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V.A.C.™ Instillation: in vitro model. Part 1

V.A.C.™ Instillation: ein in vitro Model. Teil 1

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The reproducibility of a V.A.C.™ (Vacuum Assisted Closure) instillation system was investigated by means of an in vitro model. The relation between the volume of a delivered solution and its removal from the system was studied in foams of various size. The relationship of instillation time periods and the volume of delivered solution was determined.

Mittels eines in vitro Models wurde die Reproduzierbarkeit der V.A.C.™ (Vacuum Assisted Closure) instillation untersucht. Die Beziehung zwischen den Volumina der infundierten Flüssigkeiten und des Abflusses wurde in Schaumstoffen verschiedener Grösse untersucht. Das Verhältnis zwischen Instillationszeit und Volumen der infundierten Flüssigkeit wurde ermittelt.

Introduction

The vacuum assisted closure (V.A.C.™) became the standard technique in management of problematic wounds in the course of last ten years [1]. Its modification, the V.A.C.™ instillation, was reported few years ago [2,3]. The principle of the technique is a local application of drugs (e. g. antibiotic or antiseptic solutions) within the framework of V.A.C.™ in case of infected wounds. The system operates as follows: the V.A.C.™ therapy i. e. the phase of a negative pressure is periodically suspended and replaced by an instillation phase where the evacuated polyurethane foam situated in the wound is filled in part with a drug solution. After a time interval, the hold, where the foam serves as a drug-release system, the V.A.C.™ therapy is activated again and simultaneously the foam content is removed, together with the wound fluid, into a container. The process is repeated and a new portion of the drug solution is introduced. A prototype of an automatic valve system was reported which repeatedly opens and closes the supply tubing, affording a three hours V.A.C.™ therapy followed by a 30 minutes instillation which serves also as the hold phase [2]. An automatic device, regulating the three phases, the V.A.C.™ therapy, the instillation and the hold time, independently of each other, was presented recently [4].

This study reports a hand operated experimental V.A.C.™ instillation in vitro model and first results showing some properties of the system. We investigated the reproducibility of the system in general and the relation between the volume of a solution delivered into the system (inlet) and removed from it (outlet) using V.A.C.™ foams of various size. The dependence of the delivered fluid volume upon the instillation time interval was determined.

Material and Methods

1. Determination of free outflow from iv bottle and iv bag

An iv bottle (Ecotainer® plus 1000 ml, B. Braun Melsungen AG, Melsungen, Germany) filed with a Ringerlactate solution or an iv bag (Ringerlactate B. Braun, B. Braun Medical AG, Emmenbrücke, Switzerland) were connected with an infusion set (CODAN, Medizinische Geräte GmbH & Co KG, Lensahn, Germany), the fluid in the drip chamber set at the mark, the vent hole opened and the bottle / bag hanged on a iv pole. The meniscus in the drip chamber was 6 cm above the outlet tubing-end opening. The fluid was allowed to fill the entire tubing. The roller clamp (thumb-wheel) was completely opened for a desired time interval, the outflow collected in a calibrated vessel and the outflow volume estimated. The bottle and the bag, when refilled or changed, were equipped with a new infusion set and the former with a new screw cap.

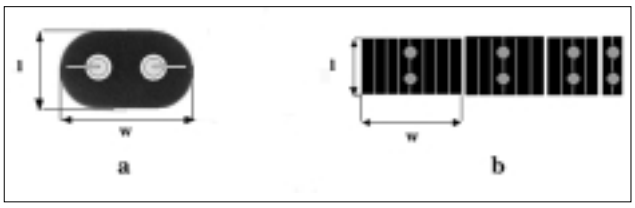


Fig 1. Polyurethane foams *(Kinetic Concepts Inc., San Antonio, TX, U.S.A.) l = length, w = width, h = height, V = volume,*
Fig 1a. *oval with sketched TRAC™ PADs position ($V = \pi*(w^2/4)*h + (l - w)*w*h$). Small: l = 9.5 cm, w = 7.5 cm, h = 3.0 cm, V = 178 cm³, weight 0.0262 g/cm³; Medium: l = 18.0 cm, w = 12.4 cm, h = 3.3 cm, V = 570 cm³, weight 0.0250 g/cm³; Large: l = 25.0 cm, w = 14.5 cm, h = 3.3 cm; V = 952 cm³, weight 0.0272 g/cm³.*
Fig 1b. *rectangular with 20 pre-incised strips and sketched TRAC™ PADs position. Extra Large: l = 59.0 cm, w = 29.0 cm, h = 1.8 cm (strip: l = 29.0 cm, w = 2.95 cm, h = 1.8 cm). Cut out foam sizes: 2 strips: l = 14.5 cm, w = 5.9 cm, h = 1.8 cm, V = 154 cm³; 4 strips: l = 14.5 cm, w = 11.8 cm, h = 1.8 cm, V = 308 cm³; 6 strips: l = 14.5 cm, w = 17.7 cm, h = 1.8 cm, V = 462 cm³; 8 strips: l = 14.5 cm, w = 23.6 cm, h = 1.8 cm, V = 616 cm³, weight 0.0270 g/cm³.*

