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Protocols to compare infusion distribution of wound catheters

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ABSTRACT

Multi-holed wound catheters are increasingly used in clinical practice to administer analgesic/anaesthetic locally to the painful region. The distribution of flow infused during controlled (continuous or intermittent) administration of medication is believed to be an important issue for successful pain relief. Nevertheless, this information is not available from the literature. In this paper, we propose protocols to screen the performance of wound infusion catheters in the laboratory environment. Four wound infusion systems (PAINfusor by Baxter, OnQ Pump with Soaker catheter by I-Flow, PolyFuser Polymedic by Temena and Infiltralong by Pajunk) have been tested. Test results demonstrate that the distribution of the infused flow is different for the four catheters and closely connected to the catheter design (i.e. hole size and position, lumen diameter). Catheters characterized by small size holes (e.g. Baxter, Pajunk) distribute the flow more homogeneously than catheters characterized by large size holes (e.g. I-Flow, Temena). The distribution of infused flow does not change significantly during continuous or intermittent infusion.

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1. Introduction

Wound infusion systems are increasingly used in clinical practice for pain management and regional postoperative analgesia [1,2]. Wound infusion kits are composed of (i) the catheter, a closed-end, thin hollow tube with side holes in the distal part (infusing region) and (ii) the infusing device (either an elastomeric or an electronic pump). The catheter is placed in the wound at the end of surgery before closure and local analgesic/anaesthetic is administered continuously in the wound area. Some days after, once the treatment is completed, the catheter is removed.

Infusion systems differ in configuration (type of infusion pump, catheter design) and price. Currently, no objective method is available to evaluate their performance and to support clinical choices between the different systems. The objective of this work is to develop protocols and to screen the performance of four infusion systems in the laboratory environment, under controlled conditions.

The distribution of infused medication (infusion pattern) is believed to be an important issue for successful pain relief: catheters with multiple holes might provide a wider area of infusion and a larger spread of local anaesthetic into the wound. Even if there is still no clinical evidence in this sense [3], previous studies performed in vitro using multi-hole catheters (epidural

catheters with three holes) have shown that, even for very simple configurations, the infusion pattern may change significantly depending on the specific pressure waveform generated by the infusion device [4]; the infusion pattern may also change during continuous infusion at typical hospital conditions and during the infusion of manual boluses (i.e. patient controlled intermittent infusion) [5]. The relationship between the infusion pattern produced by the catheter during intermittent boluses or continuous infusion of local anaesthetic and pain relief is even more unclear [6], since the characteristics of the environment in which the catheter is infusing (the epidural space or a wound) may play a significant role.

From the patient/clinician view point, the therapy should deliver the prescribed quantity of local anaesthetic with the specific infusion pattern demanded by the painful region. This objective could be met by the clinician if the infusion pattern produced by the apparatus was known. As discussed by [3], it is not straightforward to associate the optimal type of catheter to the infusion pattern produced “in vivo” due to inherent difficulties of performing these experiments. In this work, we developed protocols to measure, “in vitro”, the distribution of flow delivered by a catheter either under continuous or bolus infusion. The laboratory measured flow rates and distribution may not match real “in vivo” infusion patterns, however, the objective characterization of catheters is necessary to set up systematic and repeatable clinical trials.

We developed the protocol and tested four wound infusion systems used in European hospitals (PAINfusor by Baxter, Infiltralong by Pajunk, On-Q PainBuster with Soaker catheter by I-Flow and PolyFuser by Temena). Results show that catheter design is very

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important to control the infusion pattern produced “in vitro” and might be important also to control infusion pattern produced “in vivo”.

2. Materials and methods

2.1. Basic principles of fluid mechanics

The catheter is a micro-scale flow distributor operating in the laminar regime. In this regime, the pressure drop, ΔP , to infuse the flow, Q , is given by a Hagen–Poiseuille type formula [7]:

$$\Delta P = P(0) - P_{out} = \mu(T) \cdot K \cdot Q$$

where $P(0)$ and P_{out} are the pressure upstream of the catheter and in the outside environment, $\mu(T)$ is the (temperature dependent) fluid viscosity and K is a constant which depends on the specific geometry of the system (internal diameter, thickness, hole diameter and hole spacing). The pressure, generated upstream of the catheter either by an elastomeric or a syringe pump, decreases along the catheter. The pressure drop, ΔP_i , between each point i , inside the catheter, P_i , and the outer environment, P_{out} , will fix the flow, q_i , delivered through each hole:

$$\Delta P_i = \mu(T) \cdot K' \cdot q_i$$

where K' is a function of hole geometry.

