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Retrospective evaluation of diagnostic accuracy of free flap monitoring with the Cook-Swartz-Doppler probe in head and neck reconstruction

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ABSTRACT

The Cook-Swartz-Doppler probe is an easy to handle and reliable tool for free flap monitoring. In the head and neck region different confounders can affect the read out. We therefore analyzed the use of the Doppler probe regarding these potential difficulties and to compare the diagnostic accuracy in arterial or venous monitoring of free flaps in the head and neck region.

A retrospective study was performed in which all patients were included who underwent free flap surgery in the head and neck region in the Department of Plastic Surgery and the Department of Maxillofacial Surgery of our institution between 2010 and 2018 and were monitored with an implanted Doppler probe.

147 free tissue transfers were included. No significance was found for arterial and venous placement of the Doppler probe for sensitivity (artery 83.3%; vein 84.6%; $p = 0.87$), specificity (artery 89.2%; vein 96.1%; $p = 0.17$) and negative predictive value (artery 96.7%; vein 94.2%; $p = 0.55$). A better positive predictive value for placing the Doppler probe around the artery (82.7%) than the vein (61.1%) was found in our study ($p = 0.056$).

The better positive predictive value in arterial monitoring suggests that this is the more reliable measuring method to assess flap perfusion in the head and neck region.

1. Introduction

Free flaps in head and neck surgery are in the majority of cases elaborate and lengthy operations. Potential complications in head and neck surgery are particularly severe for the patient because of the visibility and the functional significance. Because of distinctive scarring of subcutaneous tissue in the face, subsequent revision surgeries are even more aggravated (Ho et al., 2014). Hence, successful initial flap surgery and early recognition of complications are of particular importance in head and neck surgery (Nakatsuka et al., 2003; Whitaker et al., 2007). Therefore post-operative perfusion monitoring is crucial for these cases (Wax, 2014). This can be complicated when so called buried flaps are used, which cannot be monitored clinically (Schmulder et al., 2011), e.g. in functional muscle transfer for facial reanimation or vascularized bone transfer in midface or mandibular reconstruction. Also, clinical monitoring of skin grafted muscle flaps can be difficult or, in case of additional vacuum closure, impossible (Bannasch et al., 2008; Eisenhardt et al., 2010; Lenz et al., 2017).

Different methods were introduced to control flap perfusion, like surface temperature probe, microdialysis, or transcutaneous laser Doppler flow monitoring (Whitaker et al., 2010; Rothenberger et al., 2013; Chae et al., 2015; Frost et al., 2015; Kaariainen et al., 2018). Most of them have been used in clinical trials but have not made their way into everyday clinical routine, because of either high costs, or technical difficulties. Because of its simplicity in application and interpretation, the implanted Cook-Swartz-Doppler probe has become the method of choice for post-operative patency control of the vascular pedicle in many

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institutions (Rozen et al., 2010; Poder et al., 2013). Practicability and efficiency of the Cook-Swartz-Doppler probe have already been proven in multiple studies (Um et al., 2014; Chang et al., 2016b) and a higher salvage rate and flap survival compared to clinical monitoring was found (Han et al., 2016). However, there is still an ongoing debate regarding whether the implanted Doppler probe should be placed around the artery or the draining vein of the flap. Early studies placed the Doppler probe around the artery (Swartz et al., 1988), while later venous placement was suggested for early detection of venous thrombosis (Swartz et al., 1994). However, recent published studies could not detect differences in sensitivity and specificity between arterial and venous placement of the Doppler probe (Chang et al., 2016a).

To our knowledge only a few studies have been published addressing arterial or venous positioning of the Doppler probe in head and neck surgery (Pryor et al., 2006; Guillemaud et al., 2008; Fujiwara et al., 2018). The situation for free flap monitoring in the head and neck region is unique in that this region undergoes changes in venous pressure depending on the position of the head. Additionally the neck is usually highly mobile, potentially affecting the read out of an implantable monitoring device. Regarding these potential difficulties, we aimed to compare the diagnostic accuracy of the Cook-Swartz probe in arterial or venous monitoring of free flaps in the head and neck region.

