Medical Devices: Evidence and Research

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Mechanical performances of elastomers used in diffusers

This article was published in the following Dove Press journal:
Medical Devices: Evidence and Research
13 June 2011
Number of times this article has been viewed

Gérard Guiffant[1]
Jean-Jacques Durussel[1]
Patrice Flaud[1]
Jean-Pierre Vigier[1]
Christian Dupont[2]
Philippe Bourget[3]
Jacques Merckx[1]

[1]University Paris Diderot, Paris, France; [2]University Teaching Hospital Cochin, Paris, France; [3]University Teaching Hospital Necker-Enfants Malades, Paris, France

Abstract: The use of elastomeric diffusers (EDs) has grown together with the expansion of home care. In these devices, the fill volume of the drug reservoir and the flow rate are preset and cannot be modified. The elastomer, which makes up the reservoir walls, is what makes the infusate flow due to the pressure it exerts. The purpose of this work was to quantify, under standardized experimental conditions and following recommended conditions of use, the mechanical performances of the 2 commonly used elastomers (silicone and polyisoprene) and their impact on infusion flow rate consistency. Results show that they exhibit different mechanical performances which leads to concerns regarding the use of these devices for some intravenous (IV) therapies.

Keywords: elastomeric diffusers, perfusion, drug administration rate, infusion flow, infusion devices

Introduction

Portable diffusers are nonimplantable, sterile, single use, nonprogrammable pumps. They function without an external source of energy and by a gravity independent mechanism.[1,2] They take up little space, are light and preserve patient mobility. They have no maintenance costs and are without risk of presenting an erroneous flow rate. Among them, diffusers with a balloon (reservoir) or elastomeric diffusers (EDs) are the most common. Their use is increasing, together with the increased prevalence of home care in various therapeutic fields (oncology, antibiotherapy, peripheral nerve block analgesia), as well as with the search for greater patient comfort and autonomy. Their efficiency in administering various therapies has been documented,[3–9] as well as their level of performance, which has been questioned.[10–12]

A major ED specification is the flow rate. In volumetric and syringe-pumps, the flow rate is set by the operator. The electric motor maintains it by exerting pressure on a syringe plunger for example, which varies according to fluid path resistance. EDs function differently. The elastomer, which makes up the reservoir walls, is what causes the flow, through the pressure (P) it exerts on the IV fluid. The difference between the pressure ($P \approx 380$ mmHg) and the venous pressure P_v allows the infusate to flow out of the reservoir. It does so through a calibrated capillary hydraulic resistance (R_h) which is set into the proximal or distal end of a flexible tube tied to one end of the reservoir (Figure 1). These 3 parameters (P, P_v, and R_h) interact to give the flow rate (Q) as per the following formula: $Q = (P\text{-}P_v)/R_h$.[13] This tells us that Q cannot be constant if P changes. When in use, as the reservoir empties, its volume decreases, which directly impacts the stress forces on the elastomer. Therefore, its mechanical performances

Correspondence: Gérard Guiffant
Université Paris Diderot, MSC, UMR CNRS 7057, 10 rue Alice Domon et Léonie Duquet, 75205 Paris, cedex 13, France
Tel +33 01 57 27 70 41
Fax +33 01 57 27 62 11
Email gerard.guiffant@univ-paris-diderot.fr

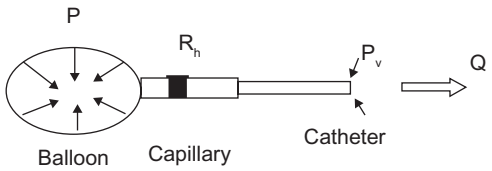

Figure 1 Schematic representation of the ED working principle.

are of crucial importance in maintaining constant pressure during the infusion period.

The purpose of this work was to quantify, under standardized experimental conditions, the mechanical performances of 2 commonly used elastomers (silicone and polyisoprene) and their impact on infusion flow rate regularity.