The infusion pattern generated by each catheter will be evaluated as the fraction of flow infused along the catheter, q_i/Q ($q_i, i = 1, N_H$, where N_H is the number of holes). The quantity $q_i/Q = f(K'/K)$ depends only on catheter geometry and can be evaluated independently of many test conditions (i.e. fluid temperature, type of infusion device, overall flow delivered). The values of the geometrical constants, K and K' determine the precise variation of pressure along the catheter and the specific infusion pattern that will be generated along the length of the catheter’s infusing region. The larger the variation of pressure inside the catheter between the proximal (inlet section) and distal ends (closed tip), the larger the variation in the amount of flow infused by different holes will be [8].

2.2. Wound infusion systems

Wound infusion systems selected for testing were chosen from commercial brands used in European hospitals. From the clinical

view point, there are many factors which make one wound infusion system different from another. Clinicians choose the infusion system to use based on the length of the catheter infusing region (chosen according to the specific infusion task to be performed), the type of infusion device (portable, like elastomeric pumps, or stationary, like a syringe pump), the flow rate of medication to be delivered and the catheter strength (i.e. the risk of breaking the catheter when pulling it out of the patient body). We chose to focus on a subset of wound infusion systems manufactured according to different design concepts (different type of infusion device, different catheter material and geometrical dimensions). As shown in Table 1, systems have infusing regions of similar length (12.5–15 cm), but while Baxter, I-Flow and Temena wound infusion catheters are sold with elastomeric pumps, Pajunk’s catheter is sold with no specific infusing device. Elastomeric pumps chosen for testing deliver similar flow rates (2–5 ml/h) at nominal conditions and a syringe pump (Flo-Gard Infusion pump, Baxter) delivering the same flow rate (5 ml/h) was chosen to perform the tests with Pajunk’s model.

From a fluid mechanic view point, catheter geometrical characteristics should be the most important parameter which control the infusion pattern. Geometrical details of catheters obtained from catalogue information and from the microscopic analysis of a few samples are shown in Fig. 1. The microscopic pictures of lumen sections (a)–(d) indicate that the ratio between the lumen diameter and outer diameter is 65% for Baxter, 50% for I-Flow, 53% for Temena and 71% for Pajunk. Fig. 1(e) and (f) shows the geometrical characteristics of infusing holes, such as outer diameters and spacings. Two of the systems (Baxter and Pajunk) are characterized by a large number of small, equally spaced infusing holes; the other two (Temena and I-Flow) use a smaller number of larger holes to deliver the flow. The variability in the hole size is larger for the larger holes, obtained by mechanical methods, than for the smaller holes, obtained by laser micro drilling. The system with the largest holes (I-Flow) is equipped with an internal porous membrane.

2.3. Testing protocols

2.3.1. Qualitative evaluation of infused flow distribution

Visualizations of infused flow distribution were made as sketched in Figs. 2(a) and 3(a). The catheter was submerged in a fixed position in a water tank and primed using a 5 ml syringe filled with distilled water. Colored water was infused during the tests

Table 1
 Main characteristics of wound infusion systems chosen for benchmark comparison: data of infusing device and geometrical characteristics of catheters.

Brand	Comparison among wound infusion systems			
	Baxter	I-Flow	Temena	Pajunk
Infusing device				
Recommended in kit	LV5	On-Q PainBuster	PolyFuser	Any pump
Used for test	LV5	On-Q PainBuster	PolyFuser	Baxter Flo-Gard
Type	Elastomeric	Elastomeric	Elastomeric	Syringe
Flow rate ^a [ml/s]	5	5	2	5
Catheter				
Nominal diameter, Dc [mm]	19G	20G	20G	19G
Measured diam. ^b [mm]	1.067	0.908	0.908	1.067
Measured diam. ^b [mm]	1.015 ± 0.025	1.094 ± 0.025	0.896 ± 0.002	0.985 ± 0.004
Lumen diam. ^b [mm]	0.635 ± 0.025	0.532 ± 0.003	0.4879 ± 0.011	0.0707 ± 0.010
Hole diam. ^b [μm]	34.9 ± 4.63	360.24 ± 35.11	282.56 ± 54.10	70.04 ± 7.79
Hole spacing ^b [mm]	3.653 ± 0.042	4.820 ± 0.088	4.203 ± 0.464	2.455 ± 0.029
N. holes	40	25	12	60
Infusing region [mm]	150	125	150 ^c	150
Flow section [mm ²]	0.317	0.223	0.181	0.393
Infusion area [mm ²]	0.038	2.548	0.752	0.231

^a At nominal conditions for elastomeric pumps.