2. Material and methods

All patients who underwent free flap surgery in the head and neck region in the Department of Plastic and Hand Surgery and the Department of Oral and Maxillofacial Surgery of our institution and were monitored with an implanted Cook-Swartz-Doppler (Cook Medical Europe Ltd., Limerick, Ireland) probe between 2010 and 2018 were included in this retrospective study (Fig. 1).

In the standardized clinical follow-up for every free tissue transfer, the perfusion was checked hourly with the Cook-Swartz-Doppler for the initial five post-operative days. Then the interval was extended to every 4 h until the 8th post-operative day.

All data were collected with the clinical internal documentary systems according to the ethical approval by the ethics committee

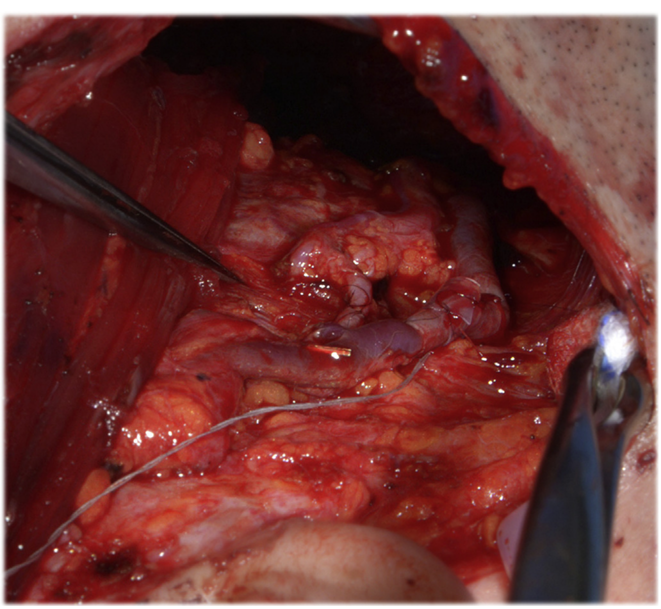

Fig. 1. In this intra-operative picture the Cook-Swartz-Doppler probe is placed around the vein proximal to the anastomosis. The probe cable pierces the skin intra-lesionaly and can be removed from the seventh post-operative day by a light axial pull.

of the University Freiburg and conform to the World Medical Association Declaration of Helsinki (June 1964) and subsequent amendments. For further analyses the following data of the patients were collected: age, sex, surgery time, inpatient stay, kind of flap, location of the Cook-Swartz-Doppler probe (artery vs. vein), recipient vessels, alterations of the Cook signal, if a revision was performed, flap loss, ischemia time of the flap, ASA (American Society of Anesthesiologists) classification of the patient, and smoking or alcohol abuse. All recorded alterations of the Cook signal (significant quieter signal or signal loss) were included into the analysis. If an alteration of the Cook signal was recognized, typically additional testing like handheld Doppler or Duplex ultrasound was performed. If additional testing showed a normal blood flow within the pedicle, no revision was necessary and the event was recorded as false positive. In case of a free flap revision we further analyzed if the revision was indicated and successful (flap salvage), if revision was indicated but failed (flap loss) or if revision was unnecessarily performed. Surgical records were reviewed for intra-operative alterations of the signal. If at the end of the operation an alteration of the Doppler occurred, which led to a revision of the anastomosis, it was classified as flap revision. Age, sex, surgery time, flap type, recipient vessels, duration of ischemia, and ASA classification were analyzed for correlation with revision or flap failure rate. Furthermore, two groups were formed with either the patency of the artery or the vein monitored by the Cook-Swartz-Doppler probe and correlated to the parameters above. A normal Doppler signal with an uneventful post-operative course and flap survival was classified as true negative. If alterations occurred in post-operative monitoring and congestion of flap perfusion was found (e.g. thrombosis found in revision surgery or flap loss), it was counted as true positive. If flap loss occurred while post-operative Doppler monitoring was uneventful, it was interpreted as false negative. A lost Cook Doppler signal, but positive blood flow (e.g. confirmed via color-coded or hand-held Doppler) was rated as a false positive signal (Fig. 2). With this information we were able to generate sensitivity and specificity as well as the positive and negative predictive value of the implanted Cook-Swartz-Doppler probe.

2.1. Statistical analyses

Statistical analyses were performed in cooperation with the Institute for Medical Biometry and Statistics, University of Freiburg.

