



Supporting Documentation
On Methods of Infusion

Disposable Infusion Pumps

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Abstract and Introduction

Abstract

Purpose: The properties, performance, and applications of nonelectric disposable infusion pumps are reviewed.

Summary: All nonelectric disposable infusion pumps exploit the same physical principle: mechanical restriction within the flow path determines the speed of pressurized fluid. The pressure generated by disposable pumps on fluid is 250-600 mm Hg, compared with 5-1200 mm Hg of pressure for electric pumps. There are several types of disposable infusion pumps, including elastomeric, positive-pressure (spring-powered and gas-pressure-powered), negative-pressure (vacuum), and patient-controlled analgesia (PCA) pumps. The accuracy of each pump's flow rate is dependent on several factors, including temperature, fluid viscosity, atmospheric pressure, back pressure, partial filling, and storage. Disposable infusion pumps can be used in many areas, including home care, PCA, patient-controlled epidural analgesia, continuous peripheral analgesia, continuous epidural analgesia, continuous i.v. analgesia, and pediatrics applications. The advantages of disposable infusion pumps include their light weight, small size, simplicity of use, independence from an external power supply, elimination of programming errors, and disposability. Disadvantages include the possibility of inaccurate flow rates, fixed reservoir volume, lack of a facility to change the flow rate and bolus-dose volume to provide adequate analgesia, inability to trace the history of the analgesia demand by patients, inability to combine PCA with background continuous infusions, and long-term cost.

Conclusion: Despite some disadvantages and limited areas of applicability, disposable infusion pumps provide patients with advantages, such as portability, simplicity, and disposability, especially for the administration of analgesia. Understanding their physical and mechanical characteristics and their appropriate application may optimize patient care.

Introduction

Nonelectric disposable infusion pumps have been in clinical use for more than 20 years. During these years the number of areas in which they are used has increased, as well as the number of patients receiving therapy with these devices. Today, disposable infusion pumps are extensively used in hospitals and home care settings to deliver therapies such as chemotherapy, antimicrobials, analgesia, and anesthesia, as well as for postoperative pain control and chronic pain management.

A wide range of disposable pumps is available (appendix). The multiple pump types employ different principles of operation and are constructed from a range of materials. These factors strongly affect device accuracy and the range of drugs that can be delivered by a particular pump.

With such a large variety of disposable pumps available, users may have difficulty selecting an appropriate infusion device that meets their clinical needs. This article reviews each type of disposable pump and the factors that may affect the quality and accuracy of any therapy

delivered via these devices. The major content of this article is compiled from the findings presented in peer-reviewed journals. A few studies are cited where devices were evaluated in a research laboratory, noting effects on flow-rate accuracy and flow continuity^[1-4] and the effect of atmospheric pressure change on flow rate.^[5,6] The major part of this review, however, looks at findings on usability and suitability to applications reported from clinical trials in the following five areas: (1) continuous analgesia for postoperative pain management,^[7-10] (2) patient-controlled analgesia (PCA),^[6,11-14] (3) delivery of chemotherapy drugs and opioids for cancer treatment,^[15-18] (4) delivery of antimicrobials in the home,^[19,20] and (5) pediatrics applications.^[8,21]

Working Principles of Disposable Infusion Pumps

All nonelectric disposable pumps exploit the same physical principle: mechanical restriction within the flow path determines the speed of pressurized fluid. The pressure on the fluid is generated by a variety of mechanisms using nonelectric power, including a stretched elastomer or compressed spring, pressure generated during a chemical reaction,^[22] and pressure supplied from a cartridge of pressurized gas.^[23] The restriction of flow in all disposable pumps is caused by narrow-bore tubing. Tubing diameter has a determining influence on the device's flow rate. Therefore, flow restrictors are usually made of materials whose dimensions change little with temperature in order to maintain accuracy. Typical materials used are glass and plastic (e.g., polyvinyl chloride [PVC]). Glass capillary-flow restrictors are typically used for devices infusing at a rate of 0.5-10 mL/hr; plastic is typically used for flow restrictors of pumps infusing at rates of 50-250 mL/hr. The flow restrictor is always integral to the administration set. The administration set can be integrated within or detachable from the pump reservoir. The former is claimed to decrease the risks of infection and inadvertent disconnection during therapy. On the other hand, detachable sets allow a range of flow rates to be achieved with one reservoir, by attaching different administration sets. The administration set commonly includes an air or particulate filter or both.

