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Preparation of B. Braun Easypump® II elastomeric devices with Chemfort™ closed system transfer devices (CSTDs) in uncontrolled environments

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Background: Outpatient parenteral antimicrobial therapy (OPAT) enables patients to receive intravenous antimicrobials outside hospital settings. Elastomeric infusion devices facilitate continuous antibiotic delivery; however, limited stability data and constrained aseptic unit capacity have led some services to adopt nurse-led 'fresh-fill' preparation in uncontrolled environments, which may increase microbial contamination risk.

Objectives: To evaluate whether preparation of B. Braun Easypump® II elastomeric devices using Chemfort™ closed system transfer devices (CSTDs) in uncontrolled environments reduces microbial contamination compared with preparation using needles and syringes.

Methods: Forty-six elastomeric devices were prepared with tryptic soy broth by eight operators across three uncontrolled rooms using either Chemfort™ CSTDs ($n=23$) or needles and syringes ($n=23$). Aseptic non-touch technique was followed. Devices were incubated at 32°C for 7 days before microbiological testing. Environmental monitoring included settle plates and finger dabs. Fisher's exact test was used to analyse contamination rates.

Results: No contamination occurred in devices prepared using CSTDs (0/23), whereas 5/23 (22%) prepared using needles were contaminated. This difference was statistically significant ($P=0.0491$). Preparation times were shorter and more consistent using CSTDs (median 26 min; range 20–40) compared with needles and syringes (median 34 min; range 22–64).

Conclusions: Preparation using Chemfort™ CSTDs was associated with reduced microbial contamination and shorter preparation times compared with needle-based methods. CSTDs may provide a useful risk-reduction strategy for nurse-prepared elastomeric infusions in OPAT services, although further evaluation in larger studies is required.

Introduction

Outpatient parenteral antimicrobial therapy (OPAT) enables medically stable patients to receive intravenous antibiotics outside hospital settings.[1,2] OPAT services have expanded considerably over the past two decades and are associated with high patient satisfaction, improved quality of life, reduced healthcare-associated infections, lower costs, and clinical outcomes comparable to inpatient care.[3,4]

Despite these advantages, OPAT delivery is often limited by antimicrobial dosing requirements, particularly where frequent dosing or prolonged infusions are needed. Consequently, antibiotics suitable for bolus or short infusions are often preferred. Elastomeric infusion devices have become increasingly important within OPAT because they allow continuous 24-h delivery of antibiotics and can be replaced daily. The 2020 Carter Report identified OPAT expansion and wider availability of ready-to-administer antibiotics as key strategies for reducing unnecessary hospital admissions, estimating that OPAT could release up to 3000 inpatient beds daily in England.[2]

A major barrier to wider OPAT adoption is the limited availability of stability data for antibiotics in elastomeric devices.[5] NHS guidance requires evidence of stability at 32°C, reflecting near-body temperatures at which elastomeric devices are worn, yet suitable evidence is lacking for many antibiotics.[6,7] In response to supply delays, limited aseptic unit capacity, and stability challenges, some services have adopted 'fresh-fill' preparation of elastomeric devices by nurses in community settings, including patients' homes.[8–10] However, this practice introduces a recognized microbial contamination risk estimated at 1%–20% in ward environments, compared with <1% for aseptic unit preparation.[9,11,12]

Elastomeric devices may be particularly vulnerable due to their multi-step preparation process and prolonged exposure to warm temperatures during infusion.[11]

The B. Braun Chemfort™ system may help reduce microbial contamination risk by preventing microorganisms and particles from entering the system.[13] Chemfort™ is a closed system transfer device (CSTD) incorporating a Toxi-Guard® system that acts as a sterile and particulate barrier, displayed in Figure 1.[13] Its effectiveness has been demonstrated through compliance with the National Institute for Occupational Safety and Health (NIOSH) performance protocol for CSTDs.[14]

Further research is therefore required to determine the microbial risk associated with fresh-fill elastomeric devices and whether Chemfort™ CSTDs can reduce this risk.

Aim

To determine whether preparation of B. Braun Easypump® II elastomeric devices using Chemfort™ CSTDs in a non-sterile, uncontrolled environment reduces the risk of microbial contamination.

Primary objectives

- To assess whether Easypump® II elastomeric devices prepared using Chemfort™ CSTDs in an uncontrolled environment remain free from microbial contamination.
- To assess whether Easypump® II elastomeric devices prepared using needles and syringes in an uncontrolled environment remain free from microbial contamination.

Secondary objective

- To compare preparation times for devices prepared using Chemfort™ CSTDs versus needles and syringes.

Materials and methods

Before undertaking the study, training on the preparation process of the elastomeric devices with both CSTDs and needles/syringes was delivered by BBraun representatives.

Prior to preparation, the work area and tray were cleaned with alcohol wipes. Operators washed their hands, applied alcohol hand gel, donned nitrile gloves, and sprayed them with 70% denatured ethanol.

A total of 46 B. Braun Easypump® II elastomeric devices were prepared with tryptic soy broth, by eight different operators, under guided supervision (Supplementary Information Table S1 (available as Supplementary data at *JAC-AMR* Online) and Table S2). Of these, 23 were prepared using Chemfort™ CSTDs and 23 prepared using needles and syringes. The operators preparing the devices included nurses, pharmacists and pharmacy technicians. Aseptic non-touch technique was followed throughout. Full details are provided in the Supplementary Information. Preparation took place in three uncontrolled, ungraded rooms, to mimic the practice of fresh-fill in patients' homes. Different elastomeric devices were used to determine if the results were device dependent.

