

## Pilot Assessment of the Angiosome Concept by Intra-operative Fluorescence Angiography After Tibial Bypass Surgery<sup>☆</sup>

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### WHAT THIS PAPER ADDS

To date, ICG fluorescence angiography has been used to examine changes in global limb perfusion. In the present study this method was used for a separate investigation of angiosomal perfusion. This could be a promising approach, as the simplistic angiosome model may be of less relevance when collateralisation can develop over a longer period of time.

**Objectives:** The “angiosome” concept as a model for decision making in revascularisation of patients with critical limb ischaemia (CLI) has been subject to lively discussion in recent years. The aim of this prospective pilot study was to use intra-operative fluorescence angiography to provide further data on the angiosome concept on the level of microcirculation after tibial bypass surgery.

**Design, materials, and methods:** This was a prospective analysis of 40 patients presenting with CLI Rutherford stage IV to VI before and after tibial bypass surgery. The macrocirculation was measured by the ankle brachial index. Skin microcirculation was assessed by intra-operative fluorescence angiography. The alteration of microcirculation was compared in direct and indirect revascularised angiosomes. Clinical follow-up investigations were performed and the wound healing rate was compared between the different revascularisation methods.

**Results:** Cumulated microcirculation parameters showed a significant improvement after surgery (ingress, ingress rate  $p < .001$ ). Likewise, general microcirculatory improvement was observed in each foot angiosome after revascularisation, regardless of the tibial artery revascularised. Furthermore, a comparison of the direct (DR) and the indirect revascularised (IR) angiosomes did not show a significant difference concerning the improvement of microcirculation (difference DR-IR, ingress: 1.69, 95% CI 71.73–75.11; ingress rate: 0.08, 95% CI –12.91 to 13.07). The wound healing rate was similar in both groups, although the time to wound healing was faster by on average 2.5 months in the DR group ( $p = .083$ ).

**Conclusion:** Microcirculatory improvement was seen over the whole foot after tibial bypass. Therefore, fluorescence angiography is a promising tool to evaluate the angiosome concept in future larger studies.

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### INTRODUCTION

The “angiosome” concept in critical limb ischaemia (CLI) remains a controversial subject in the literature. The concept was initially described by Taylor and Palmer, who found 40 distinctive angiosomes of the human body.<sup>1</sup> Attinger et al. transferred this concept to the chronic ischaemic limb by defining direct and indirect revascularisation of particular

angiosomes of the foot affected with ulcer or tissue necrosis.<sup>2</sup> They described six different angiosomes of the foot, each supplied by specific source arteries and veins, originating from the three tibial arteries.

Several retrospective studies have been conducted focusing on the evaluation of this concept, with varying results and study designs.<sup>2–9</sup> Therefore, in recent years four meta-analyses focused on this topic.<sup>10–13</sup> Most found indirect revascularisation (IR) to be inferior to direct revascularisation (DR), particularly in endovascular procedures. Simultaneously, these meta-analyses criticised the low quality of individual studies leading to a low level of meta-analytical evidence. The main sources of potential bias mentioned were the retrospective nature of most individual studies and inappropriate consideration of important co-factors influencing wound

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healing. Thus, new prospective approaches are required to evaluate the relevance of this concept.

In this context perfusion analysis prior to and after revascularisation is seen as an interesting approach, as intact microcirculation has been recognised as a relevant factor for wound healing.<sup>14–16</sup>

A relatively new and promising method, which has already proven feasible in CLI patients, providing not only quantitative but also visual topographic assessment of the microcirculation, is indocyanine green (ICG) fluorescence angiography. Several studies have aimed at investigating global limb perfusion after revascularisation.<sup>17–23</sup>

In patients with long lasting chronic ischaemia of the legs, the relevance of the initially defined angiosome concept is debatable, as wide collateralisation may have occurred. Therefore, the aim of this pilot study was to employ ICG fluorescence angiography to investigate the actual perfusion in both direct and indirectly revascularised angiosomes after tibial bypass surgery.