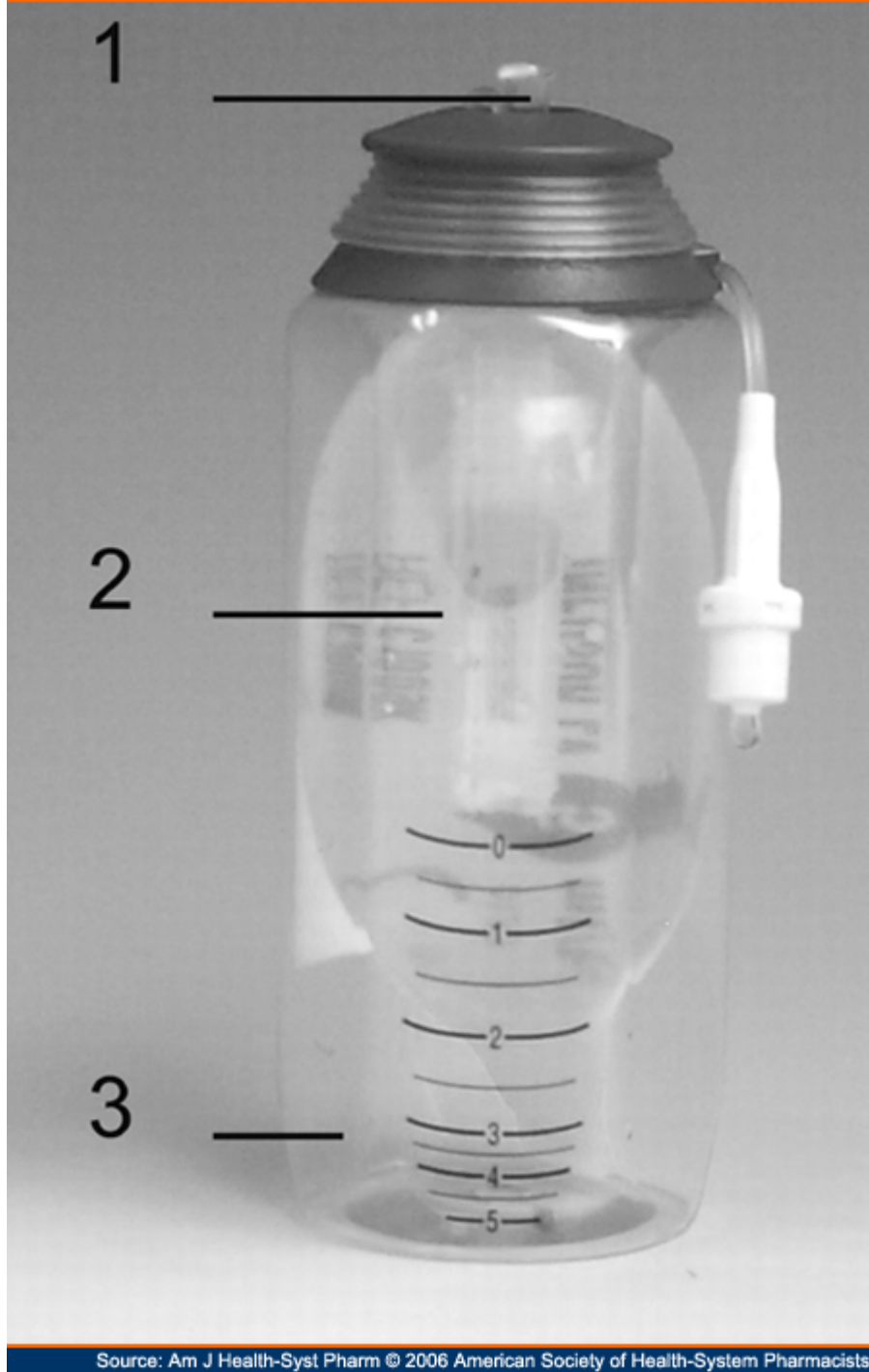
Flow rate is principally affected by the pressure gradient across the flow restrictor and by fluid viscosity. These factors may vary in clinical settings, significantly affecting the accuracy and duration of infusion therapy. The pressure gradient may be affected by (1) vertical displacement of the device relative to the infusion site (back pressure),^[1] (2) the initial filling volume (underfilling or overfilling relative to the nominal volume),^[20] (3) storage conditions (e.g., refrigeration and freezing),^[1,20] and (4) variations in barometric pressure.^[5,6,20] Fluid viscosity is strongly affected by temperature and somewhat affected by drug concentration.

The pressure generated by disposable pumps on fluid is typically within the range of 250 to 600 mm Hg, compared with a fluid reservoir pressure for electric pumps of 5 to 1200 mm Hg, depending on flow rate and cannula size. Disposable pumps can infuse at flow rates of 0.5-500 mL/hr, with running times from 30 minutes to 12 days. Reservoir volume usually ranges from 60 to 500 mL.

Types of Disposable Pumps

Elastomeric Infusion Pumps

In all elastomeric disposable devices, the pressure on the fluid is generated by the force of a stretched elastomer. Elastomeric disposable pumps consist of an elastomeric membrane, which contains the drug, that is contained within an outer protective shell (Figure 1). The outer protective shell can either be a conformable elastomer (e.g., Homepump Eclipse [I-Flow Corporation, Lake Forest, CA]) or a more rigid plastic (e.g., In-fusor [Baxter Healthcare, Deerfield, IL]). A soft elastomeric outer shell offers less protection against sharps puncture but requires less storage and disposal space.



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Figure 1.

Elastomeric infusion pump. Three parts include filling port (1), elastomeric balloon (drug-containing reservoir) (2), and outer protective shell (3).

The membranes of elastomeric pumps are made of various elastomers, both natural and synthetic (e.g., isoprene rubber, latex, and silicon), and can be made of a single or multiple layers. The type of elastomer and the geometry of the elastomeric balloon determine the pressure

generated on the fluid when the balloon is stretched.^[2] Multiple-layer elastomeric membranes can generate higher pressures than the single-layer membranes. Higher driving pressures are of benefit for achieving fast flow rates and in situations where resistance to flow is increased (e.g., use of a long or narrow catheter). However, the increased resistance required to fill the multilayered elastomeric reservoir may necessitate the purchase of special electric pumps for batch filling.^[4] Some manufacturers prestretch the balloon reservoir to facilitate filling (e.g., Accufuser [Woo Young Medical Co., Ltd., Korea]). Elastomeric pumps operate with a driving pressure of 260-520 mm Hg and infuse at rates of 0.5-500 mL/hr.

A characteristic flow pattern is common to all elastomeric pumps. The flow-rate at the beginning of an infusion is higher than during most of the infusion, with another increase close to the end of delivery.^[1,2,24-26] These flow-rate patterns are due to variations in pressure within a stretched elastomeric membrane and occur in all commonly used elastomers.^[2,24,27] Although this variation in flow rate is considered to be clinically acceptable and covered by the stated accuracy of a device (typical accuracy range under laboratory conditions for elastomeric pumps is claimed to be within 15% of the nominal flow rate),^[3,28] nonetheless, it is useful for clinical users to be aware of this performance.