^b Data not statistically significant: multiple measurements made based on one sample catheter from each catheter model.

^c 120 mm according to catalogue.

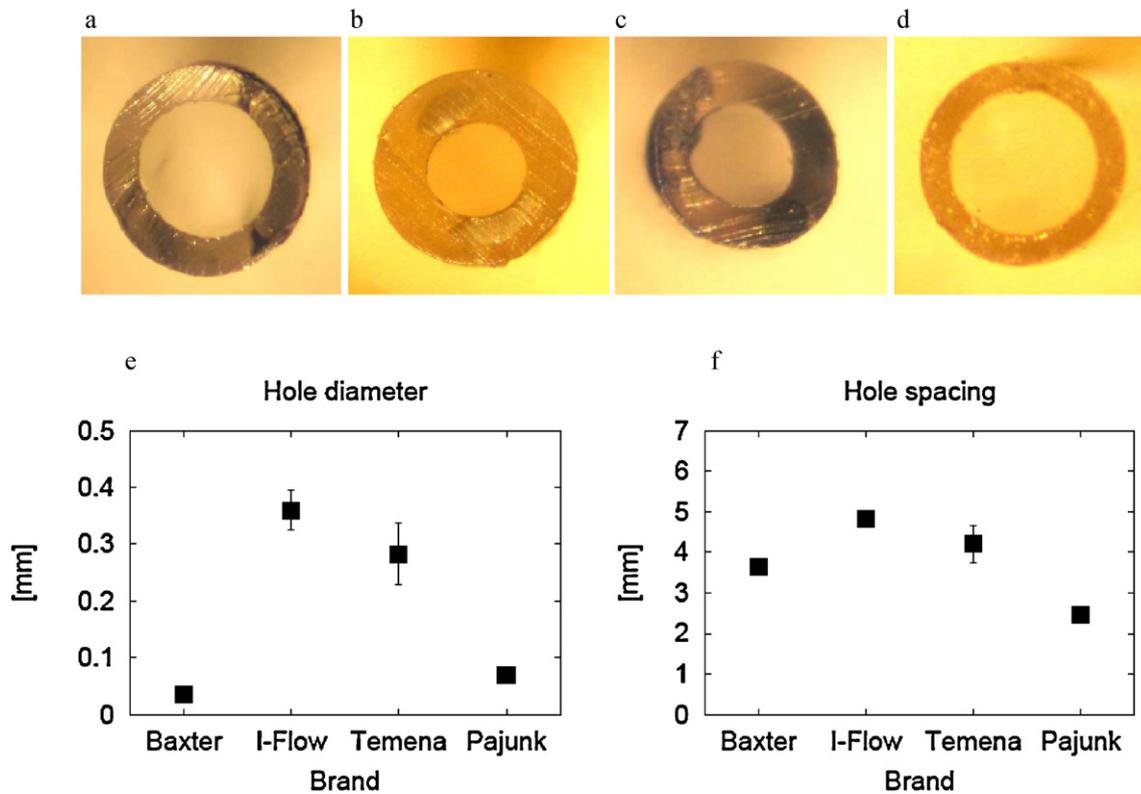


Fig. 1. Catheter geometrical characteristics: microscopic pictures of catheter lumen section ((a) Baxter PAINfusor, (b) I-Flow Soaker catheter, (c) Temena Polymedic catheter and (d) Pajunk Infiltralong); (e) mean value and standard deviation of hole diameters; (f) mean value and standard deviation of hole spacing.

performed in two conditions, the continuous or the bolus infusion mode, to visualize the flow delivered by each hole. For the continuous infusion mode, a small flow rate was infused (2–5 ml/h) for 30 min using for each catheter the pump recommended in kit (see Table 1). For the bolus infusion mode, a larger flow rate was infused (10 ml/min) for 30 s. The larger delivering pressure necessary to infuse the bolus was produced using a syringe pump (Chemix, Fusion 200), obtaining similar unsteady flow conditions for all the catheters. Due to the larger velocity of infusion, tracer dispersion may be significantly affected by convective effects. A transparent pipe (3 cm inner diameter) was used to mimic in a simple way the boundaries of the wound region and to account for the interaction between boundaries and infused flow which may enhance tracer dispersion around the catheter.

Tracer infusion was video recorded and checked at different times from the start of infusion. Each test was repeated three times to get rid of catheter variability and test conditions (see Supplementary material for details).

2.3.2. Quantitative evaluation of infused flow distribution

This test was performed only for the continuous infusion. The distribution of infused flow, q_i/Q , is difficult to obtain when the distance between the holes is as small as a few millimeters. Therefore, we split the infusing region into parts (bins) of fixed length (2 cm), each including a subset of holes, and evaluated the mass of fluid delivered (continuously) in a given time from each bin. A sketch of test set-up and relevant quantities measured during the tests is shown in Fig. 4(a).