## METHODS

### Patients

In this pilot assessment, prospective analysis of 40 consecutive patients (26 men, 14 women) presenting with CLI at Rutherford stages IV to VI, was performed. The mean age was 77 years (range 60–92 years). The data collection was performed prospectively between February 1, 2015 and August 31, 2016. Fluorescence angiography measurements were performed between February 1, 2015 and March 21, 2016. Study termination at which point follow-up investigations ended was August 31, 2016. The median follow-up was 11 months (range 4–18 months). Four patients were lost to follow-up as they did not participate at the follow-up investigation. Therefore, the follow-up index (by August 31, 2016) as defined by von Allmen et al., was 0.88 ( $\pm 0.32$ ).<sup>24</sup>

Included were consecutive patients receiving tibial bypass surgery for long segment occlusion with single vessel outflow in the lower leg in a tertiary referral hospital. Exclusion criteria depended solely on the use of iodine based ICG, therefore patients with known allergy against iodine contrast agents were excluded.

The study was conducted in accordance with the Declaration of Helsinki and further approved by the local ethics committee (279\_15B) and registered on [clinicaltrials.gov](http://clinicaltrials.gov) (NCT03012750); written informed consent was obtained from all patients. The study results are published in accordance with the guidelines for Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).<sup>25</sup>

### Study design

In this study the macro- as well as the microcirculation before and after tibial bypass surgery were evaluated. To assess the macrocirculation, measurements of ankle brachial index were made pre- and post-operatively. Patients with falsely elevated indices because of medial sclerosis (ankle brachial index  $>1.3$ ) were excluded from the calculation. Changes in

microcirculation resulting from improved macrocirculation after bypass surgery were assessed by intra-operative fluorescence angiography (IFA; SPY Elite, NOVADAQ, Canada). These measurements were performed in the operation room directly prior to the first skin incision and after wound closure of tibial bypass surgery under general anaesthesia; thus a stable circulatory situation was ensured (medium blood pressure 70–90 mmHg, heart frequency 60–80/min, haemoglobin concentration  $>9$  g/dl). The room temperature was held constant (21–23°C). Additionally, intra-operative patency assessment of the bypass graft was performed by conventional digital subtraction angiography. To assess the dorsal and the plantar foot angiosomes, both, one dorsal and one plantar measurement per foot were conducted pre- and post-operatively. Each perfusion measurement sequence lasted for 272 s; sequential dorsal and plantar measurements were performed after an interval of 5 min. This interval allowed a sufficient capillary washout of ICG between the dorsal and plantar measurements. For each perfusion sequence a quantity of 0.1 mg ICG per kg body weight was applied intravenously.

In clinical follow-up investigation, the wound status as well as the pain situation of the patients was recorded, the ankle brachial index as well as duplex ultrasound was obtained as a patency assessment of the revascularisation; the wound size was evaluated and documented by photography, wounds were graded at the time of the first investigation employing the Wound, Ischaemia and Foot Infection Score (WIFI Score) from the Society of Vascular Surgery.<sup>26</sup> Following this score, the amputation risk after one year could be predicted. Furthermore, the wound healing time was evaluated for all patients at follow-up. At this point, wound healing was defined as complete epithelialisation. Patients still presenting with wounds at follow-up investigation were defined as non-healing. A comparison was conducted of the time to wound healing and the wound healing rate depending on the revascularisation method (DR and IR).

To address the individual bypass outflow and pedal arch patency as well the individual collateralisation, the intra-operative digital subtraction angiograms were scored according to the pedal arch classification as suggested by Kawarada.<sup>27</sup> Category I was defined as complete pedal arch with a patent dorsalis pedis and plantar artery. Category IIa was characterised as a patent dorsalis pedis artery and an occluded plantar artery, accordingly, Category IIb with a patent plantar and an occluded dorsalis pedis artery. Category III was defined as collateral foot perfusion with no patent pedal vessel.

### Technical aspects of intra-operative fluorescence angiography

Fluorescence angiography is an imaging tool for capturing and viewing fluorescence images of tissue perfusion up to a depth of 5–7 mm. There are a variety of fluorescence angiography systems available; in this study, the SPY imaging system (NOVADAQ, Canada) was used, which enables quantitative assessment of the fluorescence sequences.

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