All categorical characteristics of the patients were listed using frequency and percentage, and continuous characteristics were summarized with standard deviation.

All independent risk factors for revision surgery or total flap loss were included in a multivariable logistic regression.

The influence of different variables on sensitivity or specificity was examined with chi-square test for categorical characteristics and Wilcoxon rank sum test for continuous characteristics. A p-value $\leq$0.05 was considered statistically significant.

3. Results

3.1. Patients

We identified 129 patients that received 147 free tissue transfers for head and neck reconstruction that were monitored with the Cook-Swartz-Doppler probe and could be included in this retrospective study. In 68 free flaps the Doppler probe was placed around the artery and in 79 cases around the vein. Mean age of the patients was 53.5 $\pm$ 18.1 years. Patients with arterial monitored flaps suffered more often from coronary heart disease or coagulopathies and/or more frequently took anticoagulants, but without influencing ASA classification significantly (Table 1).

	normal blood flow	impaired blood flow
normal Doppler signal	true negative	false negative
altered Doppler signal	false positive	true positive

Fig. 2. The fourfold table correlates the Cook-Swartz-Doppler signal with the real existing blood flow of the pedicle. From this the sensitivity (true positive rate from all cases with impaired blood flow), the specificity (true negative rate from all results with normal blood flow), the positive predictive value (ratio of the correct positive values from all positive classified values) and the negative predictive value (ratio of the correct negative results from all as negative classified values) can be calculated.

Table 1
Summary of patient collective.

	Artery	Vein	Overall	p-Value
Number	68	79	147	
Age	61.3 ± 13.6	46.9 ± 19	53.5 ± 18.1	<0.0001
Sex				0.143
♂	34	49	83	
♀	34	30	64	
ASA	2 ± 1	2.1 ± 0.7	2.2 ± 0.7	0.015
CHD	38	26	64	0.005
Coagulopathy	13	9	22	0.191
Radiation	25	14	39	0.009
Indication				
• Tumor resection	52	21	73	
• Defects after Radionecrosis	14	2	16	
• Facialisparalysis	02	53	53	
• Wound healing deficit	0	2	4	
• Trauma		1	1	
Surgery time [h]	13.2 ± 2.9	8.2 ± 2	10.5 ± 3.5	<0.0001
Ischemia [h]	2.29 ± 0.72	1.8 ± 0.5	2 ± 0.7	<0.0001
In-patient stay [d]	22 ± 12	11.9 ± 9.8	16.5 ± 12	<0.0001
Flaps				<0.0001
• Muscle	12	69	81	
• Bone	35	4	39	
• Fasciocutaneous	21	6	27	
Revision surgery	16 (23.5%)	13 (16.4%)	29 (19.7%)	0.351
• successful	10	7	17	
• failed	4	5	9	
• unnecessary	2	0	2	
Flap loss	4 (5.9%)	6 (7.6%)	10 (6.8%)	0.231

Abbreviations: ASA: American Society of Anesthesiologists; CHD: Congestive Heart Disease.

3.2. Operation

Of the 147 operations, 73 were defect coverage or bony reconstructions after oncological resections. 53 cases were free muscle transfers for facial reanimation surgery. 16 patients suffered from osteoradionecrosis and underwent bony and soft tissue reconstruction; one case was a reconstruction after trauma and 4 due to wound healing problems. 81 muscle flaps (53x gracilis, 28x latissimus dorsi), 39 free vascularized bone (16x scapula, 12x fibula and 11x iliac crest) grafts and 27 fasciocutaneous (26x radialis flaps, 1x anterior lateral thigh flap) free flaps were used. In both groups (arterial and venous monitoring) differences in surgery time, ischemia time and post-operative in-patient stay was detected (Table 1).

3.3. Sensitivity and specificity

Sensitivity for the Cook-Swartz-Doppler probe was 82.4% when placed around the artery and 84.6% when placed around the vein. It did not differ significantly ($p = 0.87$) between the two groups (Fig. 3a). Specificity was also not significantly different between the two groups ($p = 0.17$) of arterial (89.2%) and venous (96.1%) monitoring (Fig. 3b).