Material and methods

The two types of elastomer tested were: a silicone (Si) inorganic polymer and a polyisoprene (Pi) material close to natural rubber. In the absence of a reference liquid,[13] distilled water was chosen to fill the reservoirs. The experimental setup is shown Figure 2. The elastomeric reservoirs were taken from unused, commercially available EDs. They were fastened at each extremity to a tube (length 85 mm, internal diameter 10 mm) similar to commercial devices. Through a bypass, the reservoir's internal pressures (P) were registered by a sensor (KOBOLD type SEN 8600, Kobold Instruments Inc, Pittsburgh, PA) linked to an AUF 1000screen (Tetra Tec Instruments GmbH, Steinenbronn, Germany) at every 5 mL of fluid infused. The recorded values are the difference between the atmospheric pressure and P. The flow rate was deduced from the weight of the distilled water, in grams (g), recovered during the infusion. The mass was recorded every 30 seconds by scales (Mettler Toledo PB3002-SDR, Mettler-Toledo Inc, Columbus, OH) linked to a computer.

For each type of elastomer, we performed enough tests ($N > 4$) to ensure result reproducibility. In the first part of the tests, the reservoirs were filled to 100 mL as recommended by the manufacturers. The claimed flow rate was 200 mL/hour. In the second part, the Si reservoirs were filled to 200 or 300 mL, the Pi ones to 240 and 300 mL, as recommended by their manufacturers. The claimed flow rates were 5 mL/hour for the 200 mL Si reservoirs and the 240 mL Pi ones and 10 mL/hour for the other 2 models.

We also performed the tests applying various counter pressures, P_v, to simulate physiological and pathological venous pressure. Physiological venous pressure P_v at rest ranges between 3 and 6 mm Hg (4–8 cm H_2O), however, it can reach much higher values in some instances (eg, coughing fits, or cardiac insufficiency). Results for P_v of 3 mm and 44 mm Hg (60 cm H_2O) are reported in Figures 4 and 5. Lastly, we introduced a time delay of 12 hours between fill time and infusion duration.

Results

a. Pi and Si reservoirs filled to nominal volume, flow rate of 200 mL/hour, P = 380 mm Hg, low P_v (3 mm Hg). Reservoir internal pressure results are summarized in

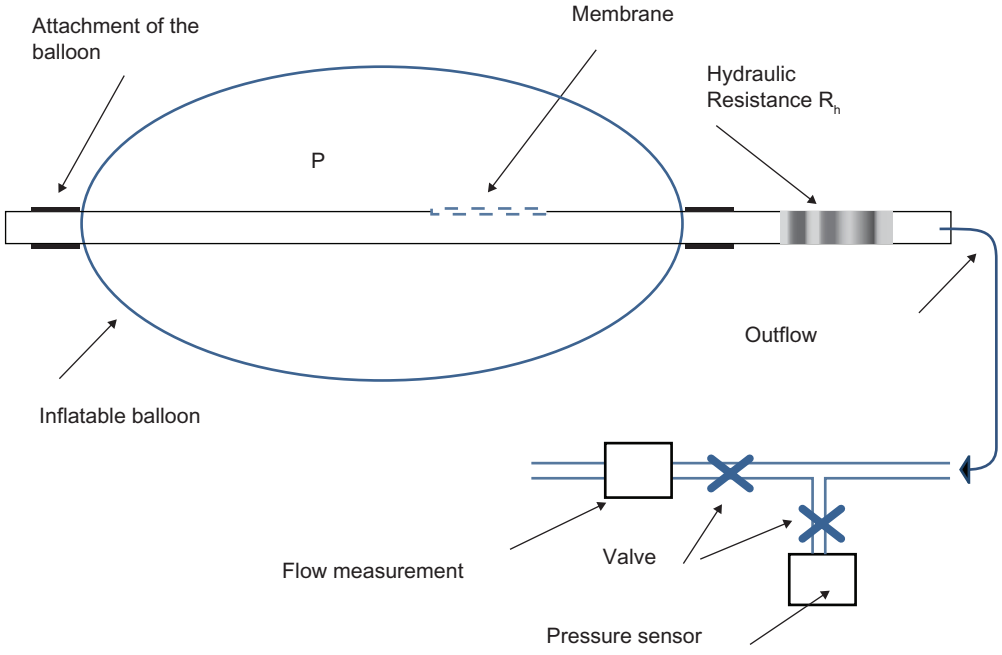

Figure 2 Schematic representation of the experimental setup.