Spring-Powered Infusion Pumps

Positive-pressure spring-powered pumps are powered by energy stored in a compressed spring (Figure 2). Some of these devices can be reusable (e.g., Sidekick and Paragon [I-Flow Corporation]), and some are for single-use only (e.g., Springfusor [Go Medical Industries, Pty, Ltd., Australia]^[29] and beeline [McKinley Medical LLC, Wheat Ridge, CO]). Only the mechanical parts of the "reusable" disposable pumps are reusable; the fluid bag and administration set are for single use only.

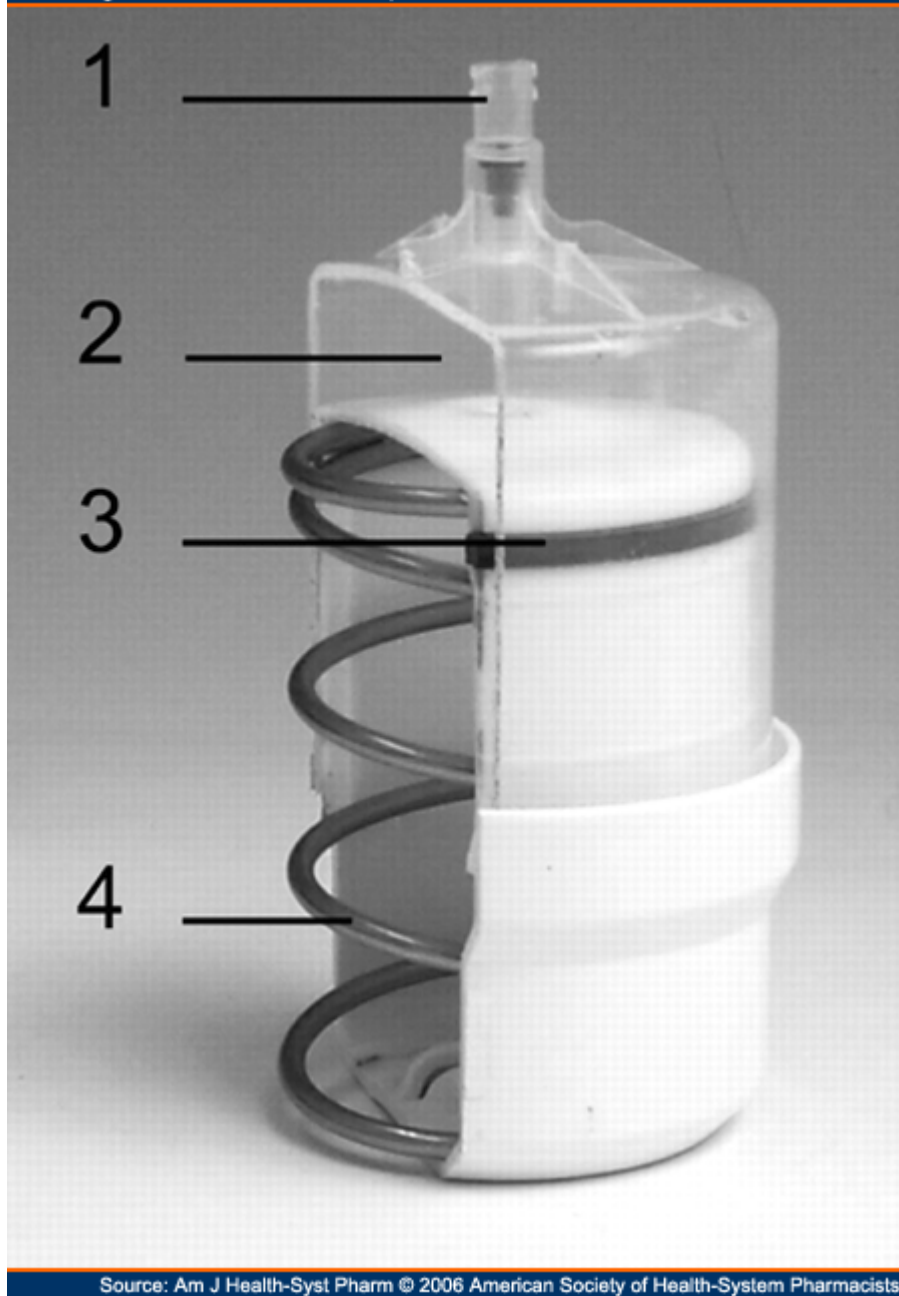


Figure 2.

Spring-powered (positive-pressure) pump. Four parts include filling port (1), drug reservoir (2), movable wall plunger (3), and simple spring (4).