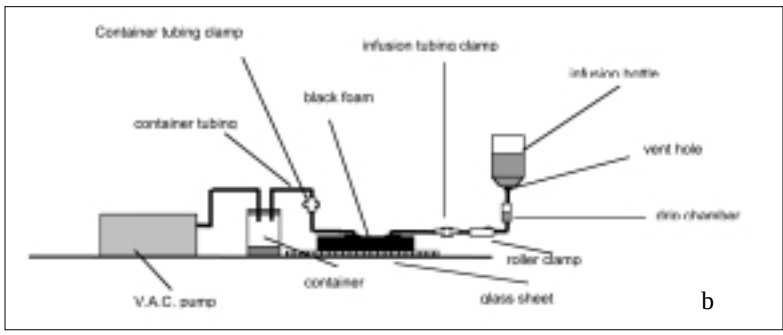


Fig 2. V.A.C.™ Instillation in vitro model
Fig 2a. General view
Fig 2b. Schematic illustration

2. VAC Instillation in vitro model

2.1 Description

A black polyurethane foam (Kinetic Concepts Inc., San Antonio, TX, U.S.A.)(Fig 1a,b) was positioned on a glass sheet and a transparent adhesive drape (Kinetic Concepts Inc., San Antonio, TX, U.S.A.) trimmed to cover the foam and about 4 cm of its surrounding to form an airtight seal. Two holes of 2 cm diameter were cut in the drape with a center-to-center spacing according to the foam size (Tab 1). Two T.R.A.C.™ PADs (Kinetic Concepts Inc., San Antonio, TX, U.S.A.) were positioned over them. The rectangular foams of extra large size were cut along the strips (Fig 1b) and positioned with the strips downwards. The PADs were fixed parallel with the strips (Fig 1b). An iv bottle filled with Ringerlactate solution was connected with an infusion set (cf. above) and the fluid in the drip chamber set at the mark. A constant distance of 6 cm was set between the meniscus in the drip chamber and the glass sheet surface. The PAD tubings were connected with the infusion set and with the container and the latter with a vacuum pump (Model 30015B, Kinetic Concepts Inc., San Antonio, TX, U.S.A)(Fig 2a). The pump was set at a constant negative pressure of 125 mm Hg.

2.2 Adjustment of the system

A functional scheme of the model is shown in Fig 2b. Container and infusion set clamps and the roller clamp were closed, the vent hole opened. The vacuum pump was started and the container clamp was opened for about one minute. The foam collapsed, the container clamp was closed and the system was left in this state for about 10 minutes to make sure that the seal was tight. If necessary, a leak was sealed by a piece of adhesive drape. The infusion set clamp was then opened and the tubing was carefully filled with the fluid by the roller clamp till the mouth of the PAD. The infusion set clamp was closed and the roller clamp completely opened. Both the bottle and the container were weighed.

2.3 Instillation, fluid delivery and removal

The time intervals of particular phases were chosen according to the foam size and are summarized in Table 1. The container clamp was opened (evacuation), closed and the infusion set clamp opened (instillation phase). The foam was filled in part with the fluid (inlet), the infusion set clamp was closed and the container clamp opened (V.A.C.™ phase) to transfer the fluid (outlet)

Tab 1. Technical data of the in vitro model

Foam		Center-to center spacing	V.A.C.™ phase	Instillation		V.A.C.™ phase	
				1st inlet	Inlets	1st outlet	Outlets
		cm	sec	sec	sec	sec	sec
Small		4	30	45	30	30	30
Medium		6	30	90	60	30	30
Large		9	30	120	90	60	60
Extra large	2 strips	5	30	30	20	30	30
	4 strips	5	30	45	30	30	30
	6 strips	5	30	60	45	60	30
	8 strips	5	30	90	60	60	30