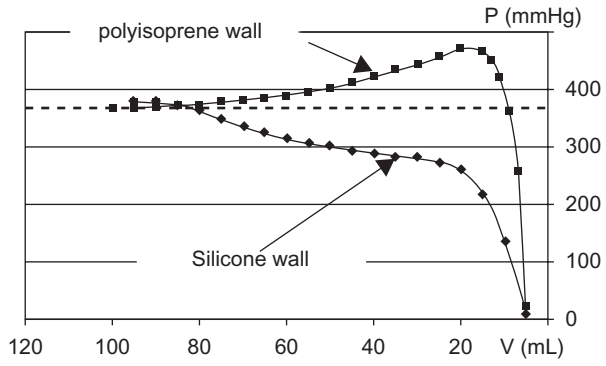

Figure 3 Internal pressure in the reservoirs in mm Hg as a function of the remaining volume to be infused.

Figure 3. The nominal internal pressure (the dotted line on the graph) shows desired stability to ensure constant flow rate. The 2 types of elastomer demonstrate different performances. With Pi, P slightly increases before dropping suddenly when the residual volume reaches about 10 mL (10% of the fill volume). With Si, P decreases constantly and drops suddenly when the residual volume reaches about 20 mL (20% of the fill volume).

b. Pi and Si reservoirs filled to nominal volume, claimed flow rate of 200 mL/hour, P = 380 mm Hg, high P_v (44 mm Hg). When increasing P_v, without changing P, Q decreases and, therefore, the time to infuse the full volume increases. Perfusion kinetics, shown in Figures 4a, 4b, 5a and 5b, is similar for both P_v values. Dotted lines in Figures 4b and 5b indicate the claimed flow rate and infusion duration.
c. Pi and Si reservoirs filled to nominal volume, claimed flow rate of 200 mL/hour, P = 380 mm Hg, low P_v (3 mmHg), time delay of 12 hours. When a time delay of 12 hours between filling and infusion is introduced, the mechanical performances are impacted as shown in Figures 6a and 6b. With Pi, the flow rate ("delayed flow") decreases slightly (≈10%) and the infusion duration increases proportionally (≈10%). However, perfusion kinetics remains similar. This could be due to a fatigue effect in the elastomer. With Si, perfusion kinetics differs significantly between delayed and immediate use. Si shows a complex response to mechanical stress, which impacts its viscoelastic features.
d. Pi and Si reservoirs filled to nominal volume, claimed flow rate of 10 or 5 mL/hour, P = 380 mm Hg, high P_v (44 mm Hg). In the case of low flow rate and long infusion time, perfusion kinetics is impacted neither by high P_v nor by the fill volume of the reservoirs. With Pi, flow rate kinetics is homothetic (Figures 7a and 7b). With Si, it is significantly different (Figures 8a and 8b) and the recorded flow rates were lower than the claimed ones.

Discussion

When using volumetric or syringe-pumps, the flow rate (Q) is set by the operator. The device motor maintains the rate. Pressure (P) is exerted on the reservoir as a function of fluid path resistances (R_h). However, to prevent damage to the vascular access device, its increase is limited. When the maximum value is reached, an alarm will ring. In EDs, pressure (P) generated by the elastomer is assumed to be constant. The real flow rate depends on the initial value of its components (P, P_v and R_h) and on their variations with time. The relationship is linear. Any change will induce a variation of Q and of infusion time of the same order. In other words, a 1% increase in R_h or P_v will slow Q by 1% and increase infusion time.

i. Because of the structure of the elastomers, P is not constant (see Figure 3), so Q is not either. Furthermore, Si and Pi exhibit different mechanical performances. Si shows a complex response to physical stress, which is