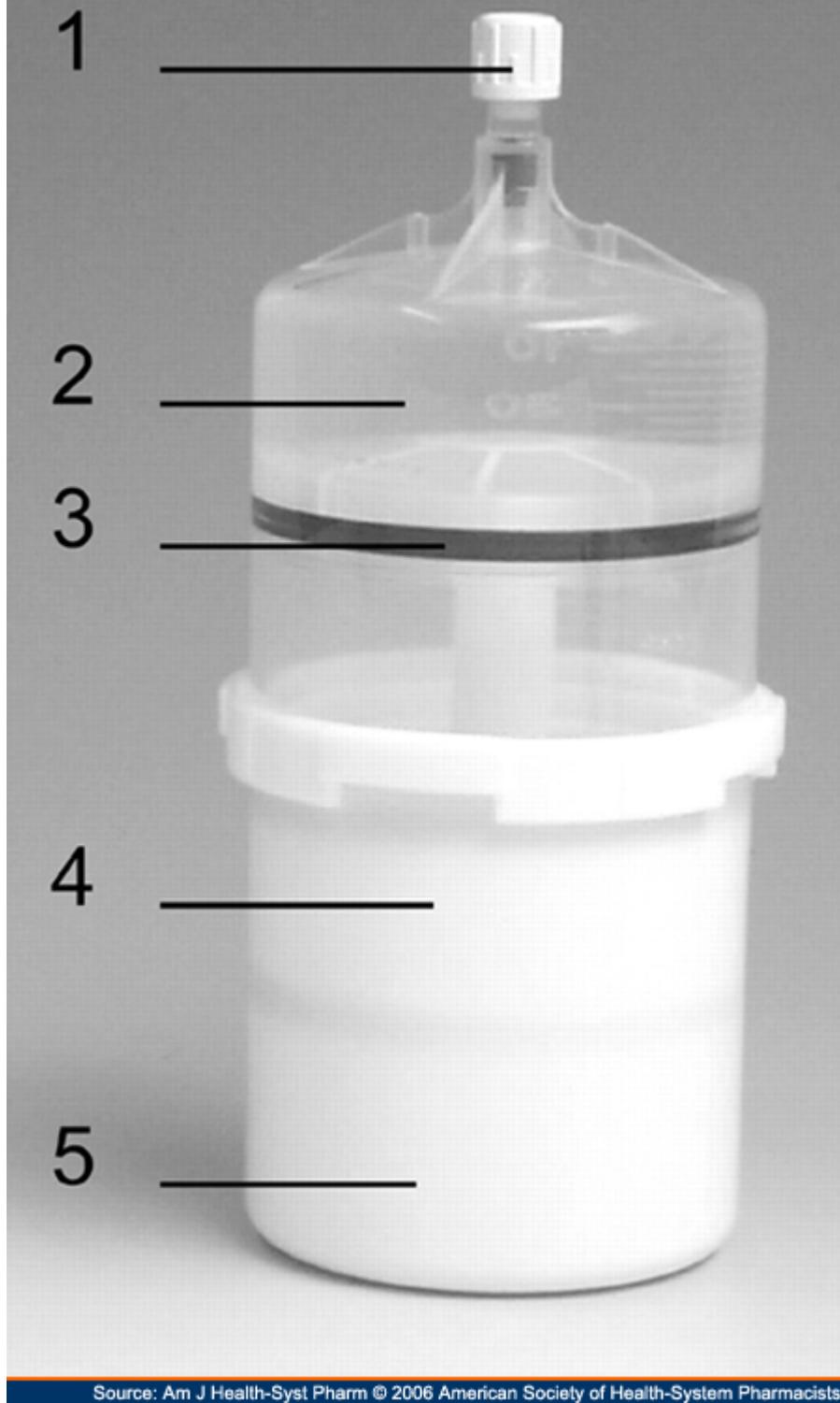
The reusable parts of spring pumps are made from materials known for their durability and compatibility (e.g., Teflon, stainless steel, and polycarbonate) and, according to manufacturers' claims, can be reused thousands of times. The disposable components are typically made from PVC and acrylic. The reusable parts of Paragon and Sidekick consist of two parts screwed together, with a spring inside the top half. When placed inside, a fluid bag compresses the device's spring, which in turn applies pressure on the bag, causing fluid to flow.^[4] For most single-use spring pumps, energy is transformed by compression of the spring caused by the increasing

volume of the fluid reservoir during filling (Figure 2).

The flow-rate patterns for simple-spring disposable pumps have typical characteristics, with the flow rate being significantly higher at the beginning of infusion than at the end.^[1,4,25,26,29,30] These variations are due to fluctuations in the pressure applied on the fluid by the compressed spring; the pressure decreases with decreases in the volume of the drug reservoir. Thus, the flow rate of a simple-spring pump decreases steadily during the course of delivery. The typical accuracy range under laboratory conditions for these devices is $\pm 15\%$ (beeLINE, Sidekick) to $\pm 20\%$ (Springfusor). The more complex spring-linkage mechanism used as a power source on the Paragon pump is claimed to sustain a more even flow rate by providing a less variable pressure on the fluid during infusion.^[1] The flow-rate accuracy of the Paragon pump is claimed to be $\pm 10\%$ under laboratory conditions.

Negative-Pressure Infusion Pumps

With negative-pressure pumps, a driving force is generated from the pressure difference across two sides of the pump's low-pressure chamber wall, with one side being at very low pressure (inside a vacuum chamber) and another side being at atmospheric pressure (Figure 3). The very low pressure in the vacuum chamber is created by the user while filling the device. Expansion of the drug reservoir, caused by the addition of fluid to the drug-containing reservoir, causes simultaneous expansion of the reduced pressure chamber, thus creating a significant vacuum. During infusion delivery, pressure on the movable wall plunger is generated by the large pressure difference between its two sides, causing it to move and compress the fluid in the drug-containing chamber. High driving pressure, around 600 mm Hg, is achievable for these pumps, which is the highest pressure achievable for disposable pumps. Flow-rate patterns for these pumps were demonstrated to be more steady compared with simple-spring and elastomeric pumps but have not been shown to be more accurate overall.^[5,25] The claimed accuracy for vacuum pumps is $\pm 10\%$ under laboratory conditions. These devices are for single use only.



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Figure 3.

Vacuum (negative-pressure) pump. Five parts include filling port (1), drug-containing reservoir (2), movable wall plunger (between vacuum chamber and open to atmosphere chamber) (3),

vacuum chamber (4), and atmosphere chamber (5).

PCA Pumps

Disposable PCA pumps have an additional fixed-volume, bolus-dose reservoir that is integrated or attached to the administration line of a standard disposable pump. When the user presses a button, a valve opens, allowing the bolus-dose reservoir to empty. The speed of filling this reservoir, regulated by the pump's flow rate, determines the device's "lockout time." For example, at a flow rate of 5 mL/hr, the lockout time for a 0.5-mL bolus dose will be six minutes. Although the lockout time does not prevent doses from being delivered during this period (a patient can receive a smaller bolus dose, whose volume will be proportional to the time allowed for the reservoir to fill), it is not possible to exceed the maximum allowed hourly flow rate of a drug.