Retention of air bubbles inside the catheter, which may alter the flow distribution, was avoided by carefully priming the catheter before the infusion test was started. Surface tension effects were minimized using a wet adsorbing medium as the outlet environment. The accuracy of the test was evaluated checking the balance

between the amount of flow delivered by the infusing device (RIM, reference infused mass) and the one collected by the bins (IM, infused mass). The mass infused by the catheter in 30 min was either measured as the variation in weight of the infusing device (RIM, reference infused mass) between the beginning and the end of the test or fixed using a syringe (volumetric) pump (NIM, nominal infused mass) (see [9,10]). The mass delivered through the holes of the catheter (IM, infused mass) was measured as the variation in weight of the wet medium between the beginning and the end of the test period (Δw_i , where i is the bin number). Evaporation from bins was minimized during the test using parafilm covers and estimated during each test by collecting data for one bin in which the catheter was not infusing ($E = \Delta w_9$). Infused mass data were corrected for evaporation ($\Delta w_{i,chk} = \Delta w_i - E$) and normalized ($\Delta w_{i,chk\%} = 100\Delta w_{i,chk}/IM$). A threshold value was fixed on evaporated mass to check the validity of the test. Each test was repeated at least five times on five different samples of the same catheter to calculate statistics based on at least 25 valid measurements for each catheter model (see Supplementary material for details).

3. Results

3.1. Qualitative evaluation of infused flow distribution during continuous infusion

Results of the qualitative tests are video recordings taken at fixed and significant steps during the 30 min experiment (see Supplementary material). Fig. 2(b)–(e) shows the distribution of infused flow for each infusion system twenty minutes after the start of infusion, at steady state conditions. The catheter tip is on the left and the flow is fed from the right; the shot is zoomed to capture only the catheter infusing region. The amount of flow delivered at the proximal and the distal ends is very similar for Baxter PAINfu-

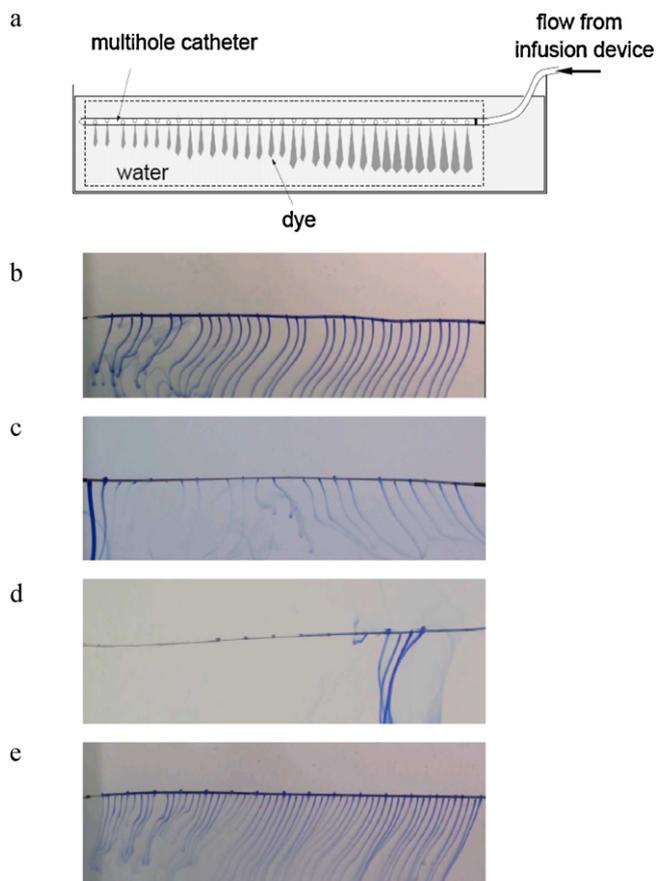


Fig. 2. Qualitative evaluation of infused flow distribution (continuous infusion): (a) test set up; distribution of infused flow at steady state infusion (after 20 min) for (b) PAINfusor catheter and Infusor by Baxter, (c) On-Q PainBuster with Soaker catheter by I-Flow, (d) Polymedic/PolyFuser infusion system by Temena and (e) InfiltraLong infusion system by Pajunk. Catheter tip is on the left. Flow is from right to left.

sor (Fig. 2(b)). Occlusion of some infusing holes can be occasionally observed. Video recordings show that a quite homogeneous flow distribution is established five minutes after the start of infusion and is consistently maintained over time.