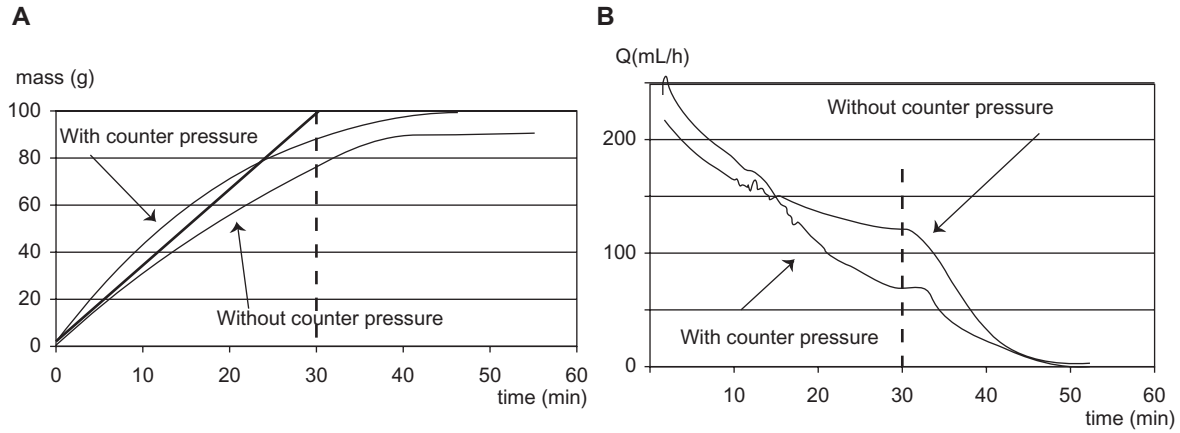

Figure 4 Mass collected (**a**) and flow rate (**b**) for Pv of 3 and 44 mm Hg, as a function of time for100 mL Si reservoirs. The straight bold line in (**a**) is the ideal time dependence of P.

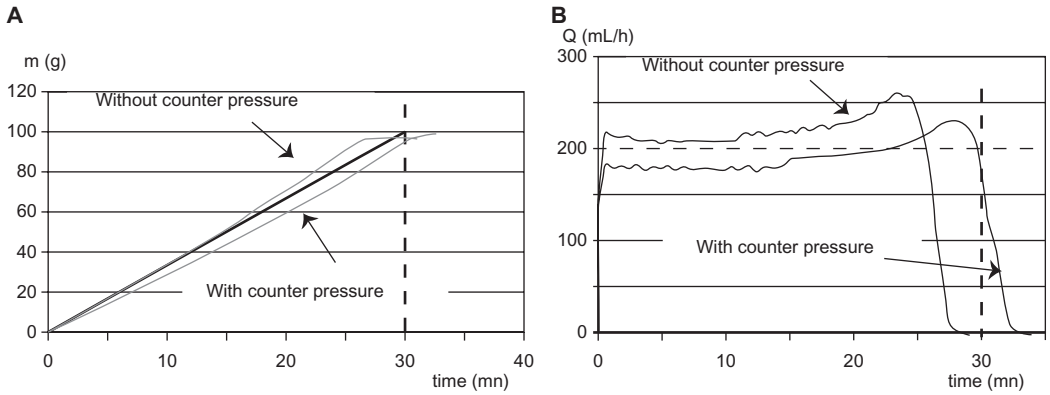

Figure 5 Mass collected (**a**) and flow (**b**) for Pv of 3 and 44 mm Hg, as a function of time for 100 mL Pi reservoirs. The straight bold line in (**a**) is the ideal time dependence of P.