Factors Affecting Flow Accuracy

The claimed flow accuracy for disposable pumps is typically within $\pm 15\%$; however, for some pumps, this can degrade to $\pm 20\%$. This accuracy looks poor when compared with the accuracy of modern electronic infusion pumps (around $\pm 3\%$ for syringe pumps and within $\pm 5\%$ for volumetric pumps). However, there are clinical areas where such performance is acceptable. In addition, the claimed flow accuracy only describes the pump's performance at calibrated and stated conditions, and the use of a disposable pump outside these conditions normally worsens its performance, which may lead to overall accuracy of $\pm 40\%$ or worse. For this reason, users should know the factors that might affect the accuracy of delivery.

Temperature

Temperature has a significant effect on disposable pump performance, mainly because a drug's viscosity changes with temperature.^[25,26,31] Maintaining the temperature of the fluid and flow restrictor at the advised level is the most important precaution when using these devices. Manufacturers' claims for accuracy usually include a statement of the type and temperature of fluid used for calibration. The most commonly used calibration solutions are either 0.9% sodium chloride injection or 5% dextrose injection. Between 0.5 and 10 mL/hr, fluid has a long transit time through a flow regulator and comes to thermal equilibrium with the regulator's temperature. The majority of low-flow-rate disposable pumps are calibrated at skin temperature, and their flow restrictors have to be taped to skin. Some devices are calibrated at peripheral skin temperature and some at more central sites, depending on the usual site of attachment of the flow regulator. Fast-flow-rate devices delivering at rates of 50-250 mL/hr are normally calibrated at room temperature, having longer flow regulators that are not taped to the skin and are sensitive to changes in ambient temperature. In general, the user can expect an increase or a decrease in the flow rate of a disposable pump by 2-3% for every 1 °C of temperature increase or decrease for water-based fluids.

Viscosity

Viscosity has an inverse effect on flow rate; the flow rate will decrease with an increase in the dynamic viscosity of the fluid. The concentration of a drug in solution can significantly affect viscosity, as can temperature fluctuations. In general, using a fluid and a temperature that differ from those used for device calibration can significantly affect flow rate.^[3,25]

Atmospheric Pressure

Although the driving mechanisms of spring and balloon pumps are not directly dependent on atmospheric pressure for their operation, their flow accuracy can be significantly affected by changes in ambient pressure.^[5,6] Negative-pressure devices are predictably affected by variations in atmospheric pressure.

Under low ambient pressure (600 mm Hg), a 35-64% reduction in flow rate was recorded for four disposable pumps, including spring, elastomeric, and negative-pressure pumps.^[5] In the same study, variations of pressure at the catheter tip were also shown to affect flow rate. By inference, the use of a catheter or route of administration different from that recommended by the manufacturer could also affect flow accuracy because of the different back pressure endured by the device.

Back Pressure

Some disposable pumps are calibrated to infuse at a certain back pressure, so changing the pump's position relative to the infusion site might affect its accuracy. Some manufacturers inform their users about the effect of the pump's vertical displacement on stated accuracy. For Baxter Healthcare's disposable pumps, the flow rate is affected by 0.5% for every 2.54 cm of pump displacement.

Partial Filling

Partial filling of a disposable pump can affect the internal pressure of an elastomeric balloon and the level of compression of a spring in simple-spring pumps. Rich^[20] reported that the 110-mL capacity elastomeric Homepump (Block Medical, Inc., Carlsbad, CA) partially filled with 50 mL of solution infused significantly faster (up to 34% faster) than the nominal flow rate. Internal pressure generated by the balloon was higher for a partially filled device than when the device was filled to its nominal volume. Baxter claims that its pumps' flow rates will increase by 10% if the filling volume is reduced by 60% from the nominal volume.

Storage

It has been reported that disposable pumps infuse at a lower rate after storage. One of the reasons is seen to be in starting infusions when the temperature of the infusate is still low. Infusions with fluid temperature lower than recommended resulted in lower flow rates and prolonged times of infusion.^[19,20] It is important, therefore, to allow pumps to warm after storage and before infusion therapy. Pumps with a large-volume reservoir require a longer period to reach ambient temperature than smaller-volume pumps. I-Flow Corporation recommends allowing 6-10 hours (depending on volume) for the Homepump Eclipse C-Series before beginning the infusion after storage in a refrigerator and about 12-18 hours if the pump was frozen.

Storage may also affect the pressure generated by elastomeric pumps. These devices had a 21% decrease in flow rate when previously frozen, likely because low temperatures during storage stiffened the elastomeric membrane and caused it to collapse more slowly.^[19] The viscosity of fluids also increases at low temperatures, thus contributing to the decrease in the flow rate after storage if the fluid is not allowed sufficient time to equilibrate with the ambient temperature.^[19]

Some manufacturers specify how storage may affect the flow rate of their devices. The manufacturer of the Homepump Eclipse recommends filling pumps at least four hours before use, allowing the internal pressure of the infuser to stabilize. Premature start of infusion can increase the flow rate by 20%. However, the Homepump Eclipse C-Series is calibrated for infusions starting immediately after filling, but the manufacturer warns users that storage longer than eight days after filling may increase the time of infusion by 10%.

Applications of Disposable Infusion Pumps

Home Care

Disposable pumps are widely used for drug delivery to ambulatory and home care patients.^[19] One of the largest areas of use of disposable devices in home care is the delivery of antimicrobial therapies^[20] and chemotherapy drugs and opioids for cancer treatment and palliative care

patients.^[15-18] Patients prefer disposable pumps to electric pumps mainly because of the disposable pumps' small size, simplicity in use, and disposability.^[20] The small size of disposable pumps is particularly attractive for patients receiving long-term infusions, as these pumps can be used with minimal restrictions to routine daily life.

