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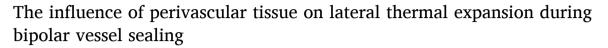
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Research Article





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ABSTRACT

Background: Lateral heat propagation has been an unavoidable effect of bipolar sealing with the risk of damage to surrounding structures. It is presently unknown whether leaving the perivascular tissue in situ may be advantageous in the sense of an isolation effect.

Material and methods: Two groups were formed from ex vivo carotid specimens. Group A (n=10) consisted of carotid artery with the perivascular connective tissue in place (mean preparation diameter: 10.57 ± 0.16 mm) and group B (n=10) of skeletonized carotids (mean vessel diameter: 5.21 ± 0.12 mm). All specimens were fixed on a plastic plate and mounted vertically in a holder. Sealing was performed perpendicular to the axis of the specimens. The temperature during the sealing process was recorded by a thermal camera. Group comparison was performed by a nonparametric test and significance was set at p<0.05.

Results: Mean sealing time in group A was 3.71 ± 0.37 s compared to 3.42 ± 0.37 s (p=0.009) in group B. The maximum temperature in the middle of the jaws was significantly different. Group A had a temperature of $71.4\pm3.9\,^{\circ}\text{C}$ and group B had a temperature of $91.4\pm7.4\,^{\circ}\text{C}$ (p<0.0001). RILATE risk scores (percent of necrotic zone in relation to potential area of necrosis) at both upper and lower sides of instrumental jaws were significantly different. For group A, it was 14.9 ± 1.6 at the upper side of jaws, 20.4 ± 2.63 at the lower side of jaws and for group B, it was 21.9 ± 3.5 at the upper side of jaws, 30.2 ± 6.2 at the lower side of jaws.

Conclusion: Perivascular connective tissue acts as an insulator with respect to lateral heat propagation. Peak temperature between instrument jaws is significantly reduced with perivascular tissue in situ. This may result in a negative impact on sealing quality.

Background

In several fields of surgery, bipolar vessel sealing has been successfully used for many years [1-4]. The technology offers several advantages: faster operation, no interruption of surgical preparation by changing instruments and secure sealing of vessels up to a diameter of 7 mm [5-10].

In clinical practice after visualization of the vessel to be occluded, the instrument jaws are passed underneath. The vessel is grasped, and the jaws are closed, compressing the vessel with constant pressure. An electrical current pass through the jaws and the tissue, converting electrical into thermal energy. Temperature usually rises [11] above $100~^{\circ}\text{C}$ between jaws, causing the tissue to coagulate and the collagen

fibers to melt [12–14]. These melted cross-linked collagen fibers form the basis for tight vessel sealing. As a result, the output impedance, which is continuously measured, changes. At a defined threshold impedance, the sealing process is automatically terminated, the sealing process is complete. The vessel is cut by extending a knife integrated into the instrument. The instrument jaws are opened, and preparation continues.

During the sealing process, thermal energy spreads into the surrounding environment [15]. This process is referred to as lateral heat propagation [15–17]. It is clinically relevant because adjacent biological structures may suffer damage. Cases of damage to the recurrent laryngeal nerve [18,19], ureter [20], and vena cava [21] have been described in the literature. Therefore, when developing a new sealing instrument,

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care is taken to limit lateral heat expansion [22].

In surgery in contrast to many experimental studies on bipolar sealing, vessels are often not skeletonized. In this study an ex vivo model of porcine carotids is used to investigate whether lateral heat propagation is influenced by leaving perivascular tissue in situ.

Material and methods

In freshly slaughtered pigs (EU - standard: 90 kg, sex unknown) the carotids with surrounding tissue were harvested en bloc. Two groups (A and B) of 10 specimens each were formed. The diameters of the preparations were determined by a caliper. In the first group A, vessel with perivascular soft tissue in situ, with a total diameter of approximately 1 cm, was prepared (mean preparation diameter: 10.57 mm \pm 0.16, range: 0.5). The preparations were checked for integrity. In the second group B the carotids were skeletonized, i.e. all perivascular tissue was removed (mean vessel diameter: 5.21 mm \pm 0.13, range: 0.4). Again, all specimens were checked for integrity, and altered specimens were discarded. All preparations were wrapped in a moist compress and immediately transported to the laboratory.

In the research laboratory, each preparation was fixed on a plastic plate with two needles. Each plate was fixed vertically in a holding device. Different coloring of the needle head allowed the position of the specimen to be clearly identified as ``upper'' and ``lower'' sides.