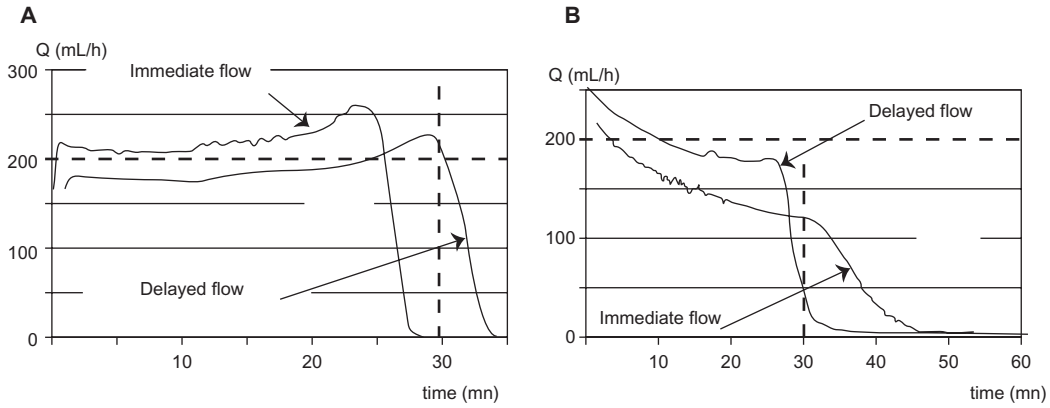

Figure 6 Flow rate as a function of time with ("delayed flow") and without ("immediate flow") a 12 hour time delay for Pi (**a**) and Si (**b**)100 mL reservoirs.

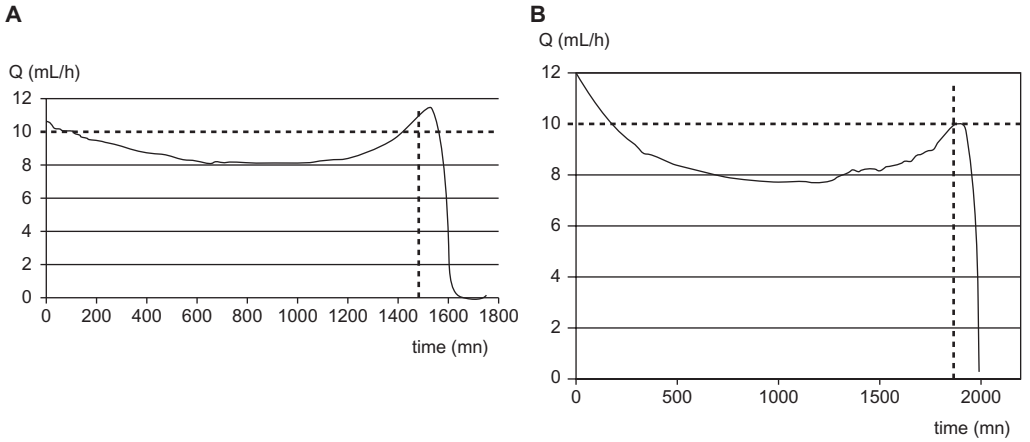

Figure 7 Flow rate as a function of time for a Pi reservoir filled respectively with 240 mL (**a**) and 300 mL (**b**) both for a 10 mL/h claimed flow rate value.

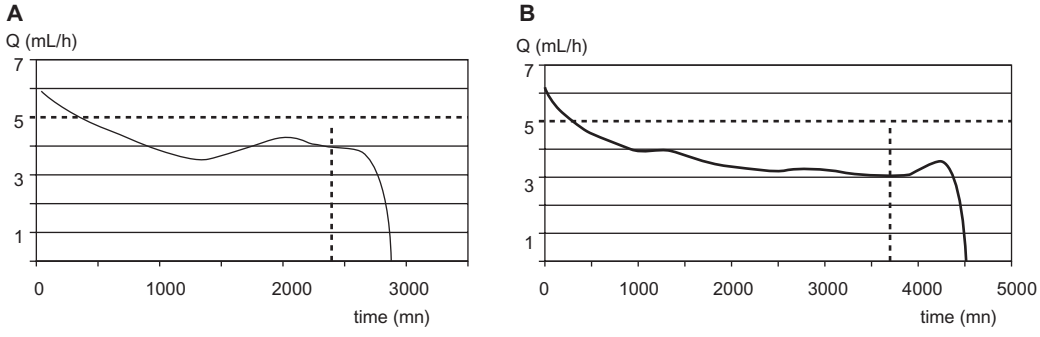

Figure 8 Flow rates as a function of time for a Si reservoir filled respectively with 200 mL (**a**) and 300 mL (**b**) both for a 5 mL/h claimed flow rate value.

