion of the flap. The process of arteriovenous embolization may last 1 to 4 hours[15]; therefore, intermittent monitoring may miss key information regarding changes in blood flow during the monitoring intervals. Ideally, continuous monitoring of postoperative blood supply should be performed to ensure the detection of key information regarding blood supply and missed opportunities for flap rescue.

Free fibular flaps have always involved the use of skin islands as windows for postoperative observation of blood supply because bone segments of free fibular flaps are covered by soft tissue[16]; however, the "window" is not always reliable in all situations. Two patients in this

FIGURE 9. Swelling and ecchymosis of the skin island due to collateral vessel embolism.

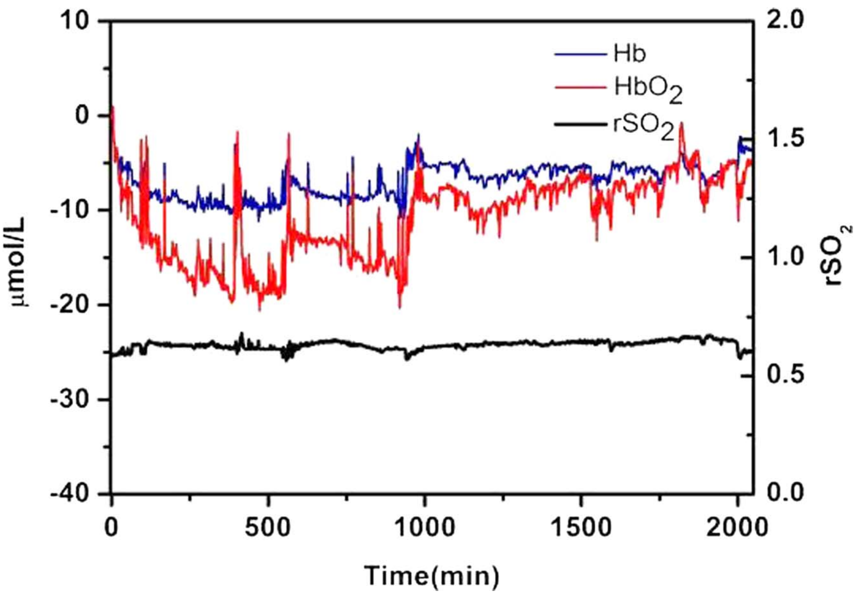

FIGURE 10. Continuous monitoring of changes in blood flow of a fibular flap with skin island collateral vessel embolism.

study developed perforation vessel embolism in the flaps, which resulted in false-positive results and increased the patients' medical costs and pain. However, the rSO_2 values obtained by the TSAH-100 indicated good blood supply, which indirectly confirmed the reliability and clinical value of the NIRS technology.

Near-infrared spectroscopy technology can noninvasively, continuously, sensitively, and visually detect changes in rSO_2 values and blood perfusion volumes in local tissues; moreover, it is easy to operate and inexpensive, which is ideal for clinical monitoring of postoperative blood supply to free flaps. However, this approach has limitations. When near-infrared light penetrates biological tissue, its path is curved; some of its energy is absorbed and some is scattered. A longer path of near-infrared light through tissue results in greater attenuation and weaker emergent light.[7] When the emergent light is reduced below a certain intensity, the instrument's receiver cannot detect the outgoing light, which leads to the collection of inaccurate data. Thus, although near-infrared light can penetrate skin, muscle, and bone, its measurement depth cannot be increased indefinitely. Currently, the detection depth of the TSAH-100 for clinical use is less than 2.0 cm. Therefore, when the covering tissue thickness of the free fibular flap exceeds that limit, it is difficult to measure the blood supply of the buried fibular flap by near-infrared light. For obese patients or those with severe postoperative swelling in this area, especially after exploratory surgery, the parameters measured by the TSAH-100 may indicate normal blood flow despite an abnormal fibular segment. This is also one of the main reasons for false-negative results in clinical practice. If the sensitivity of the probe receiver to near-infrared light was further improved, the detection depth could be increased; this would enable monitoring of the blood supply of buried flap tissue at greater depth.

During NIRS monitoring, visible light interference should be avoided as much as possible to ensure the accuracy of the measurement data. Therefore, the edge of the detector should be maintained close to the skin and should not be moved during measurement. In the continuous postoperative monitoring process, the TSAH-100 instrument detector is hard and inflexible, so the sensor is not always reliably sticky and frequent repositioning maybe necessary when fixed to the surface for long periods. That was probably another reason for the false-negative results in group A and group B; thus, the fourth generation of NIRS oximeter manufactured emphasized on improving the detector, which was more flexible and thinner than former detectors. Stable fixation and marginal tightness would reduce the incidence of false-negative rates.

Pulse oximetry measures the arterial blood oxygen saturation of extremities through the fingertips and reflects the general oxygenation condition of the whole body.[17] It is of great clinical value for routine bedside care. New generations of instruments can avoid the disadvantages of the probe while using a similar bedside monitoring mode. Postoperative real-time continuous bedside monitoring of free flaps will aid clinical staff in estimating the blood perfusion conditions of free fibular flaps.

CONCLUSIONS

Near-infrared spectroscopy is a noninvasive, continuous, and real-time monitoring method for monitoring blood oxygen saturation and changes in blood perfusion of local tissue. It is also portable, inexpensive, and easy to operate. The amount of blood perfusion in transplanted free fibular flaps is lower than that in the opposite mandible, with rSO_2 values ranging between 55% and 70%; values lower than 55% should serve as indicators for observers and surgeons to confirm the blood supply to the flap. In addition, further larger sample sizes studies and randomized clinical trials are required to better elucidate any correlation between potential variables and flap perfusion. The detection depth of NIRS (TSAH-100) is about 2.0 cm, which can be used for monitoring buried flaps with depths less than 2.0 cm.

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