Tab 2. Free outflow from iv bottle and iv bag

	Outflow (ml / 1min)							
	iv bottle				iv bag			
Mean	67	67	68	64	83	85	80	85
SD	0.9	1.0	1.6	1.4	14.1	12.9	11.7	11.4
SEM	0.26	0.25	0.44	0.36	4.25	3.71	3.12	3.43
max	68	68	70	66	98	102	98	96
min	66	66	64	62	58	62	54	62

from the collapsing foam into the container. The container clamp was closed and both the bottle (inlet) and the container (outlet) weighed. The inlet and outlet weight difference was expressed in milliliters (ml) and the whole procedure repeated. In case that the bottle had to be refilled, a new infusion set and a new screw cup were used. When the experiment was finished, the foam was discarded. Each experiment was carried out always with a new foam and a new infusion set. In the course of the first outlet transfer to the container and about three following ones, bubbles appeared in the container tubing. The tubing was then completely filled with the fluid and a system resulted which we call "stabilized".

3. Variation of instillation time interval

The estimation was carried out with a system "stabilized" beforehand (foam medium size, Fig 1a). The bottle was weighed and first instillation was preceded by 30 seconds evacuation. After each instillation followed a 30 seconds V.A.C.™ phase (fluid transfer and weighing the bottle). Each particular instillation time interval included 10 determinations. The inlet volume was estimated by weighing the bottle and expressed in ml. The process was interrupted when a refilling of the bottle was necessary. The refilled bottle was equipped with a new screw cup and connected with a new infusion set.

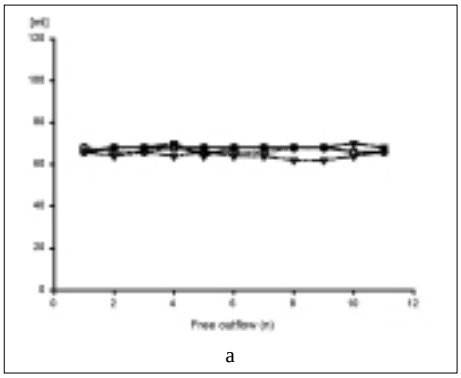
Results

1. Free outflow

The 10 minutes free outflow carried out with 20 iv bottles and infusion sets amounted 677 ± 19.8 ml (mean ± SD) or 677 ± 4.4 ml (mean ± SEM) and max / min volume of 710 / 630 ml. A series of 60 sec free outflows was carried out in an identical manner with four iv bottles and four iv bags and eleven outflows were determined with each supply vessel (Table 2). In contrast to the nearly regular and uniform outflows from the bottles, less satisfactory results were obtained with the bags (Fig 3).

2. Instillation

The initial instillation experiment was carried out with a foam of medium size (Fig 1a) (for time intervals of particular phases see Table 1). In this experiment and all other instillations reported further, the hold phase was left out i. e. the V.A.C.™ phase followed immediately after the instillation phase. As the significance of the hold phase is in its physiological function it was for our purposes irrelevant. The course of 10 subsequent instillations and V.A.C.™ phases is shown in detail in Fig 4. At the beginning, a considerable difference was observed between the first inlet and the corresponding outlet. The disparity then diminished and became finally negligible in instillations that followed. A considerable volume of the fluid, equal to the difference of inlet and corresponding outlet, remains in the foam (residual volume) and mixes with inlets that follow. A series of instillation measurements was carried out in the above manner with 33 foams. In order not to get the first outlet too small, the first inlet was chosen always larger than the following ones. As the volume of the first inlet and outlet differed substantially from the following ones, the statistical data of the first instillation were treated separately. The difference of total volume of all inlets and outlets gave the total residual volume. All measurements were carried out without refilling the iv bottle. As the sum of the inlet volumina in particular experiments slightly varied, the number of inlets alternated, between nine (11 experiments) and ten (22 experiments). The data obtained are summarized in Table 3.



a

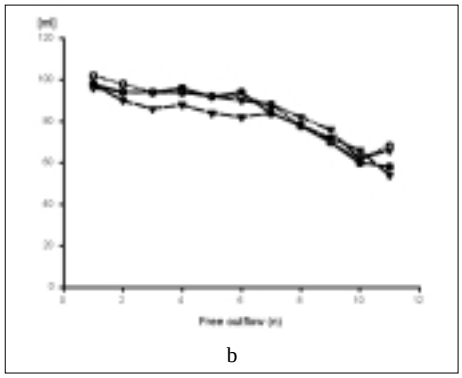


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Fig 3. Free outflow (60 sec) from bottles and bags
Fig 3a. 4 iv Bottles
Fig 3b. 4 iv Bags