Various confounders were evaluated for their influence on sensitivity and specificity. No statistically significant impact was found for sex ($p = 0.47$), pre-operative radiation ($p = 0.73$), coronary heart disease ($p = 0.52$), coagulopathies ($p = 0.67$), nicotine abuse ($p = 0.87$), duration of flap ischemia ($p = 0.78$), or surgery time ($p = 0.87$). Also the type of free flap used, namely free muscle vs. free bone graft ($p = 0.84$) vs. fasciocutaneous flap ($p = 0.8$), did not influence sensitivity and specificity significantly.

3.4. Positive and negative predictive value

The positive predictive value (PPV) for placing the Doppler probe around the artery was 82.7% and surpassed the venous monitoring, with a PPV of 61.1% ($p = 0.056$) (Fig. 4a). Negative predictive value (NPV) was 96.7% for arterial and 94.2% for venous monitoring ($p = 0.55$) (Fig. 4b).

3.5. Revision surgery

Revision surgeries were performed in 29 cases (19.7%). Seventeen times a revision was indicated and the flap was salvaged, concluding in a salvage rate of 63% of all indicated revision surgeries (17 out of 27 indicated revisions). Revision surgery failed in 9 cases, leading to complete flap loss. Twice revision surgery was performed because of a signal loss of the Cook-Swartz-Doppler probe, in which the vascular pedicle was shown to be patent intra-operatively (Table 1). In these two cases the revisions were done unnecessarily. This resulted in a rate of unnecessary revision surgeries of 1.4% of all 147 surgical procedures.

The time elapsed until the revision surgery was performed was not recorded, because in some cases the exact time of detection of the impaired Cook signal was not ascertainable.

Different confounders were tested regarding their impact on likelihood for revision surgery. These results showed that using neck vessels as recipient vessels led to a significantly higher revision rate than using facial vessels like superficial temporal artery and vein or facial artery and vein (OR 1.3; 95% CI 0.39–2.21; $p = 0.005$). An ischemia time longer than 2 h was associated with a 66-times higher risk for re-operation (OR 1.66; 95% CI 0.45–2.88; $p = 0.007$). Smokers had a higher risk for salvage procedures (OR 1.43; 95% CI 0.42–2.44; $p = 0.005$).

Other possible confounders (age, sex, surgery time, flap type, and ASA classification) had no significant influence on the revision rate.

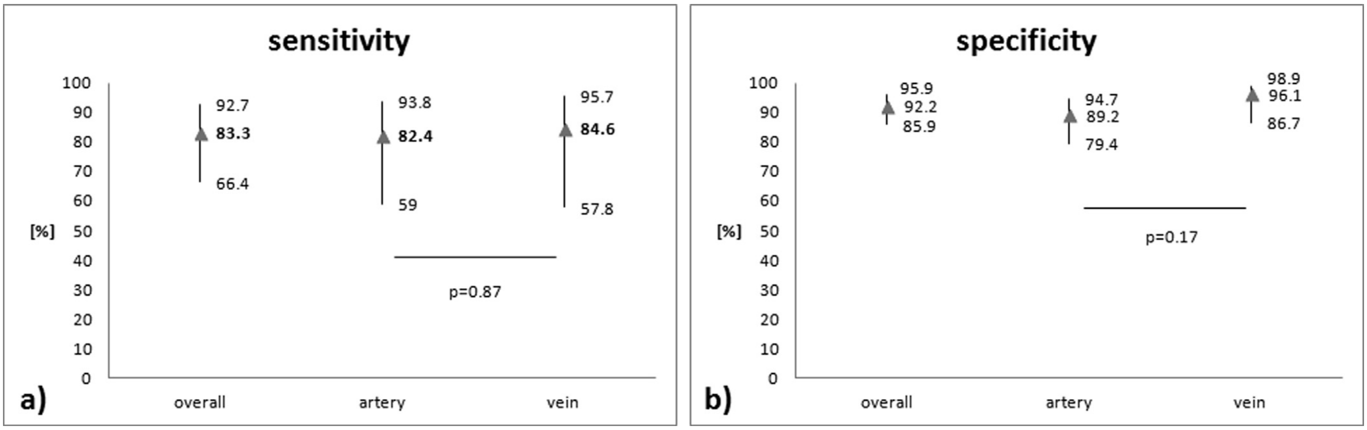

Fig. 3. a) Sensitivity did not differ between arterial and venous placement of the Cook-Swartz-Doppler probe (p = 0.87). Overall sensitivity was 83.3%. b) Specificity did not differ when the probe was applied to artery or to vein (p = 0.17).

