Journal of Cranio-Maxillo-Facial Surgery 44 (2016) 1889–1895

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Free flap rescue using an extracorporeal perfusion device

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ARTICLE INFO

Article history:
Paper received 6 July 2016
Accepted 19 September 2016
Available online 23 September 2016

Keywords:
Extracorporeal membrane oxygenation
Free tissue flaps
Ischaemia
Warm ischaemia
Microcirculation

ABSTRACT

The warm ischaemia time of microvascular free flaps is limited. Incalculable events, such as lack of adequate recipient vessels or intraoperative medical emergencies, can lead to prolonged ischaemia and potentially to flap loss. In this study, critically perfused ischaemic or congested flaps were temporarily perfused with an extracorporeal perfusion system until anastomosis could be commenced. Temporary extracorporeal perfusion was performed in 8 radial forearm flaps for 147 ± 52 (range 77–237) minutes. Flap perfusion was assessed using Indocyanine Green fluorescence angiography and combined laser Doppler flowmetry and remission spectroscopy. Results were compared with those of 30 patients who underwent conventional reconstruction with radial forearm flaps. Flap survival, flap microcirculation, postoperative complications, and hospital stay did not differ between groups. We report successful free flap transfer after short-term extracorporeal perfusion for up to 4 h in 8 patient cases. Temporary extracorporeal free flap perfusion reduces the warm ischaemia time in emergency situations and can help to prevent flap failure in critically perfused or congested flaps. The trial is registered with ClinicalTrials.gov, number NCT02449525.

1. Introduction

With today's experience with microsurgical techniques, the critical ischaemia period of free flaps is rarely exceeded in the daily routine. However, incalculable events occurring after flap harvesting, such as medical emergencies, lack of adequate recipient vessels, vascular occlusion, or venous congestion following anastomoses may prolong flap ischaemia for an indefinite period of time, potentially jeopardizing flap success. These risks are especially high in the previously operated and irradiated neck (Hanasono et al., 2009). Each flap failure means a serious setback in the healing process, and the necessary corrective interventions are cost-intensive and often lead to inferior results with corresponding functional and psychosocial consequences.

Preliminary clinical (Greaney et al., 2010; Newsome et al., 2005; Wolff et al., 2016) and experimental (Dragu et al., 2011; Fichter et al., 2016; Mayer et al., 1994; Müller et al., 2013; Taeger et al., 2015) studies suggest that free flap viability can be prolonged for a limited time using extracorporeal perfusion (ECP). Only recently, our study group reported the first three cases of free flap transplantations without conventional anastomosis using ECP in patients with desolate vessel status in the head and neck area (Wolff et al., 2016). The objective of this study was to use ECP for the temporary perfusion of ischaemic or congested free flaps in emergency situations as a means to bridge the time until conventional anastomosis can be commenced. Therefore, a miniaturised extracorporeal perfusion device was developed and made readily available in our operating room for the past 4 years. The system could be assembled in a sterile way and connected to an ischaemic free flap to reestablish blood flow within minutes, if needed.

2. Material and methods

2.1. Ethics statement

All clinical investigations have been conducted according to the principles expressed in the Declaration of Helsinki. The study was approved by the institutional ethics committee of the Technische

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http://dx.doi.org/10.1016/j.jcms.2016.09.010
1010-5182/

Universität München, Klinikum rechts der Isar (project numbers: 2922/10 and 263/14). Patients provided written consent. The study was registered at ClinicalTrials.gov, number (NCT02449525). The authors confirm that all ongoing and related trials for this intervention are registered.

2.2. Patients

Between June 2011 and November 2015, a total of 8 radial forearm flaps (RFF) were temporarily perfused using ECP. All patients had a history of oral squamous cell carcinoma (OSCC) of the oral cavity and were planned for reconstruction with an RFF. The decision to temporarily perfuse a flap by means of ECP was made, as soon as the estimated total ischaemia time was more than 4 h. Reasons for prolonged flap ischaemia were insufficient blood flow through the prepared donor artery (n = 2), intraoperative perfusion stop due to arterial occlusion within 45 min (n = 2) to several hours (n = 1) after anastomoses, short pedicle length requiring an interpositional vein graft (n = 1), or venous congestion (n = 2). Six of 8 patients had undergone multiple operations and/or received radiotherapy in the past. In each of these cases, alternative recipient vessels, or in one case an interpositional vein graft had to be found and the decision was made to temporarily perfuse the ischaemic flaps extracorporeally. As a control group, 30 patients with a history of OSCC were used, who received standard RFF reconstruction between April 2014 and June 2015. Patients with a history of failing microvascular flaps were excluded.