Fig. 2(c) shows that the amount of flow delivered at the proximal and the distal ends of I-Flow On-Q PainBuster with Soaker catheter is quite different: a quite homogeneous flow distribution is found for the main portion of the catheter while a significantly larger amount of flow is infused at the tip.

Two-thirds of the infusing region are not significantly infusing for Temena Polymedic/PolyFuser (Fig. 2(d)): the flow is unevenly distributed in the infusion region, with the proximal part infusing most of the flow.

The amount of flow delivered at the proximal and the distal end is very similar for Pajunk InfiltraLong (Fig. 2(e)). Occlusion of some infusing holes can be occasionally observed. The flow is evenly distributed in the infusion region; video recordings show that a quite homogeneous infusion pattern is established five minutes after the start of infusion and is consistently maintained over time.

Video recordings show that the different qualitative behavior of catheters under steady state, continuous infusion depend on the geometrical characteristics of each system. For Pajunk and Baxter catheters, characterized by the larger flow sections, the pressure drop along the catheter is small and the fluid moves quickly toward the catheter tip before being infused through the side holes. The resistance to flow through the side holes is lower for Pajunk (infusion area larger than Baxter). For Temena and I-Flow catheters, characterized by smaller flow sections, the pressure drop along the

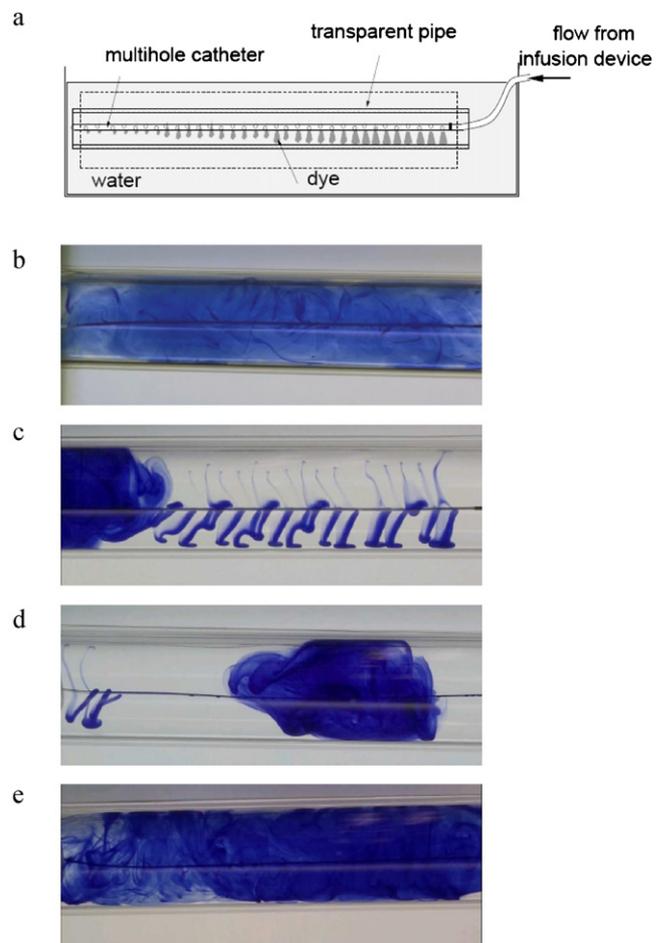


Fig. 3. Qualitative evaluation of infused flow distribution (bolus infusion): (a) test set up; distribution of infused flow at the end of bolus injection (after 30 s) for (b) PAINfusor catheter and Infusor by Baxter, (c) On-Q PainBuster with Soaker catheter by I-Flow, (d) Polymedic/PolyFuser infusion system by Temena and (e) InfiltraLong infusion system by Pajunk. Catheter tip is on the left. Flow is from right to left.

catheter is larger and the fluid moves slowly toward the tip of the catheter. The large hole size of Temena promotes the infusion of fluid through the proximal holes. The porous material of the hollow membrane inside I-Flow promotes the motion of fluid toward the tip of the catheter, delaying the lateral infusion and resulting in more flow through the distal holes than through the proximal holes.

3.2. Quantitative evaluation of flow distribution during continuous infusion

Fig. 4(b)–(e) shows the results of quantitative tests. Each histogram shows the mean value of percent flow infused per bin, $\Delta w_{i,chk} = 100 \Delta w_{i,chk} / IM$, whereas errorbars identify the mean \pm the standard deviation of percent flow calculated for each bin. More complete statistics are available as [supplementary material](#). After discussion with clinicians, we chose to consider a homogeneous distribution as the “reference” infusion pattern to benchmark infusion performance. The dashed line represents the percent flow expected by uniform infusion over eight bins, which cover the entire infusion region. A sketch of the catheter is superposed on the graph to identify the position of the tip. The last segment of the catheter is shorter than the bin, and the infusion from that part is therefore reduced.