Each elastomeric device was filled to the maximum volume of 270 mL using 32 manipulation steps, to mimic the more complex preparations required. Device lines were not primed. During preparation, a settle plate was exposed for the duration of the procedure, and finger dab samples were taken at completion, to identify the potential microbial challenge to the system. Prepared devices were stored at 32°C for seven days to simulate near-body temperature conditions before transfer to an external analytical laboratory (Quality Control North West, Stockport, UK) for microbiological testing. A seven-day holding period was chosen to monitor the highest risk eventuality, for devices that infuse over 7 days. Devices and settle plates were incubated at 20°C–25°C for seven days followed by 30°C–35°C for seven days before assessment for microbial contamination.

Fertility testing was subsequently performed on five elastomeric devices using *A. brasiliensis*, *B. subtilis*, *S. aureus*, *C. albicans*, and *P. aeruginosa* to confirm that the tryptic soy broth supported microbial growth, based on guidance from the British Pharmacopoeia.[15]

Categorical data were analysed using Fisher's Exact Test, with $P < 0.05$ considered statistically significant. The null hypothesis stated that there would be no significant difference in contamination rates between devices prepared using CSTDs and those prepared using needles.

Results

Among the 46 elastomeric devices prepared, none of the 23 devices prepared using Chemfort™ CSTDs demonstrated microbial contamination, whereas 5/23 (22%) prepared using needles and syringes tested positive for contamination (Supplementary Information Tables S3 and S4). Fisher's Exact Test demonstrated a statistically significant reduction in contamination when CSTDs were used ($P = 0.0491$).

Fertility testing confirmed that all five broth samples supported growth of the test organisms, validating the suitability of tryptic soy broth as a growth medium (Supplementary Information Table S5).

Environmental monitoring through settle plates and finger dabs demonstrated microbial challenge during preparation. Species identified in contaminated devices included *Dermacoccus nishinomiyaensis*, *Kocuria rhizophila*, *Staphylococcus capitis*, and *Micrococcus luteus*. Only one contaminated device demonstrated matching organisms on both settle plates and finger dabs (Supplementary Information Tables S6–S8).

Preparation times varied across operators and rooms. Devices prepared using Chemfort™ CSTDs required 20–40 min (median 26 min), whereas needle-and-syringe preparation required 22–64 min (median 34 min), with several procedures exceeding one hour. Overall, CSTDs were associated with shorter and more consistent preparation times.

These findings demonstrate that Chemfort™ CSTDs were associated with lower microbial contamination rates and improved operational efficiency compared with needle-and-syringe preparation.

Discussion

This study confirms that preparation of elastomeric devices using needles in uncontrolled environments carries a measurable microbial contamination risk. These findings are consistent with previous research demonstrating increased microbial risk when injectable medicines are prepared outside aseptic units.[11,12] The results support concerns regarding 'fresh-fill' preparation practices used within some OPAT services.[9]

Although contamination was identified in several needle-prepared devices, no consistent relationship was observed between organisms isolated from elastomeric devices and those identified on settle plates or finger dabs. Consequently, the precise source of contamination could not be determined. While longer preparation times appeared to coincide with contamination events, this study was not designed to establish causality. Importantly, there is currently no evidence from this work that

Figure 1. Chemfort® Toxi-Guard® System[13].

contamination of elastomeric devices directly results in patient infection. OPAT services utilizing fresh-fill preparation have not reported increased infection rates, suggesting contamination does not necessarily translate into clinical harm.[8,10,16]

The study also demonstrated that Chemfort™ CSTDs substantially reduced microbial contamination compared with needle-and-syringe preparation, with no contaminated devices identified in the CSTD group. This suggests that Chemfort™ CSTDs may represent a valuable risk-reduction strategy for services undertaking fresh-fill preparation in uncontrolled environments. However, the sample size was limited, and absence of contamination does not confirm elimination of risk.

For patient safety, use of Chemfort™ CSTDs could therefore complement existing guidance on preparation of injectable medicines outside aseptic units. This includes administering preparations immediately, ideally within 30 min, and completing administration within 24 h.[11,17]

Additional safety considerations also remain relevant. The multi-step nature of elastomeric device preparation increases the potential for medication preparation errors. Injectable medicines are recognized as carrying a higher risk of error than other dosage forms, particularly outside controlled environments.[17,18] Risk assessments should therefore determine which medicines are suitable for nurse preparation and which require aseptic unit preparation. Outsourced ready-to-administer elastomeric devices produced under a Manufacturer's Specials Licence may also help address limited NHS aseptic capacity.[1,2] Other important risk-reduction measures include development of standardized procedures, staff training, and regular audit of practice.[17,18]

Alongside reduced contamination, Chemfort™ CSTDs demonstrated operational advantages. Preparation times were shorter and more consistent than with needles and syringes, potentially supporting workload management within busy OPAT services. Additional potential benefits include reduced occupational exposure to antibiotics, which may lower the risk of hypersensitivity reactions and other adverse effects among healthcare workers.[19]

Overall, these findings contribute evidence to an important operational challenge within OPAT services: maintaining safe and efficient preparation of elastomeric devices when aseptic unit capacity is limited. Although larger multicentre studies are required, this work provides a useful foundation for services considering implementation of nurse-prepared elastomeric infusions.

Conclusion

Preparation of elastomeric devices using Chemfort™ CSTDs in uncontrolled environments was associated with significantly lower microbial contamination and shorter preparation times than conventional needle-and-syringe preparation. These findings suggest that CSTDs may provide a useful risk-reduction strategy for nurse-led fresh-fill OPAT services where aseptic capacity is limited. However, the study was limited by its small sample size and simulated design, and the absence of contamination does not demonstrate elimination of risk or improved clinical outcomes. Larger real-world studies are needed to confirm these findings and evaluate their clinical impact.

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Supplementary data

Tables S1 to S6 is available as Supplementary data at *JAC-AMR* Online.

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