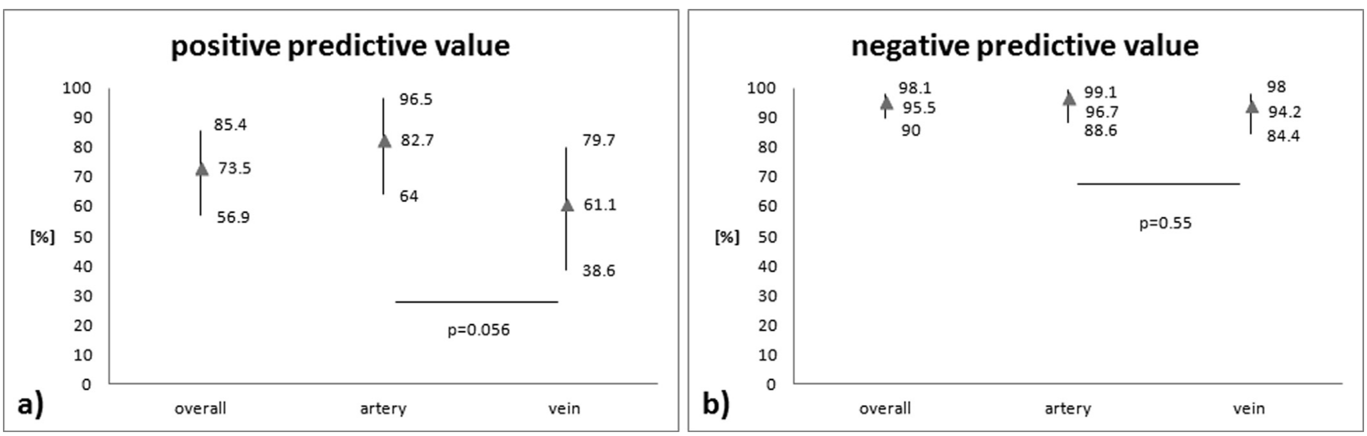

Fig. 4. a) PPV for arterial placement surpasses (82.7%) the venous placement (61.1%) without reaching level of significance with a p-value of 0.056. b) No differences were seen between arterial and venous placement regarding the NPV.

3.6. *Flap losses*

Overall 10 flaps were lost (6.8%) (Table 1). 4 of them were monitored arterially (5.9% flap loss), in all of which revision surgery was unsuccessful. In 2 cases the Doppler probe detected disturbed blood flow (true positive), but revision surgery failed to salvage the flap. Twice a normal Doppler signal was recorded, though both flaps became completely necrotic. In the venously monitored group, 6 flaps were lost (7.6% flap loss). 3 flaps were unsuccessfully re-operated after losing the Doppler signal (true positive). 2 flap losses occurred despite a normal Doppler signal (false negative). In one of these cases the Cook-Swartz probe detected disturbed blood flow, but this was misinterpreted as a probe malfunction and no revision surgery was undertaken. Rates in flap loss or flap survival did not differ significantly between arterial or venous measurement (p = 0.23).

4. Discussion

Arterial and venous monitoring of free flaps in the head and neck region showed equally good results regarding sensitivity. Specificity was excellent in both groups, while venous monitoring showed a trend to be superior to arterial monitoring without being statistically significant. Even though sensitivity and specificity describe the quality of a test, in this particular scenario under investigation the positive predictive value might be more relevant in daily clinical practice. This value indicates the likelihood that a disturbed blood flow in the vascular pedicle is present when a pathological signal is transduced by the Doppler probe. Our results suggest that in this specific parameter monitoring the artery seems to be superior to the vein. However, significant differences could not be detected with a p-value of 0.056. It is tempting to speculate that larger group sizes will allow detecting a significant difference in the PPV between both groups (Guillemaud et al., 2008; Chang et al., 2016a; Lenz et al., 2017); however a clear conclusion can only be obtained in larger prospective studies.