For Baxter PAINfusor (Fig. 4(b)), the flow infused into bins from 1 to 7 is close to the uniform value, indicating a homogeneous infu-

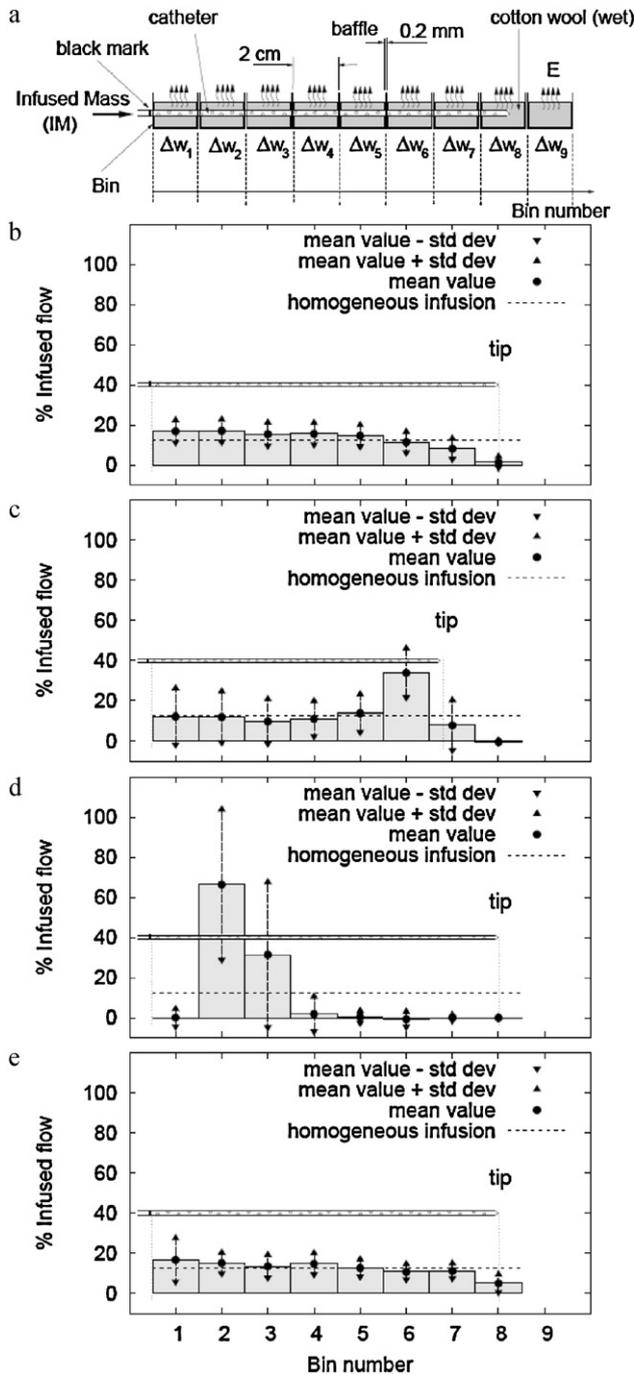


Fig. 4. Quantitative evaluation of infused flow distribution: (a) test set-up and measured quantities; mean value (histogram) and standard deviation (bars) of infused flow per Bin for (b) PAINfusor (Baxter), (c) On-Q PainBuster (I-Flow), (d) Polymeric/PolyFuser (Temena) and (e) InfiltralLong (Pajunk). Flow is from left to right. Statistics are based on 25 measurements.

sion over the catheter length. The value is smaller for bin 8, where the catheter is only infusing in part. The standard deviation from the mean is low for all the bins (about 5%). For I-Flow On-Q PainBuster with Soaker catheter (Fig. 4(c)) the flow infused in bin 6 is about 2.5 times larger than the uniform value, and is close to the uniform value for all the other bins from 1 to 7. As observed from qualitative tests, a larger amount of tracer is infused near to the catheter tip, whereas infusion is much lower for the main portion of the catheter. The standard deviation from the mean is about 12%.