A sealing instrument marSeal5 plus Maryland (KLS Martin, Gebrüder Martin GmbH & Co. KG, Tuttlingen) was clamped horizontally in a holding device. The opened jaws were passed over- and underneath the vessel. A maXium® generator (KLS Martin, Gebrüder Martin GmbH & Co. KG, Tuttlingen) was connected to the sealing instrument. A thermal camera (Optris PI640, Berlin, Germany) was adjusted perpendicular to this set-up in order to continuously record temperature changes of the specimen [23–27]. The distance to the experimental setup was a constant 30 cm. Ambient temperature was kept at constant at 24 °C. (Fig. 1).

After closing the instrument jaws, the sealing process was started. Sealing was automatically completed and indicated by an acoustic signal. The jaws were opened, the specimen including the plastic plate was released from the fixation clamps and transferred to a container with formalin. Histological sections were prepared in the Pathological Institute of the University Hospital of Marburg. The vessels were sectioned longitudinally and hematoxylin - eosin (HE) staining was performed. All sections were digitized and examined under a microscope at appropriate magnification. Measurement of the extent of the necrosis zones on the digitized histological section was performed by an experienced pathologist. (Fig. 2).

Temperatures recorded via the thermal camera were evaluated using numerical mathematics software Scilab regarding the maximum temperature values reached at a distance from the instrument branches jaws and displayed graphically. (Fig. 3).

The RILATE score – previously described - was determined for both

groups [28]. It represents in percent of the extent of the necrotic zone in relation to the potential area of necrosis with measured temperatures >50 °C. Due to the small number of cases results of groups A and B were analyzed for significant differences by a nonparametric Wilcoxon–Mann–Whitney test. Significance was set at p < 0.05.

Results

 $\underline{\mbox{Table 1}}$ gives a comparative overview of the individual parameters of groups A and B.

1. total duration of the sealing process (in seconds):

In group A, the total sealing process took 3.7 ± 0.37 s, while in group B it was completed after 3.41 ± 0.32 s. Comparing both groups, the sealing process lasted significantly [p=0.009, (**)] longer in group A than in group B.

2. $\underline{\text{maximum temperature reached (in °C)}}$ at the center of the instrument jaws:

In group A, the maximum temperature reached during the sealing process in this position was 71.37 ± 3.9 °C. In group B, the maximum temperature reached in the middle of the sector was 91.43 ± 7.4 °C. Thus, comparing both groups, there was a significant difference [p < 0.001, (***)], as the temperatures in group B were significantly higher.

3. duration (in seconds) of temperatures≥50 °C - upper side of jaws:

In the upper side of jaws area of group A, critical temperatures above 50 °C lasted for 14.77 ± 2.5 s, while 17.45 ± 3.2 s were recorded for group B. There was a significant difference [p=0.04, (*)] between groups.

4. duration (in seconds) of temperature $\geq\!50~^{\circ}\text{C}$ - lower side of jaws:

Above 50 °C in the lower side of jaws area of 15.2 \pm 3.2 s was determined for group A and 19.28 \pm 4.1 s for group B. Both groups differ significantly [p=0.028, (*)] from each other.

5. extension (in mm) of the critical zone above 50 °C - upper side of jaws:

Group A had a mean extension of the zone above 50 °C of 1.2 ± 0.34 mm. In group B 2.07 ± 0.52 mm was calculated. Comparison of both groups showed a highly significant difference in favor of group B [p=0.004, (***)].

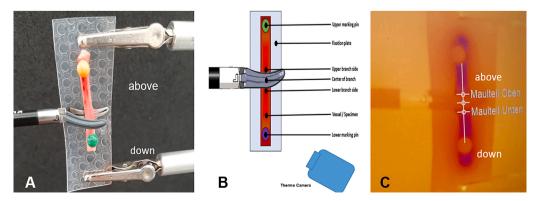


Fig. 1. Overview of the experimental setup (A): specimen mounted on a plastic plate, which is grasped between the jaws of a sealing instrument. (B): Drawing of the experimental setup (C): Temperature measurement by a thermocamera.

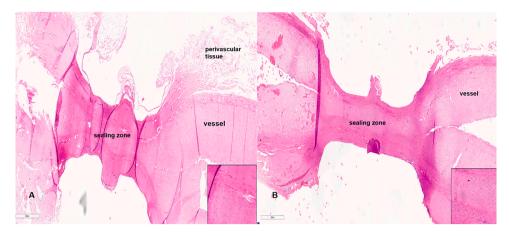


Fig. 2. Histology (A): Skeletonized vessel after sealing (B): Sealed vessel with perivascular tissue.

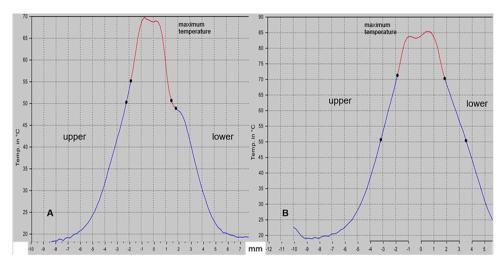


Fig. 3. Example for group A and B: graph of the highest temperatures reached in the area of the upper and lower sides of jaws.