Choosing recipient vessels in the neck region increases the risk for revision surgery compared to using the vessels in the face. There are several explanations possible for this finding. Firstly, the neck is highly mobile and this might increase stress on the anastomosis. Secondly this mobility might increase the risk of unwanted probe dislocations. Thirdly, in our patient clientele the neck vessels were used commonly in more complex cases.

Also a prolonged flap ischemia longer than 2 h in the primary surgery (cold ischemia) led to increased risk for revision surgery. This might be a consequence of ischemic tissue injury. We decided to use 2 h as the cut off for flap ischemia. Flap tissues differ in their tolerance to ischemia. Muscle flaps are less tolerant to ischemia than adipocutaneous flaps (Eichhorn et al., 2009). 2-hour ischemia is known to be safe for muscle tissue without causing permanent damage to the tissue (Wolff et al., 1993). Prolonged ischemia can also be an indication for a technically more demanding operation or a less experienced microsurgeon, leading to a higher revision rate.

Our results also emphasize the importance of smoking restriction in the perioperative phase after free flap surgery, and the increased risk for serious complications and revision surgery after free flap transplantation in smokers is well known (Sanati-Mehrizy et al., 2016; Cannady et al., 2017).

The aforementioned observations and potential confounders highlight the limitations of the retrospective character of our study. A clear causation of our observations would need a prospective trial. While the initiation of a prospective trial in theory would be possible, other studies have shown that achieving statistically significant differences between groups within a prospective trial evaluating a monitoring device can be challenging. Due to the low number of flap losses these days any prospective trial would need a high patient number in order to reach significance. Even larger series than ours with over 600 free flaps have failed to show a significant improvement in flap salvage of the Cook-Swartz-Doppler Doppler probe when compared to conventional monitoring strategies (Smit et al., 2010, 2012). We therefore accepted the limitations of our study design when starting this retrospective trial, as we did not want to focus on the overall advantages of the implantable Doppler probe when compared to conventional monitoring strategies. We rather wanted to focus on the analysis of the strengths and weaknesses of this monitoring device in a very selected patient clientele, namely patients undergoing head and neck reconstruction.

This was done for two reasons: firstly in our clinical practice we found the interpretation of the venous signal in the head and neck sometimes more difficult to interpret, as particularly in the operating theater when the head is in a non elevated position the jugular venous pulse can make the venous signal difficult to interpret and does not cease immediately when the artery is occluded, which is in contrast to the situation in lower extremity reconstruction (Lenz et al., 2017). This raised the question whether the artery might be more sensitive in monitoring a free flap in the head and neck region. Secondly, we have observed several secondary dislocations of the Cook Doppler probe in head and neck cases, due to the high mobility of this region e.g. upon turning the head. This again is in contrast to lower extremity reconstruction where we do not observe secondary dislocations as the patients usually stay in bed for one week after free flap reconstruction. This raised the question whether the implantable Doppler probe is less reliable in the head and neck region, compared to lower extremity reconstruction independently from indication or selected free flap. This study attempted to investigate both factors. Regarding the effectiveness of monitoring of the artery, we could show a trend toward a more effective monitoring in the artery than on the vein. However this outcome has to be interpreted in the light of our recent study on the Cook-Swartz-Doppler probe in lower extremity reconstruction, in which we observed a trend toward increased flap salvage rates with venous monitoring (Lenz et al., 2017). Overall, the arterial monitoring seems to be a valuable option in head and neck reconstruction that might simplify interpretation of the Doppler signal.

Regarding our data, several confounders and selection biases need to be mentioned to avoid overinterpretation of our data. This also affects the decision making process of whether a flap was arterially or venously monitored. Again this was not randomized but rather depended on the surgical team that was treating the patient. While the Cook-Swartz-Doppler probe was almost exclusively placed around the vein by the plastic surgeons, the maxillofacial surgeons mainly used the artery for Doppler probe fixation. This resulted in different patient collectives and surgical conditions, which can be seen by significant differences between age, indication for operation, or choice of flap (Table 1). In the Department of Oral and Maxillofacial Surgery, free flap transfers were mostly performed after tumor excisions or defects of radionecrosis (Bourget et al., 2011). Thus, the amount of pre-operative radiation and vascularized bone transfers were higher in the arterially monitored group. Arterial monitoring is preferable in free bone grafting, because venous backflow in these cases can be low, as the blood flow can also be drained via the bone marrow. Even if there is no clear evidence regarding the positioning of the Cook-Swartz-Doppler probe monitoring free bone grafts, most authors use arterial placement for bone transfer (Pryor et al., 2006; Guillemaud et al., 2008). In the Department of Plastic and Hand Surgery the indications for free flap surgery in the head and neck region were in the majority of the cases facial reanimation surgery (mainly free functional gracilis transfers) and defect closure after tumor excision. The distinctive differences in operation time and ischemic time, as well as the post-operative hospitalization times between these two subgroups, reflect this distinct patient clientele.