For Temena Polymedic/PolyFuser (Fig. 4(d)) the flow infused in bins 2 and 3 is about 5 and 2.5 times larger (respectively) than the

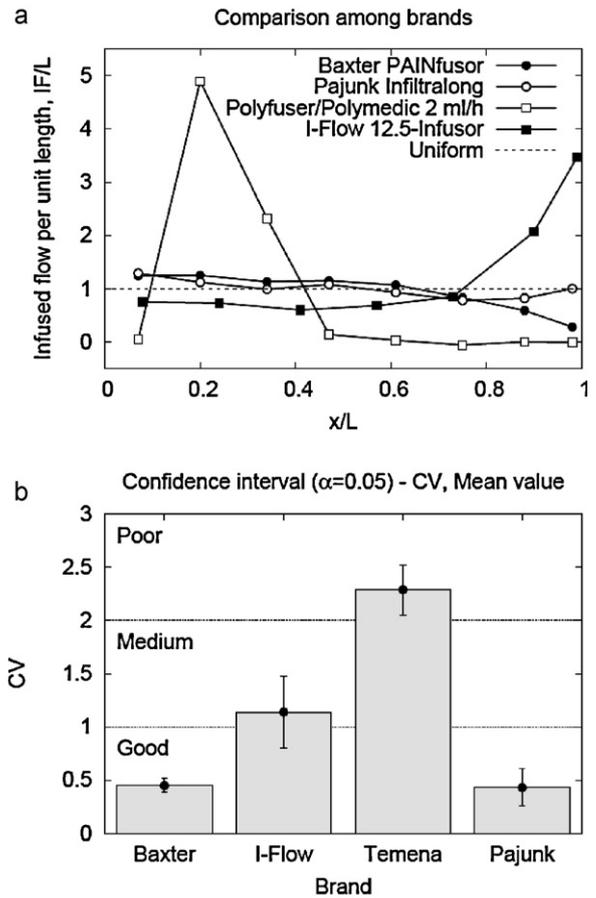


Fig. 5. Infused flow per unit length of catheter: (a) comparison among different infusion systems: uniform infusion (dashed) and flow distribution measured for Baxter PAINfusor (solid circle), I-Flow On-Q PainBuster (solid square), Temena Polymedic/PolyFuser (empty square) and Pajunk InfiltralLong (empty circle); (b) variability of infusion along catheter length. Statistics are based on 25 measurements.

uniform value, and is almost nil for all the other bins. As indicated by qualitative tests, a larger amount of tracer is infused at the proximal end, whereas infusion from the remaining portion of the catheter is negligible. The standard deviation from the mean is about 36% for bins 2 and 3. For Pajunk InfiltralLong (Fig. 4(e)) the flow infused in bins from 1 to 7 is close to the uniform value, indicating homogeneous infusion over the catheter length. The value is smaller for bin 8, where the catheter is infusing only in part. The standard deviation from the mean is reduced over the test set, with values about 14% in bin 1 and about 5% in all the other bins.

Percent flow infused per bin can be further processed to evaluate the distribution of flow infused per unit length of the catheter, q_{UL} , as:

$$q_{UL}(i) = \frac{\Delta w_{i,chk}}{\Delta x_{bin,i}}$$

where $\Delta x_{bin,i}$ is the length of catheter infusing inside bin i (≤ 2 cm, the bin length). This quantity can be made dimensionless using the flow infused per unit length under homogeneous infusion, q_{uni} as the reference value,

$$q^*(i) = \frac{q_{UL}(i)}{q_{uni}} = \frac{\Delta w_{i,chk}}{\Delta x_{bin,i}} \frac{L}{IM} = \frac{\Delta w_{i,chk\%}}{W(i)}$$

where $W(i)$ represents the fraction of catheter length infusing in bin i . The profile of q^* along the catheter gives a powerful representation of the homogeneity/dis-homogeneity of the flow infused

along the catheter length: the closer the profile to the unit line, the more homogeneous the infusion.

Fig. 5(a) shows the values of q^* calculated for each catheter as a function of x/L , the position of the bin inside the infusing region. The horizontal line ($q^* = 1$) represents the infusion pattern corresponding to uniform infusion. The infusion profiles measured for Baxter and Pajunk lie close to the unit line, whereas a large deviation is observed at the proximal end for Temena and at the distal end for I-Flow. We can define a synthetic measure of infusion dishomogeneity based on the variability of q^* , calculated as $CV = \sigma/\mu$ where μ and σ are the mean value and the standard deviation of q^* :

$$\mu = \sum_{i=1}^{N_{bin}} W(i) \cdot q^*(i) = 1 \quad \sigma = \sqrt{\sum_{i=1}^{N_{bin}} W(i) \cdot (q^*(i) - \mu)^2}$$