In home-based evaluations, Homepump was the most accurate of the five elastomeric devices tested.^[4,30] This was attributed to the fluid reservoir's triple-layer membrane.^[30] However, because a multilayer membrane has a strong resistance while filling, the user must purchase a separate filling apparatus.^[4] Problems reported by patients in using Homepump were mostly related to slowness of pump infusions after storage.^[20] Of the 44 reported problems, 25 were related to the devices that were frozen before use. In this study, the failure rate for Homepump was 1.6%.

Hardy et al.^[16] evaluated the performance (accuracy and precision), cost (capital cost, estimated monthly cost, cost of consumables), and patient comfort of six pumps typically used for delivering cytotoxic drugs (five electric and one elastomeric pump). Unsurprisingly, the disposable elastomeric pump was the least accurate, with its accuracy varying between -5% and 13% while delivering fluorouracil. The authors expressed their concern about the acceptability of this pump for delivering cytotoxic drugs with a narrow therapeutic range. Although there was no capital cost for the pump, the estimated monthly cost for using the disposable pump was higher than for the five electric pumps.^[16]

Disposable pumps have long been used in postoperative pain control, in both clinical settings and at home, by using devices for continuous infusions or PCA.

PCA

Early evaluation of one of the first disposable PCA pumps, used to deliver 0.5-mL bolus doses of morphine sulfate i.v. on demand, revealed that different groups of patients required different bolus-dose volumes to achieve adequate analgesia and that a disposable, fixed-volume bolus-dose PCA pump could not always offer that flexibility.^[32] However, the Baxter Infusor (Baxter Health-care, Deerfield, IL) was found to be an effective device for providing PCA. Pain relief was satisfactory in 90% of patients, although drug concentration had to be changed in 19% of patients (10 of 53) to obtain adequate pain relief.^[32] The amount of drug consumed by patients was normally estimated by visual examination of the volume left in the device. The history of patient attempts versus actual injection was not available.^[31]

In the study conducted by Sawaki et al.,^[33] the performance of Baxter PCA Infusor was compared with that of four electronic PCA devices using either morphine (2 or 4 mg/mL) or me-peridine (20 or 40 mg/mL). Mechanical problems were less frequent with the Baxter PCA Infusor, and patients and nurses felt more comfortable using the disposable device than the electronic pumps. Patients also found the disposable pump easier to use, especially at night. In general, 80% of nurses preferred the Baxter PCA Infusor over the four widely used electronic PCA devices for the management of acute postoperative pain.^[33]

The use of disposable pumps designed for continuous infusions for providing patient-controlled postoperative analgesia at home was reported in two studies.^[12,13] This practice is highly undesirable and an off-label use of these products, as it provides the patient with no safeguards against overdose.

Patient-Controlled Epidural Analgesia

Banks and Pavy^[34] described the performance and effectiveness of the Go-Medical patient-controlled epidural injector in providing patient-controlled epidural analgesia, based on responses given by patients and nurses. The device was delivering a 4-mL bolus dose of 20 mg pethidine over 10-15 seconds into the epidural space on patient demand to provide postoperative pain management after cesarean section. The lockout time for bolus-dose delivery was 15 minutes.

Most (72%) nurses preferred the Go-Medical pump to any other patient-controlled analgesic devices they used in their practice. Effective use of a disposable PCA pump delivering a 3-mL bolus dose of fentanyl with bupivacaine for patient-controlled epidural analgesia after elective gynecological surgery was also reported by Kakehata et al.^[35]

Continuous Peripheral Analgesia

Disposable pumps have been used extensively to provide continuous postoperative analgesia. The disposable elastomeric C-Bloc Continuous Peripheral Nerve Block System (I-Flow Corporation) was successfully used to provide continuous analgesia using 0.2% ropivacaine through interscalene catheters after a wide variety of surgeries.^[36] The elastomeric pump was considered to be reliable and had some obvious advantages, including the pump's simplicity, with no need for patient or staff interventions during the infusion. Perceived limitations of the system were the inability to change the flow rate or deliver a bolus dose of local anesthetic and the inability to identify emergency situations, such as catheter occlusion.

In another study, effective postoperative pain relief through peripheral nerve block (PNB) was achieved by continuous infusion of ropivacaine using a Baxter Infusor LV5 (Baxter Healthcare).^[11] Pain relief was effective, and the use of an elastomeric disposable pump was associated with fewer technical problems and led to better patient-satisfaction scores compared with electronic pumps.

Continuous Epidural Analgesia

Epidural infusion of analgesics is an established method of drug administration, providing relief to patients suffering from chronic pain^[37] or to patients with terminal cancer pain.^[38] Disposable pumps have been extensively used in these therapies.^[30] In a study conducted by Tsujiguchi et al.,^[39] the accuracy of the Coopdech Syrinjector (Daiken Medical, Japan)—a negative-pressure disposable pump—used for continuous epidural infusion of 0.25% bupivacaine at 2-3 mL/hr was evaluated. The pump's performance was satisfactory, and the pump was recommended for continuous epidural analgesia infusions. Kakehata et al.^[35] also reported that disposable pumps successfully provided continuous infusions of fentanyl with bupivacaine epidurally at 2 mL/hr after elective gynecological surgery.

Continuous i.v. Analgesia

Reekie et al.^[27] evaluated elastomeric disposable pumps for continuous i.v. delivery of either ketamine or morphine in 5% dextrose injection to provide postoperative analgesia. The Baxter Infusor pump was found to be robust, light, self-powered, and well suited for i.v. applications. It was particularly useful in providing sustained infusions for analgesia or sedations during transportation of patients between hospitals.