6. extension (in mm) of the necrosis zone above 50 $^{\circ}$ C - upper side of jaws:

The extent of the necrosis zone on the histological specimen in group A was measured as 0.18 ± 0.07 mm. Group B amounted to 0.437 ± 0.11 mm. Thus, the extent of the necrosis zone in group B was significantly larger [p < 0.001, (***)] compared to group A.

7. RILATE - score - upper side of jaws:

A RILATE - score of 14.9 ± 1.69 was calculated for group A in the upper side of jaws area. The RILATE - score in the area of the upper side of jaws of group B is 21.07 ± 2.54 . In group comparison a significantly increased RILATE - score [p < 0.0001, (***)] of group B to A results.

8. extension (in mm) critical zone above 50 $^{\circ}\text{C}$ - lower side of jaws:

The extent of the critical zone above 50 $^{\circ}$ C in group A in the lower side of jaws was 0.409 \pm 0.21 mm. In group B, it was determined to be 1.443 \pm 0.44 mm in the same area. There is a highly significant difference [p < 0.0001, (***)] of groups.

9. extension (in mm) necrosis zone above 50 $^{\circ}\text{C}$ - lower side of jaws:

On the histological specimen, the extent of the necrosis zone in the lower side of jaws in group A was measured to be 0.084 \pm 0.04 mm. In

group B, the extension of the necrosis zone in the lower side of jaws was 0.4 \pm 0.09 mm. Thus, the extent of necrosis zone in group B was significantly [p < 0.0001, (****)] larger as compared to group A.

10. RILATE -Score: lower side of jaws:

The calculated RILATE -Score for group A in the lower side of jaws range was 20.4 ± 2.63 . For group B in the same area, there is a RILATE -score of 28.71 ± 5.1 . Thus, the RILATE -score in the lower side of jaws area of group B is highly significant [p < 0.0001, (****)] larger compared to group A.

Table 2 presents an overview of averaged data and the calculated statistical significances in group comparison.

Discussion

Bipolar sealing is used in many areas of surgery for occlusion and transection of vessels [1,3,4,9,29,30]. During each sealing procedure, heat escapes between the instrument jaws [31]. This process is referred to as lateral heat propagation [17]. Clinically, this is relevant because it can damage surrounding structures. In most experimental work, lateral thermal expansion is studied in isolated vessels [16,28]. This does not correspond to surgical practice, since often vessels to be sealed are not completely dissected, but rather surrounding tissue is included. In the present work, we investigated whether perivascular tissue has an influence on lateral thermal expansion during bipolar sealing. For better

Table 1 Listing of measured values for critical zone above 50 $^{\circ}$ C, necrosis zone, and RILATE score for groups A and B (n=10 per group).

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n	Critical zone > 50 °C upper jaw side (mm)	Zone of necrosis upper side of jaws (mm)	RILATE- score upper side of jaws (%)	Critical zone > 50 °C lower side of jaws (mm)	Zone of necrosis lower side of jaws (mm)	RILATE -score lower side of jaws (%)
grou	p A (perivaso	cular tissue +	carotid):			
1	1.37	0.22	16.1	0.37	0.07	18.9
2	1.1	0.14	12.72	0.1	0.02	20
3	1.3	0.19	14.61	0.35	0.06	17.1
4	0.56	0.08	14.30	0.19	0.04	21.05
5	0.74	0.1	13.51	0.39	0.09	23.07
6	1.67	0.31	18.56	0.8	0.18	22.5
7	1.48	0.2	13.51	0.74	0.14	18.9
8	1.19	0.18	15.12	0.41	0.09	21.9
9	1.11	0.16	14.4	0.37	0.06	16.21
10	1.48	0.24	16.21	0.37	0.09	24.32
2nd	group B (ske	letonized card	otid):			
1	2.22	0.39	17.56	1.85	0.48	25.94
2	2.3	0.45	19.53	1.67	0.43	25.70
3	2.67	0.52	19.47	1.3	0.34	26.10
4	2.92	0.68	23.38	1.85	0.48	25.90
5	1.3	0.23	17.69	1.85	0.52	28.10
6	2.48	0.51	20.56	0.92	0.31	33.7
7	1.92	0.42	21.87	1.85	0.39	21,08
8	1.48	0.34	22,97	0.92	0.36	39,13
9	1.74	0.44	25.28	1.48	0.47	31.76
10	1.74	0.39	22.41	0.74	0.22	29.72

Table 2 Overview of data analysis groups A and B compared (n = 10 per group).