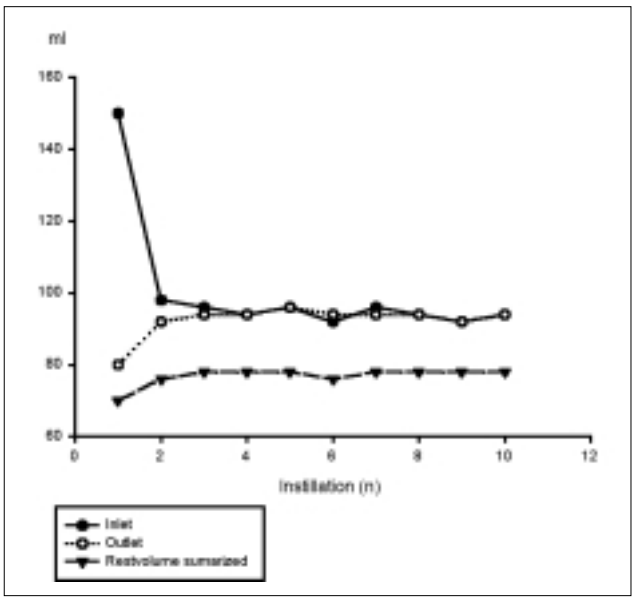

Fig 4. Fluid delivery (inlet) and removal (outlet)

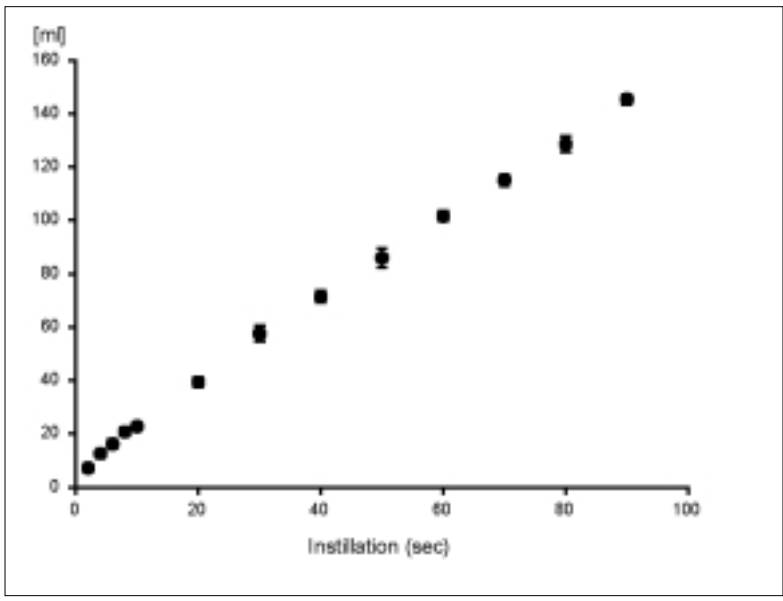

Fig 5. Instillation time and volume (mean + SD)

Identical instillation measurements were performed with a limited number of foams of various sizes (Fig 1). Eleven instillations (1st inlet and 10 following inlets) were carried out with each foam of a series of four foams of identical size (3 foams in one case). If necessary, the iv bottle was refilled. The results are summarized in Table 3.

3. Relation of instillation time and fluid volume

A "stabilised" system (see above) was applied for estimation of inlet volumina taken in time intervals from 2 seconds up to 90 seconds (Fig 5).

Discussion

However the V.A.C.™ instillation system has been used successfully in the clinical practice, the reproducibility or the scope of inlet and outlet volume and their relation have remained to a large extent unknown. By means of an in vitro model we tried to answer some of these questions. We are aware that the model gives a only limited feature of the reality. Nevertheless we hope that the results obtained give some insight how the V.A.C.™ instillation system functions.