2.3. Perfusion protocol

The custom-built perfusion system (Fig. 1) consisted of a roller pump (Ing. Büro Humbs, Valley, Germany), a membrane oxygenator (type Oxyphan PP50/280, Fa. Membrana GmbH, Wuppertal, Germany), and 2 reservoirs (arterial and venous) that served as bubble traps. The venous reservoir was connected to a vacuum that could generate an adjustable negative pressure to the venous system. The blood pressure before the flap was continuously measured (Panasonic Electric Works SUNX Co., Ltd. Kasugai City, Aichi, Japan). A programmable, pressure-controlled shunt between arterial and venous reservoir was implemented to avoid uncontrolled pressure spikes. The tubing system consisted of platinum-curing silicones (USP class IV). All individual parts (tubes, connectors, reservoirs, and membrane oxygenator) that came in contact with blood were Food and Drug Administration (FDA) approved and could be sterilised, assembled, and filled with blood under sterile conditions. All materials were steam sterilised before use and discarded thereafter. Heparinised (10 IE heparin/ml blood), diluted (2 ml Ringer solution/10 ml) autologous arterial whole blood was used as perfusate. The maximum systolic perfusion pressure and perfusion flow were set at 140 mm Hg and 5 ml/min, respectively, corresponding with high normal values of the radial artery (Lorenzetti et al., 2001).

2.4. Assessment of flap perfusion

In addition to observing flap colour and capillary refill (Fig. 2), combined laser Doppler flowmetry and remission spectroscopy (O_2C, equipped with an LF-2 probe, Lea Medizintechnik, Giessen, Germany) was used for noninvasive measurement of tissue oxygen saturation (SO_2 in percent), haemoglobin level (Hb, in arbitrary units (AU)), blood flow (in AU) and velocity (in AU). This technique is an established procedure for the assessment of free flaps that has been described elsewhere in detail (Hölzle et al., 2010). All measurements were taken from the central part of the flap at tissue depths of 2 (superficial, S) and 8 mm (deep, D) and compared to the same area. Measurements were performed regularly during extracorporeal perfusion, as well as on postoperative days 1 and 7. During ECP, the perfused flap area was further assessed using Indocyanine Green (ICG, Pulsion Medical Systems SE, Feldkirchen, Germany) fluorescence angiography. The fluorescence signal was recorded using a mobile near infrared (NIR) fluorescence camera (PDE Photodynamic Eye, Pulsion Medical Systems SE, Feldkirchen, Germany).

2.5. Statistical analysis

was used for statistical analysis. A two-sided Student unpaired t-test was used to detect statistically significant differences between groups. Differences within one group were assessed using a paired two-sided Student t-test. All analyses were performed using the statistical software Prism for Mac OS X (Version 7.0a, GraphPad

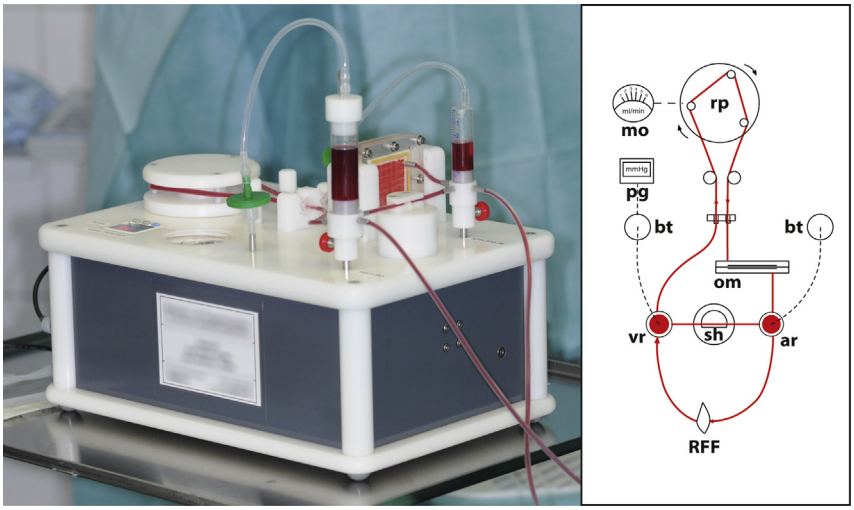

Fig. 1. The perfusion system. (Left) Assembled extracorporeal perfusion unit. (Right) Schematic drawing of the experimental setup. A motor (mo) driven roller pump (rp) transports heparinised autologous blood through an oxygenator membrane (om). The arterialised blood passes an arterial reservoir (ar) and flows into the radial forearm flap (RFF), while the venous return is collected in another reservoir (vr) connected to a pressure gauge (pg). If the pressure in the system surpasses a certain threshold, the pressure equalises by opening a shunt (sh) between the arterial and venous reservoirs. Both reservoirs function as bubble traps (bt).