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Parameter	Group A	Group B	p - value
mean diameter of preparation (mm)	10.57 \pm	5.21 \pm	< 0.0001
	0.16	0.12	(****)
mean sealing duration (s)	3.708 \pm	3.415 \pm	0.009 (**)
	0.37	0.37	
maximal temperature (°C) central	71.37 ± 3.9	91.43 \pm	< 0.0001
between jaws		742	(****)
duration(s) > 50 °C upper side of	14.77 \pm	17.45 \pm	0.04 (*)
jaws	2.515	3.2	
duration(s) > 50 °C lower side of	15.2 ± 3.23	19.28 \pm	0.028 (*)
jaws		4.06	
critical zone $>$ 50 $^{\circ}$ C upper side of	1.2 ± 0.34	$2.07~\pm$	0.0004 (***)
jaws (mm)		0.52	
zone of necrosis upper side of jaws	0.18 \pm	0.43 \pm	< 0.0001
(mm)	0.067	0.11	(****)
RILATE - Score Upper side of jaws	14.90 \pm	21.07 \pm	< 0.0001
(%)	1.697	2.54	(****)
critical zone $>$ 50 $^{\circ}$ C lower side of	$0.409~\pm$	1.43 \pm	< 0.0001
jaws (mm)	0.21	0.44	(****)
zone of necrosis lower side of jaws	0.084 \pm	$\textbf{0.4} \pm \textbf{0.09}$	< 0.0001
(mm)	0.04		(****)
RILATE - Score Lower side of jaws	20.4 ± 2.63	28.71 \pm	< 0.0001
(%)		5.1	(****)

reproducibility, studies were performed on an ex vivo model of porcine carotids under standardized conditions. Group A with perivascular tissue around carotid arteries was contrasted with group B with skeletonized carotids. Significant differences were found between the two groups. Although the sealing duration was significantly longer in group A compared to group B, significantly lower maximum temperatures were reached in the midline of the branch jaw. The time period during which the tissue was heated above 50 °C by lateral heat propagation was significantly shorter in group A than in group 5. In general, there was significantly less lateral heat propagation overall in group A compared to group B. The RILATE score of group A was significantly lower in both

the upper and lower sides of jaws compared to group B.

These results can be explained by the fact that conductivity of the vessel wall is probably higher than the conductivity of the perivascular tissue. Therefore, the current and as a result also the heat in group A flows in a more directed manner between the jaws. In group B, the conductivity is lower, so that the current partially flows beyond the edges to the opposite electrode. Moreover, as the carotid artery is completely encircled by perivascular connective tissue, after closing, the instrument jaws have exclusive contact with the perivascular tissue. Since the specific heat capacity of the perivascular tissue is also greater than that of the vessel, there is a faster rise in temperature. According to its technical algorithm the sealing process is stopped after a defined multiple of the initial impedance, ending the sealing process faster in group A. Overall, less thermal energy is applied to the tissue in group A, so that a lower maximum overall temperature result. In consequence, lateral thermal expansion is significantly lower in group A as compared to group B. The perivascular tissue acts in a figurative sense as a thermal insulator and therefore has a positive effect on the overall reduction of lateral thermal expansion.

Histological evidence demonstrated that the necrosis zones of group A were significantly smaller than those of group B indicating a reduced risk of necrosis. In our opinion, this positive effect is due to the primary difference in electrophysical properties of the two types of tissue.

Our investigations demonstrated unambiguous results reproducibly. Missing blood flow in the ex vivo set-up in our view plays a subordinate role. As the instrument jaws completely compress the grasped tissue, blood flow stops in this area. In addition, the considerable heat generated evaporates both fluid and blood in the tissue.

Technically speaking, in order to avoid incorrect temperature measurements, care must be taken to ensure that the thermal camera is aligned exactly perpendicular to the specimen. Vibration must be avoided at all costs, as it degrades the recording quality of the examinations.

In summary, it must be concluded from the experimental data collected that regarding a reduction of lateral thermal expansion.

However, it must be considered that peak temperature was measured to be distinctly lower between instrument jaws. This aspect may be of consequence regarding the sealing result.

In a further ex vivo study, we therefore plan to investigate whether leaving perivascular tissue in situ affects the overall outcome quality of vessel sealing.

Conclusion

Leaving perivascular tissue on the vessel to be surgically sealed reduces lateral heat propagation due to a thermal insulation effect. The risk of damage to surrounding structures is reduced. An effect on the sealing process is yet to be investigated.

Disclosure stare

The authors reported no proprietary or commercial interest in any product mentioned or concept discussed in this article.

Institutional review board statement

As the preparations were cadaveric, an animal welfare application was not needed.

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Informed consent statement

Not applicable.

CRediT authorship contribution statement

Andreas Kirschbaum: Data curation, Formal analysis, Writing – original draft, Writing – review & editing. Paula Sauer: Data curation, Formal analysis, Methodology. Anika Pehl: Formal analysis. Nikolas Mirow: Conceptualization, Methodology, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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