In the reported V.A.C.™ instillation in vitro model, the instillation time interval and thus the delivered fluid volume (inlet) is regulated by opening and closing the instillation clamp (Fig. 2b), as is also the case of the automatic device [4], and not by the roller clamp which is completely open during the whole procedure to get reproducible thumb wheel position. This arrangement differs from the routine clinical practice of infusions, where the roller clamp controls the timing of a rather slow and drop-by-drop outflow. It was a priori not certain if the above system affords reproducible and comparable results when a new infusion set is used each time. The free outflow experiments were carried out to answer this question. The result of a 10 min free outflow from iv bottle was more or less satisfactory regarding the large volume and the fact that the inlets generally are taken in shorter time periods, up to two minutes in maximum. The corresponding experiments carried out with 60 sec free outflows using four iv bottles and four iv bags gave interesting results. The iv bottle from hard plastic material with an open vent hole and completely open roller clamp afforded quite regular and reproducible outflows (Tab 2 and Fig 3). The elastic iv bag which compensates the loss of its content by stepwise shrinking together (and only towards the end the vent hole starts to work), yields by a drop-by-drop arrangement controlled by the roller clamp entirely regular volumina. Under the above conditions however, the bag has a tendency to slow down successively the flow rate (Table 2 and Fig 3). This fact should be considered when an iv bag is used as a supply vessel of a V.A.C.™ instillation system.

In the instillation system published [2], the instillation and the hold phase formed a unit. A 3 hours V.A.C.™ therapy phase alternated with a 30 minutes instillation in the course of which the evacuated foam was allowed to fill with a not nearly specified volume of a drug solution. When the V.A.C.™ therapy is started again, the content of the foam is transferred into a container. The commercial automatic device [4] on the other hand, separates the instillation and the hold phase. The instillation volume (inlet) there is defined merely by the time interval (2 sec to 2 min) of a solution delivery, however without specification of the resulting volume. In the measurements reported in this study and carried out in the in vitro instillation model evaluating quantitatively the volume of inlets and outlets, the hold phase was omitted.

The question of first priority was the reproducibility of the system. To eliminate some factors, we used always the same distance of the drip chamber meniscus from the glass sheet, a constant negative pressure and a constant instillation time period. The total 33 measurements carried out with medium size foam showed that the disposable material (foam, iv bottle, infusion set), a new one for each experiment, afforded comparable results (Table 3). The inlet volume shown in Table 3 is substantially larger than the

Tab 3. Instillations: Fluid delivery and removal

Foam		Number of deteminations	Instillation	Fluid volume (ml)			Residual volume	
				Mean	SD	SEM	% foam volume	ml/cm³
Medium		33	1st inlet (90 sec)	154	6.2	1.08		
		286	Inlets (60 sec)	96	4.7	0.28		
		33	1st outlet	87	8.3	1.44		
		286	Outlets	95	4.4	0.26		
		33	Residual volume	78	4.2	0.73	13.7	0.14
Small		4	1st inlet (45 sec)	72	1.4	0.71		
		40	Inlets (30 sec)	42	3.1	0.49		
		4	1st outlet	48	3.3	1.64		
		40	Outlets	42	2.9	0.46		
		4	Residual volume	26	3.5	1.73	14.6	0.15
Large		3	1st inlet (120 sec)	233	9.0	5.21		
		30	Inlets (90 sec)	152	8.3	1.52		
		3	1st outlet	95	11.4	6.57		
		30	Outlets	152	8.7	1.59		
		3	Residual volume	135	4.6	2.67	14.2	0.14
Extra large	2 strips	4	1st inlet (30 sec)	54	3.0	1.48		
		40	Inlets (20sec)	32	1.6	0.25		
		4	1st outlet	29	3.3	1.64		
		40	Outlets	32	1.7	0.26		
		4	Residual volume	30	2.2	1.09	19.5	0.2
	4 strips	4	1st inlet (45 sec)	82	5.1	2.55		
		40	Inlets (30 sec)	47	4.6	0.73		
		4	1st outlet	33	5.9	3.96		
		40	Outlets	47	4.4	0.69		
		4	Residual volume	49	3.3	1.66	15.9	0.16
	6 strips	4	1st inlet (60 sec)	115	3.3	1.66		
		40	Inlets (45 sec)	73	5.6	0.88		
		4	1st outlet	51	3.3	1.66		
		40	Outlets	72	4.6	0.73		
		4	Residual volume	73	2.2	1.12	15.8	0.16
	8 strips	4	1st inlet (90 sec)	169	0.9	0.43		
		40	Inlets (60 sec)	104	7.4	1.17		
		4	1st outlet	107	1.7	0.83		
		40	Outlets	101	8.0	1.27		
		4	Residual volume	97	4.6	2.28	15.7	0.16

free outflow from the iv bottles (Tab 2), both taken during the same time interval of 60 seconds. This obviously is due to an additional factor, the suction caused by the foam elasticity, operating together with the fluid gradient. The fluid which filled the initially empty container tubing (about 8 ml) was neglected and not added to the first outlet volume because of a presence of numerous bubbles that did not allow an exact estimation of this small volume.

