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Free flap transplantation using an extracorporeal perfusion device: First three cases☆

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ABSTRACT

Background: Free flap transplantation may not be feasible in patients with inadequate or absent recipient vessels. We report successful mandibular composite reconstructions without anastomosis in three consecutive patients with vessel-depleted neck. Based on clinical reports describing early neovascularisation, temporary extracorporeal perfusion of flaps was maintained until the flaps had become independent from the extracorporeal blood supply.

Methods: A blood transfusion bag filled with the patients' arterialised blood was connected to the flap artery and set under rhythmic compression to ensure continuous blood supply to the flap. The returning venous blood was collected but not reinfused. Extracorporeal circulation was sustained for 10–13 days until flaps had become independent from the external blood supply. Flap viability was assessed every 2 h using combined laser Doppler flowmetry and remission spectroscopy.

Results: Successful bony reconstructions were achieved in all three consecutive patients substantiated by MRI-, CT-scan or bone scintigraphy. Neovascularisation occurred within the soft tissues of all flaps with the exception of one skin paddle, which later developed necrosis. Systemic transfusion of 12–25 units of packed red cells was necessary to compensate for the blood loss.

Conclusions: With this technique, transplantation of composite free flaps becomes feasible even in the absence of recipient vessels, opening up new treatment options to a broad range of complex surgical problems. Blood reinfusion should be pursued in the future to avoid excessive blood transfusions. The trial is registered with ClinicalTrials.gov, number NCT02449525.

1. Introduction

For reconstruction of the mandible in irradiated patients, vascularised bone flaps are essential to achieve long term complication-free healing and recovery (Deutsch et al., 1999; Ang et al., 2003; Buchbinder and St Hilaire, 2006; Hirsch et al., 2008; Cannady et al., 2011). However, in some cases this is far more difficult or all but impossible. For instance, if suitable neck vessels have already been removed in former operations like neck dissections or salvage surgery with inadvertent vascular injury or ligation of potential recipient vessels. In such situations, recipient vessels of the thoracoacromial or cephalic system can provide an alternative source of blood supply. However, vein grafts or vascular loops are necessary to provide a pedicle long enough for tensionless anastomosis (Urken et al., 2006; Ethunandan et al., 2007; Aycock et al., 2008; Quilichini et al., 2012; Roche et al., 2012; Karle et al., 2013), significantly increasing the risk for flap loss (Bozikov and Arnez, 2006). For these patients, we described a temporary perfusion of composite fibular flaps by anastomosing the flaps to the radial vessels ("carrier flap") with long-term fixation of the arm in an elevated position (Wolff et al., 2003, 2009). Repetitive occlusion of the vascular bridge was performed to induce gradually increasing ischemic periods. By doing so, flap autonomisation occurred as

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early as day 16 and 18, respectively (Wolff et al., 2003, 2009). Other clinical reports have described a complete survival of free flaps after an inadvertent early disruption of the blood supply between days 7 and 17 (Chen et al., 2002; Wise et al., 2011), but not in irradiated defects (Salgado et al., 2002). On the basis of published reports as well as the cumulative anecdotal experience of many surgeons, it was concluded that most flaps might safely be divided between 10 days and 3 weeks (Kayser, 1999). With this in mind, we developed an extracorporeal perfusion device to provide temporary blood supply to the flap until neovascularisation had taken place.

2. Materials and methods

2.1. Ethical 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 Universität München, Klinikum rechts der Isar. Patient consent was written. 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. Development of an extracorporeal perfusion device

According to in vivo measurements that have revealed flow rates between 6 ml/min in radial forearm and 16 ml/min in latissimus dorsi flaps (Lorenzetti et al., 2001, 2010, 2012), the device here was developed to enable pulsatile flow with adjustable pressure and pulse rates for small ejection fractions. All blood conducting parts of the system were approved for medical use.

The main components of the device were (1) a ventricle-like clack driven by a programmable electric motor and (2) a blood transfusion bag, which was set under rhythmic compression by the clack, generating adjustable systolic pressures between 20 and 180 mmHg (Fig. 1). Diastolic pressure was generated by an inflatable blood pressure cuff positioned behind the transfusion bag. The pulse rate could be adjusted between 5 and 100 beats per minute (bpm) and programmed to include pauses after a chosen number of ejections. Perfusion of the flap was ensured by pumping arterialised patients' blood into the flap's artery and collecting the venous return. Before clinical use, the system was tested in fresh and embalmed cadavers and proofed for causing no haemolysis in donated human blood (Wolff et al., 2014).