However, no selection was performed within arterial and venous monitored groups. Uncomplicated and more complex cases or radiated and non-radiated operation fields were treated equally. The surgeon did not choose placement of the Cook-Swartz-Doppler probe deliberately or spontaneously, instead craniofacial surgeons used it arterially and plastic surgeons used it around the vein.

Nevertheless the more accurate PPV in arterial monitored free flaps in the head and neck region questions the commonly performed routine of venous monitoring of free flaps, which has been propagated by some since 1994 (Swartz et al., 1994). The basic rationale behind this routine is that monitoring the vein allows detecting congestion of in- and outflow whereas arterial monitoring can show some delays in monitoring a venous congestion (Swartz et al., 1994). This is particularly true for flaps with a large microcirculation, such as large latissimus dorsi flaps.

In clinical practice additional factors might play a role in why placing the Doppler probe around the artery leads to better PPV. A recently published study by Chang et al. confirmed that PPV is more accurate in arterial than in venous monitoring; while sensitivity and specificity is almost equal (Chang et al., 2016a). Different studies already showed that a high false-positive rate is a weakness of the venous placed Doppler probe (Kind et al., 1998; de la Torre et al., 2003; Rosenberg et al., 2006), while arterial placement leads to better PPV (Guillemaud et al., 2008).

We recently published a slightly better PPV for venous monitoring of free flaps for post-traumatic lower limb reconstructions (Lenz et al., 2017). Rather than contradicting our findings here this report highlights the relevance of accurate interpretation of the results obtained with the implantable Doppler probe regarding the region of reconstruction. As mentioned above the jugular venous pulse can make the interpretation of the signal difficult for untrained staff as it can mimic an arterial pulsatile signal. In the lower extremity, the patient rests in bed after reconstruction until the beginning of dangling procedures usually after one week (Kolbenschlag et al., 2014, 2015; McGhee et al., 2017). Therefore the monitoring situation is more stable and reproducible. In this situation the more sensitive, but potentially more delicate venous monitoring might be of advantage.

In our opinion placing the Doppler probe around the artery has some advantages in the head and neck region and is therefore useful for some distinctive fields of application. The pulsatile flow of the artery is easier to identify than the continuous rushing of the vein (Pryor et al., 2006). This becomes particularly important if post-operative monitoring is done by less experienced staff, e.g. if the patient is brought post-operatively to the intensive care unit (Guillemaud et al., 2008; Smit et al., 2010). Especially with high volume the noise floor of the Doppler probe can be mistaken for a normal venous signal and thus an impaired blood flow can be missed (false negative).

Placing the Doppler probe around the vein is still adequate because of the immediate detectability of a venous stasis (Oliver et al., 2005), particularly in free flap monitoring for lower extremity reconstruction (Lenz et al., 2017). This applies in particular if post-operative monitoring is done by experienced and well trained staff. Also a false positive test does not inevitably need reoperation. Often more experienced staff or the surgeon are able to rectify perfusion control by additional testing like handheld Doppler or Duplex ultrasound of the vascular pedicle (Rosenberg et al., 2006).

5. Conclusion

In conclusion our results show that the implantable Doppler probe is a powerful tool for free flaps monitoring in the head and neck region. Our data suggest that there might be application differences between the head and neck region, where arterial monitoring might be beneficial, and other body regions. We see a trend toward improved outcome when using the artery compared to the vein.

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Authors' contributions

N.L. and A.H.-P. made substantial contributions for acquisition of data.

G.B.S. and R.S. made substantial contributions for interpretation of data.

S.U.E. and P.V. made substantial contributions to conception and design.

M.M. has been involved in drafting the manuscript or revising it critically for important intellectual content.

Declaration of Competing Interest

None.

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