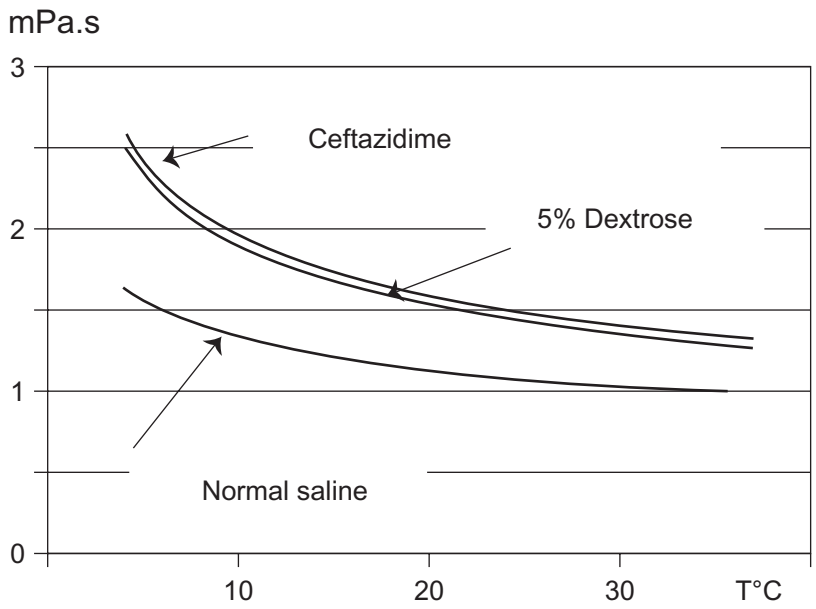

Figure 9 Change of viscosity with temperature of some IV fluids or drugs.

time dependent. Therefore, the hypothesis of constant and stable infusion kinetics is unreasonable. Pi has a much shorter relaxation time, which does not significantly impact infusion kinetics (see Figures 7 and 8).

ii. Moreover, P_v can dramatically increase under various pathological conditions. As an example, primary and secondary chronic obstructive pulmonary diseases such as cystic fibrosis are associated with coughing fits during which intrathoracic pressure can reach 45 mm Hg and sometimes 300 mm Hg[15] for a short time. Their intensity and repetition can lead to blood backflow into the vascular access device lumen ($P_v > P$), decreasing their patency and further impacting the flow rate.

iii. Other factors can potentially impact the flow rate. One of these is IV fluid viscosity, which not only covers a wide range but also changes with temperature as shown for 2 IV fluids (normal saline, 5% dextrose) and one IV drug (ceftazidime 4 g/100 mL) in Figure 9. Even if the use of EDs to maintain the patency of vascular access devices has been advocated,[13] they are mainly used to administer IV therapies. In such cases, the dose is prescribed according to patient weight or body surface area among other criteria, including pharmacokinetics (ie, blood concentration) to reach the optimal benefit/risk ratio. It is clear that a passive device cannot strictly meet this demand because of ineluctable interpersonal variations in addition to mechanical variations, which cannot be preliminarily quantified. Likewise, one should keep in mind that the differences between the prescribed flow rate parameters (ie, mg/kg/hour) and the effectively infused ones, may lead to toxicity in the case of overdosing or to a loss of effectiveness or potential resistance (underdosing). Therefore, EDs are suitable for some IV therapies, but not when the flow rate must remain stable at the claimed value.[14]

iv. Last, but not least, a time delay between filling and infusion times also impacts the flow rate, as shown in Figure 6. This parameter should also be taken into account.