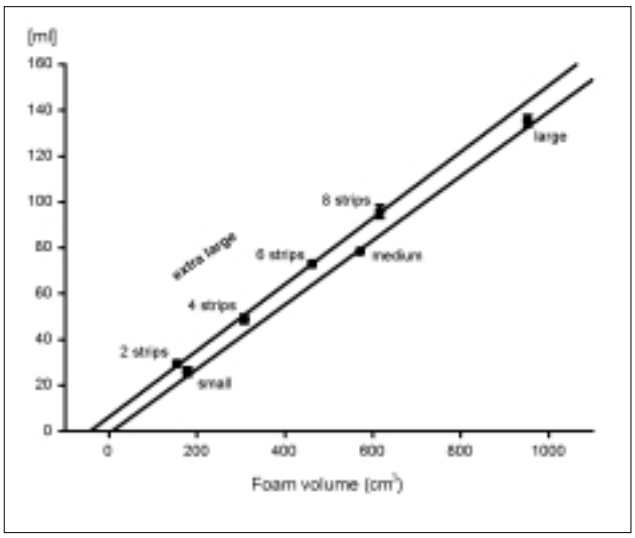

Fig 6. Foam size and residual volume (mean + SEM)

An important result of the inlet / outlet determination was the substantially smaller first outlet volume in comparison with the first inlet (Fig 4 and Table 3). A considerable part of the first inlet, specified here as the residual volume, was retained back in the foam replacing the air which remained there after the V.A.C.™ phase. Consequently, bubbles appeared in the container tubing together with the removed fluid. The same happened again, however in a smaller scale, in two or three outlets which followed. Finally the canister tubing was filled with the fluid and subsequent outlet volumina were comparable with the corresponding inlets (Fig 4 and Table 3).

In view of the existence of the residual volume, the prevailing opinion about the fluid exchange in the foam in the course of successive instillations should be reconsidered. The drug solution in the foam cannot be completely removed and substituted by a fresh solution in a single inlet / outlet step [3]. In addition, the foam is in reality open below and on the sides towards the wound surface and consequently after each V.A.C.™ phase the residual volume and the new solution delivery mix with a difficult to define amount of the wound secret. It seems that the fluid exchange is a rather complicated multi-step process which depends also of the behavior of the fluid in the foam. Part 2 of this study deals with some of these questions.

Out of foams of medium size, instillation experiments were performed with a limited number of diverse foam sizes as well (Tab 3). We were interested, in this context, in dependence of the residual volume on the size of the foams. A rather surprising result is shown in Fig 6. The oval foams (small, medium, large, cf. Fig 1a) showed a linear course of the residual volume with 14.2 % of the foam volume in an average (Tab 3). The regression line of the residual volume of the rectangular foams (Fig 1b) proceeded parallel with the above values but about 2.5 % higher. The rectangular foams consist of parallel pre-incised strips and differ thus from the homogeneous oval foams. We encountered a problem with the positioning of the TRAC™ PADs over these foams. Regarding Fig 1b, it would have been logical to position the PADs in the two greatest foams across the strips with larger centre-to-centre distance. This however, would have left the two remaining smaller sizes with PADs placed in parallel position to the strips. We preferred therefore to fix the PADs uniformly parallel to the strips in all foams (Fig 1b). Whether the PADs position or some other cause influences the difference in the residual volume remains unanswered at present.

At last, the relationship between the instillation time interval (range 2 to 90 seconds) and the corresponding inlet volume was investigated. The determinations were performed under the conditions reported above using a "stabilised" system and a foam of medium size. As expected, the dependence of the inlet volumina on the time interval was almost linear (Fig. 5).

In conclusion, disposable material (foams, iv bottles, infusion sets) affords reproducible results under the condition that certain factors of the system remain constant. The hitherto unknown relation between instillation time intervals and corresponding volumina was estimated. The inlet / outlet relation was investigated on commercially available foams of various size and form. A part of the delivered solution remained in the foam after the V.A.C.™ phase (residual volume) and its proportion to foam volume was determined. The residual volume mixes with following instillations and in reality also with the wound fluid. Consequently the resulting mixing process is not a simple replacement of two fluids but a rather complex proceeding.

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