Pediatrics Applications

In a study conducted by Dadure et al.,^[8] a disposable elastomeric 200-mL Baxter LV pump was used to deliver 0.2% ropivacaine at various flow rates (2, 5, and 7 mL/hr) to provide continuous PNB in the postoperative period for children after orthopedic surgery. In another study, the quality of PCA with children using Baxter PCA elastomeric disposable pumps was evaluated.^[21] The Baxter PCA pump could provide a bolus dose of 0.5 mL at six-minute intervals and was found to be suitable for select children age five years or older, and analgesia delivery was similar to that of electronic PCA pumps. No children in the study required adjustment of bolus-dose volume or lockout interval.^[21]

Advantages of Disposable Pumps

The light weight and small size of these devices make them more comfortable to carry, allowing

receive medication in public.^[27]

Simplicity of use is perhaps the most attractive feature of these pumps.^[14] The simplicity of elastomeric disposable pumps allowed them to be used for children who required postoperative analgesia with continuous PNB.^[8] Disposable pumps allowed greater freedom of movement for children with continuous PNB than electronic devices.

Disposable pumps do not require any external power supply to deliver and are a convenient means of providing infusions of drugs during patient transportation.^[27] However, they are affected by hypobaric conditions. Care must be taken when using disposable devices in high-altitude areas and during transportation of patients by plane.^[5]

Elimination of programming errors is seen as one of the major advantages of disposable pumps over electronic ones.^[14,21] These devices are delivering a fixed volume of a drug and at flow rates determined by the flow restrictor of the administration set; these parameters cannot be altered by a user. However, it remains possible to select the wrong flow restrictor or disposable device.

Disposability was found to be a very attractive feature of disposable pumps, particularly for ambulatory care patients.^[20,33,40]

In a few studies, cost was mentioned as being the main advantage of disposable pumps.^[21] The estimated cost of using disposable devices in providing postoperative analgesia was lower than that of electronic devices.^[41,42] In another study, the use of disposable infusion pumps was considered to be a good alternative to more expensive computerized pumps.^[30] The typical price range for disposable infusion pumps is \$30-\$86. The price range for electric pumps is wide, typically \$1200-\$3500. However, despite the obvious difference in price, there is no clear consensus about the overall cost advantages of disposable devices over electronic pumps, as discussed below.

Disadvantages of Disposable Pumps

Despite numerous advantages, disposable pumps are not without problems. The accuracy of these devices is low if compared with the accuracy of modern electronic infusion pumps and is only valid under specially controlled calibration conditions. Unfortunately, there is little standardization of these conditions. Pumps from different manufacturers are calibrated under different conditions, including operating pressure, viscosity of fluid, backpressure, temperature at the flow restrictor site, and time recommended between filling of the device and beginning of infusion. This makes it difficult to make any comparisons of performance or issue general recommendations or guidance. In addition, not all manufacturers provide users with information on how variation of each of these parameters might affect the accuracy of an infusion.

In one study, patients complained of prolonged infusions, sometimes up to twice the nominal time specified by the manufacturer.^[19] In two other studies, concern was raised about lack of consistency in infusion times, which varied by 50-150%.^[12,25] Quality of analgesia with disposable pumps due to the lack of consistency and unpredictability of the infusion duration was also criticized.^[2] An analysis of data on disposable infusers from the Manufacturer and User Facility Device Experience Database revealed reports of numerous adverse incidents due to pump malfunction or misuse (leakage or bursting at various points of the device, numerous incidents of failing to deliver and incidents where a device delivered the intended dose over a much shorter time than intended). In addition, incidents are recorded where a user has inadvertently selected the wrong device, and thus the wrong flow rate (e.g., delivery of 4400 mg of fluorouracil over two hours instead of the intended four days).

Patients and staff using disposable pumps for PCA found the main disadvantages to be the lack of a facility to change the bolus-dose volume to provide adequate analgesia, fixed-volume reservoirs, inability to trace the history of the analgesia demand by patients,^[21,31] and inability to

combine PCA with background continuous infusions.^[43] In addition, the amount of drug used by a patient is normally estimated by visual examination of the volume left in the device. This method is far from accurate.^[31]

Attempting to have flexible PCA by using a disposable device designed for continuous infusions and regulating a bolus dose by opening and closing the clamp are potentially lethal (e.g., when the patient forgets to close the clamp and the entire pump's content can be delivered as a single dose).^[13] Partial filling of disposable pumps, which might be used to allow wider use of devices with a fixed-volume reservoir (e.g., pediatrics applications), results in reported inaccuracies of up to 34% in delivery rate.^[20]

In a few studies, the long-term use of low-price disposable devices was more costly than the one-time purchase of an electric infusion pump and the associated disposables.^[16,33,34] The cost of the filling apparatus for disposable pumps should also be taken into account, as well as the cost of using pharmacy facilities in case the drug concentration must be changed.

Discussion and General Recommendations

Stored-energy disposable pumps perform differently depending on their power source. Elastomeric pumps deliver at higher flow rates at the beginning and end of an infusion, spring pumps deliver at higher flow rates at the beginning of an infusion and at much lower flow rates at the end of an infusion, and a vacuum pump delivers at higher flow rates through the entire infusion.^[25] Clinical evaluations of these devices have shown that these variations in flow rates were not clinically significant and did not present a hazard to patients.^[28,44] However, clinicians and health care providers should be aware of this variety of flow-rate profiles for disposable pumps to maximize patient safety.

Poor flow accuracy of disposable devices ($\pm 10\%$ or worse) makes them inappropriate for therapies that require accurate drug delivery. However, drugs administered in ambulatory care settings usually have relatively long half-lives,^[20] and the use of disposable pumps can be justified. Identification of the clinical situation where a disposable pump will be used is critical and should be considered a first step in selecting the optimal device. Such variables as acceptable infusion rate accuracy, patient-controlled bolus-dose availability, desired infusion duration, infusion-rate profile, and total drug volume of reservoir should be taken into account.