$N_{bin} = 8$ is the number of bins (and available measuring points). $CV = 0$ identifies uniform infusion and the value of CV can be used to benchmark different infusion systems: the smaller the CV , the more uniform the infused flow. Fig. 5(b) shows values of CV calculated for the systems tested. The histogram represents the mean value of CV calculated over the (at least 25 valid) tests. Error bar identifies the confidence interval ($\alpha = 5\%$). Horizontal lines at $CV = 1$ and $CV = 2$ identify arbitrarily chosen threshold values of CV for which the quality of infusion can be defined as good ($CV < 1$), medium ($1 < CV < 2$) and poor ($CV > 2$) with respect to the “reference” uniform infusion. According to the thresholds defined for CV , the uniformity of infusion measured for Baxter and Pajunk is good, is medium for I-Flow and is poor for Temena. Fisher tests on the variance of flow infused per bin, CV^2 (see [11]) indicate that the variability of infused flow (i) cannot be considered statistically different ($\alpha = 5\%$) for Baxter and Pajunk (p -level 45%); (ii) are to be considered statistically different ($\alpha = 5\%$) for Baxter and Temena (p -level 0.02%), for Baxter and I-Flow (p -level 1.27%), for Pajunk and I-Flow (p -level 0.1%), for Pajunk and Temena (p -level 0.00011%) and for I-Flow and Temena (p -level 4.29%).

3.3. Qualitative evaluation of flow distribution during boluses

The infusion pattern generated by each catheter during the bolus injection is described by video recordings are available as supplementary material. Fig. 3(b)–(e) shows snapshots taken from the videos at the end of the test (30 s). The shot is zoomed to capture only the catheter infusing region; the catheter tip is on the left and the flow is fed from the right.

As the infusion starts, colored dye moves along the Baxter PAINfusor catheter toward the distal hole, while thin, high momentum jets of fluid exit from the side holes. The jets interact with the transparent pipe wall, dispersing quickly. After 20 s (Fig. 3(b)), the spreading of tracer is quite homogeneous. The tracer is evenly distributed all around the catheter.

As the infusion starts, the tracer moves toward the tip of I-Flow Soaker catheter: a thick jet exits from the distal hole while thin jets of fluid exit from the other holes. Jets are thicker and slower than for the PAINfusor catheter because the size of side holes is about 10 times larger. After 20 s (Fig. 3(c)), the spreading of tracer is concentrated around the distal end of the catheter. The tracer injected seems to be unable to spread homogeneously all along the length of the infusing region.

As the infusion starts, thin jets of fluid exit from the side holes in the proximal portion of the Temena Polymedic catheter while the tracer has not reached the distal hole. After 10 s, the distal holes are also infusing. The momentum of proximal jets is large enough to interact with the confined environment, promoting the mixing of dye which fills the proximal portion of the transparent cavity

(Fig. 3(d)). Jets infused from the catheter tip are weaker and slower. Also, the tracer injected seems to be unable to spread around the catheter all along the infusing region.

As the infusion starts, thin jets of tracer exit from the holes all along the length of Pajunk Infiltralong catheter. These jets quickly interact with the transparent pipe wall, dispersing the dye in the confined region around the catheter. At the end of the bolus injection (Fig. 3(e)), tracer spreading is almost homogeneous all along the pipe.

4. Conclusions

Protocols to characterize the infusion pattern produced by wound infusion catheters during continuous and intermittent administration of local anaesthetic have been developed and used to test, in vitro, the performance of four wound infusion systems. Results indicate that infusion patterns produced by the four catheters tested are different and are closely linked to catheter design.

Qualitative visualizations indicate that the fluid is infused homogeneously across catheters characterized by a large flow section and small infusing area (Baxter and Pajunk) but is not infused homogeneously by catheters characterized by a small flow section and large infusing area (Temena and I-Flow).

The infusion pattern measured by quantitative tests is close to uniform for Baxter and Pajunk catheters, whereas a large deviation from uniform is observed for both I-Flow and Temena catheters. The deviation is large at the distal end for I-Flow and at the proximal end for Temena.

There was no difference observed in the flow profile of the catheters between continuous and bolus infusion modes. In Baxter and Pajunk catheters, the flow is infused homogeneously all along the catheter length. Thus, theoretically, the administration of local anaesthetics through Baxter and Pajunk catheters can be expected to provide a better analgesic effect than through the other two catheters tested. Clinical studies are needed to confirm these findings.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2011.07.033.

Conflict of interest statement

M. Campolo, D. Molin and A. Soldati do not have conflict of interest. N. Rawal has been speaker for/has received honorarium fees from: Baxter Healthcare; Jansen-Cilag; Nycomed, Sintetica, and Astra Zeneca.

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