2.3. Setup and clinical use of the extracorporeal perfusion device

A transfusion bag was filled with 150 ml of heparinised blood (Heparin-Sodium 25.000 I.E./ml, ratiopharm GmbH, Ulm, Germany, 500 I.E. per bag), taken from a central arterial catheter and connected to the flap artery via a 60 cm long extension line (type: Heidelberger, B. Braun Melsungen AG, Melsungen, Germany) and a 2 mm arteriotomy cannula (Art. No. 31002, Medtronic Inc., Minneapolis, MN, USA). A 3 mm cannula was inserted in each of the two flap veins to collect the returning blood in a second bag. Blood temperature was raised to 38 °C by wrapping the extension line around a cylinder warmed by a water circulation based heat exchanger (Hilotherm Clinic, Hilotherm® GmbH, Argenbühl-Eisenharz, Germany). Perfusion was started at 30 bpm and a pressure of 120/80 mmHg and was reduced to 100/60 mmHg after 4–6 h. Haemoglobin level (Hb), capillary blood flow, velocity and oxygen saturation (SO_2) were monitored every 2 h using combined laser Doppler flowmetry and remission spectroscopy (O2C, Oxygen to See, Lea Medizintechnik, Giessen, Germany).

Returning venous blood was collected and analysed for pO_2, pH, lactic acid and glucose, but not re-infused. Heparin was given intravenously to keep the partial thromboplastin time (PTT) at 60%. Over the following days, flaps were continuously monitored for

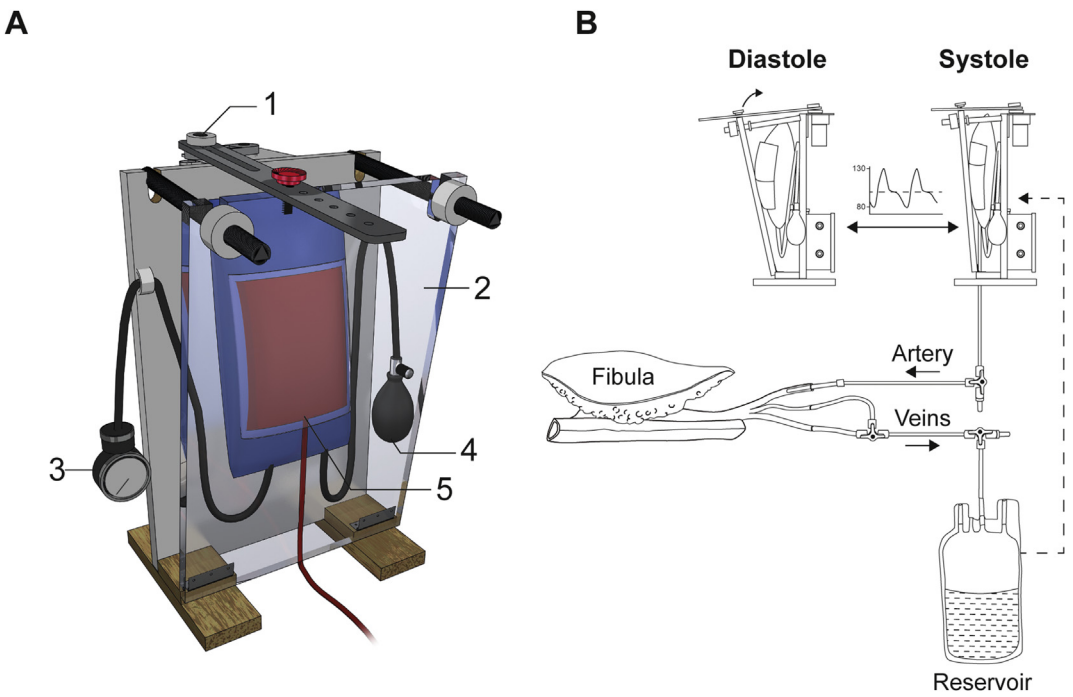

Fig. 1. Experimental setup. (A) 3D-rendering of the pulsatile pump system used in this study. Diastolic pressure is generated by inflating a conventional blood pressure cuff (4) mounted behind a blood bag filled with autologous heparinised blood (5). During systole, a glass plate (2) is pulled back by a mechanical lever arm (1), squeezing the blood bag against the inflated blood pressure cuff. A pressure indicator (3) connected to the blood pressure cuff displays all pressure changes. (B) Schematic drawing of the experimental setup. Although technically feasible (broken arrow), no blood was reinfused in the described patient cases for fear of infection.

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