Drug compatibility and stability in a fluid reservoir and administration set of a disposable pump are also important when selecting a disposable infusion device. Some disposable pumps are made from materials not typically used for fluid containers and administration lines. Therefore, users must not assume that drug stability and compatibility data for commonly used medical materials, such as PVC and polypropylene, will be applicable to disposable pumps. Separate data on drug stability and compatibility with the fluid container and fluid-contacting parts of the disposable pump are therefore necessary. Restrictions on storage time and temperature of the filled pump can significantly reduce the applicability of the disposable pumps for certain clinical scenarios. Substantial analyses of drug stability and compatibility with various containers of disposable pumps were conducted and reported in many studies and are usually available on demand from pump manufacturers.^[16,45-47]

Other important factors to be considered are pump cost, pump convenience, and patient acceptance. Clinicians and home care practitioners should be aware of the peculiarities of the selected pump's performance, and patients should be given appropriate instructions on how to minimize any unwanted effects. For example, disposable infusers should always be allowed sufficient time to warm up after being stored in a refrigerator. Because of the possibility of elastomeric pumps bursting while filling, extra caution should be taken while using these pumps with cytotoxic drugs.^[20] Special care should be taken while delivering infusion therapies in areas with high variations in ambient temperatures and under pressures different from normal atmospheric pressure. Because of the reported problems with disposable pumps' delivery rates,

regular monitoring of infusion therapy progress is strongly recommended.

Conclusion

Despite some disadvantages and limited areas of applicability, disposable infusion pumps provide patients with advantages, such as portability, simplicity, and disposability, especially for the administration of analgesia. Understanding their physical and mechanical characteristics and their appropriate application may optimize patient care.

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Appendix: Commercially Available Disposable Infusion Pumps

Commercially Available Disposable Infusion Pumps

Device (Manufacturer)	Area(s) of Use	Availability
<i>Elastomeric pumps</i>		
Accufuser (Woo Young Medical Co.) ^[30]	Oncology, analgesia, antibiotics, cystic fibrosis, thalassemia, heparin	United States, United Kingdom, Europe
Accufuser Plus (Woo Young Medical Co.) ^[31]	Patient-controlled analgesia	United States, United Kingdom, Europe
Advance Silicone Infuser (Woo Young Medical Co.) ^[8]	Oncology, analgesia, antibiotics, cystic fibrosis, thalassemia, heparin	United States, United Kingdom, Europe
Baxter LV (Baxter Healthcare) ^[14,16,17,31]	Chemotherapy, analgesia, antibiotics, desferrioxamine	United States, United Kingdom, Europe
Baxter PCA Infusor (Baxter Healthcare) ^[12,20,24,33,41]	Patient-controlled analgesia	United States, United Kingdom, Europe
Baxter Two Day Infusor (Baxter Health care) ^[7,8,27]	Chemotherapy, analgesia, antibiotics, desferrioxamine	United States, United Kingdom, Europe
C-Bloc (I-Flow Corp.) ^[30,a]	Continuous analgesia	United States
C-Bloc Continuous Peripheral Nerve Block System (I-Flow Corp.) ^[46,a]	Continuous analgesia	United States, United Kingdom
Eclipse (Block Medical) ^[10,a]	Continuous analgesia	United States, Europe
Homepump (Block Medical) ^[10,18,19,a]	Continuous analgesia (postoperative)	United States, Europe
Homepump C-Series (Block Medical) ^[7,a]	Chemotherapy, analgesia, iron chelation therapy	United States, United Kingdom, Europe
Homepump E-Series (Block Medical) ^[7,a]	Short-term infusions of antibiotics	United States, United Kingdom, Europe
Intermate (Baxter Healthcare) ^[7,10,b]	Pain control, antimicrobials	United States
Large DIB (DIB International) ^[11]	Continuous regional analgesia	Japan
MedFlo (Secure Medical) ^[10,b]	Continuous analgesia	Recalled by FDA in 1994
MedFloII (MPS Acacia) ^[30]	Continuous regional analgesia	United States
Multirate Infuser LV (Baxter Healthcare) ^[11]	Chemotherapy, desferrioxamine, analgesia, antibiotics	United States, United Kingdom, Europe
ReadyMED (Alaris) ^[10,b]	Antibiotics, antivirals	United States, Canada
Singleday Infusor (Baxter Healthcare) ^[9]	Chemotherapy, analgesia, antibiotics, desferrioxamine	United States, United Kingdom, Europe

Surefuser (NIPRO)	Chemotherapy, analgesia, cystic fibrosis	United Kingdom, Europe, Japan
<i>Spring-powered pumps</i>		
beeLINE (McKinley Medical)	Chemotherapy, antibiotics, analgesia	United Kingdom
Linear-fuser (Terumo) ^[11]	Pain control	Japan
Pain Care 3200 (BREG) ^[31]	Postoperative analgesia	United States
Paragon (I-Flow Corp.) ^[7,9]	Chemotherapy, analgesia, iron chelation therapy, antibiotics	United States, United Kingdom, Europe
Sgarlato (Sgarlato Laboratories) ^[30,c]	Postoperative analgesia	United States
Sidekick (I-Flow Corp.) ^[7,10]	Short-term infusions of antibiotics	United States, United Kingdom, Europe
Springfuser (Go Medical Industries) ^[7,32]	Pain control, muscle relaxation drugs (atracurium, vecuronium)	United States, United Kingdom, Europe
SurgiPEACE Pain Control System (Sgarlato Laboratories) ^[27,c]	Pain management	United States
<i>Negative-pressure pumps</i>		
Coopdech Syrinjector (Daiken Medical) ^[11,39]	Anesthesia	Japan
Pain Pump (Stryker Instruments) ^[30]	Postoperative analgesia	United States

^[a]Three-layer drug reservoir; middle layer is composed of latex.

^[b]Single-layer latex drug reservoir.

^[c]Now known as the PainFree pump.

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