Conclusion

The experimental conditions were chosen to test the mechanical performances of the 2 commonly used elastomers (Si and Pi) excluding other variables that also impact flow rate (including fluid viscosity, resistance of infusion tubing and links, height difference between the ED and the catheter, among others). Si shows a complex response to physical stress which is time dependent. Therefore, the hypothesis of constant and stable infusion kinetics with this material is unreasonable. On the other hand, the relaxation time of Pi is much shorter and does not significantly impact infusion kinetics.

This raises questions about the criteria for choice and optimal conditions of use of these elastomers, keeping in mind that:

- preference should be given to EDs using polyisoprene (Pi).
- available EDs fulfill ISO specifications.
- the flow rates claimed by the manufacturers are an indication valid only under given stable conditions which exclude various parameters.

– there is little information about the practical, clinical and pharmacological consequences of the various ways to prepare, store and use these devices.

Further work is planned to compare various brands and types of EDs to quantify their performances and their limits.

Disclosure

The authors report no conflicts of interest in this work.

References

1. Onkelinx L. Liste des diffuseurs remboursés par la sécurité sociale. Le Moniteur Belge. (Belgisch Staatsblad) 2nd Ed. Arrêté Royal; 2009:68347–68350.
2. Geubelle B, Duvivier F. Préparation des chimiothérapies anticancéreuses. 3ème réunion du BOPP (Belgian Oncology Pharmacy Practitioners), 2010 Nov 30–Dec 2; Grand Gigard, Belgique.
3. ISO 28620. Medical devices – Non-electrically driven portable infusion devices. 2010.
4. Remerand F, Vuitton AS, Palud M, et al. Elastomeric pump reliability in postoperative regional anesthesia: a survey of 430 consecutive devices. *Anesth Analg*. 2008;107(6):2079–2084.
5. Capdevila X, Macaire P, Aknin P, Dadure C, Bernard N, Lopez S. Patient controlled perineural analgesia after ambulatory orthopedic surgery; a comparison of electronic versus elastomeric pumps. *Anesth Analg*. 2003;96(2):414–417.
6. Gruwez B, Lecante V, Dauphin A. Assessment of three portable infusion devices used for cytotoxic drugs. *J Pharm Clin*. 2002;21(3):199–203.
7. Macaire P, Gaertner E, Capdevila X. Continuous post-operative regional analgesia at home. *Minerva Anestesiol*. 2001;67(9 Suppl 1): 109–116.
8. Bernard L, El-Hajj, Pron B, et al. Outpatient parenteral antimicrobial therapy (OPAT) for the treatment of osteomyelitis: evaluation of efficacy, tolerance and cost. *J Clin Pharm Ther*. 2001;26(6): 445–451.
9. Di Lauro V, Spazzapan S, Lombardi D, et al. Fourteen-day infusion of ifosfamide in the management of advanced breast cancer refractory to protracted continuous infusion of 5-fluorouracil. *Tumori*. 2001;87(1): 27–29.
10. Lombardi D, Magri MD, Crivellari D, et al. Combination chemotherapy with navelbine and continuous infusion of 5-fluorouracil in metastatic, chemotherapy refractory breast cancer. *Ann Onco*. 2000;11(8):1041–1043.
11. Capes DF, Asiimwe D. Performance of selected flow restricting infusion devices. *Am J Health Syst Pharm*. 1998;55(4):351–359.
12. Thiveaud D, Demazières V, Lafont J. Comparison of the performance of four elastomeric devices. *Eur J Hosp Pharm Pract*. 2005;11(2): 54–56.
13. Ackerman M, Maier S, Ing H, Bonnabry P. Evaluation of the design and reliability of three elastomeric and one mechanical infusers. *J Oncol Pharm Pract*. 2007;13(2):77–84.
14. McCool FD. Global physiology and pathophysiology of cough: ACCP evidence-based clinical practical guidelines. *Chest*. 2006;129(1 Suppl): 48S–53S.
15. Heath J, Jones S. Utilization of an elastomeric continuous infusion device to maintain catheter patency. *J Intraven Nurs*. 2001;24(2): 102–106.