

Introduction

The need for a more reliable stopcock increases in an ever-advancing industry objective towards a safer and efficient care-giving environment. Addressing lipid-induced cracking is one way to reach these objectives. Lipid and chemical induced cracks and leakages are considered under-reported adverse events or mistakenly attributed to other circumstances. Resin manufacturers have long been exploring options for a more robust resin that can better handle lipids and other aggressive solutions commonly administered, mainly through the IV route. As an answer to this need and as part of our continuous effort to enhance patient and caregiver safety, Elcam Medical is now incorporating the Eastman Tritan™ copolyester - a new, robust resin that can help minimize chemical and lipid-induced cracking in a new line of stopcocks - the Elcam Medical SafeT™ stopcocks. The SafeT™ stopcocks have been tested and proven to be resistant to 10 different drugs including lipid and other aggressive substances and IPA (propranolol). (Elcam-Medical Document # 099094). The abstract of this study is hereby described.



Experiment Setup and Methods

Three types of stopcocks with identical body design made of 3 different raw materials (Tritan, Polysulfone (PSU), and Polycarbonate (PC), were exposed to 10 different drugs and one external alcohol-based disinfectant).

- Fusid
- Heparin
- Propofol
- Nimodipine
- Noradrenaline
- Actrapid
- Vancomycin
- Phenytoin Sodium/
Natrium
- Cyclosporine
- Intralipid
- IPA

The chosen drugs cover a range of clinical applications, with an emphasis on drugs which are known to be aggressive as well as various common drugs used to treat diabetes, blood pressure etc.

The stopcocks were subjected to exposure periods of 48 and 96 hours in order to examine them under frequent and maximal product use durations.

Overall 2112 stopcocks in 66 groups (3 types of stopcocks x 11 types of drugs x 2 exposure times), with each test group containing 32 stopcocks, were tested (66 groups x 32 units per group). All tested stopcocks were naturally aged for one year and underwent 80kGy radiation and 2 cycles of Ethylene Oxide (EtO) sterilization.

The tested stopcocks were assembled together in a chain formation and fastened with an applied torque of 20 In•Oz. Exposure testing was conducted by filling the chain of stopcocks with the tested solution/drug. Stopcock handles were adjusted in such a manner that the liquid reached all the passes including the side port.

A visual test using a magnifier and a leakage test were conducted once the exposure times to the drugs (after 48 and 96 hours) were completed. 4 of the Tritan groups (2 from each time frame) were also tested after 24 hours.

It is important to note that the stopcocks involved in this test underwent treatments that represent severe conditions such as exposure to a concentrated lipid solution (20%) and three cycles of Gamma radiation that is known to have a degrading effect on polymers.

Results

The Tritan stopcocks resisted all the drugs tested for 48 and 96 hours.

As shown in Table 1 - No leakage was observed in all test groups. No cracks were observed after exposure to Noradrenaline and Vancomycin and non-leaking cracks were observed after exposure to Fusid, Heparin, Propofol, Nimodipine, Actrapid (insulin), Phenytoin Sodium, Cyclosporine, Intralipid and IPA. During exposure to Fusid, Heparin Propofol and Actrapid, cracks were observed only after 96 hours of exposure.

The Polycarbonate stopcocks resisted 8 of the 11 tested drugs for 48 and 96 hours: No cracks were observed after exposure to Fusid, Heparin, Noradrenaline, Actrapid (insulin) and Vancomycin, and non-leaking cracks were observed after exposure to Propofol, Nimodipine and IPA. During exposure to Propofol, cracks were observed only after 96 hours of exposure.

Breakages which caused leakage were found after exposure to the following drugs: Phenytoin Sodium, Cyclosporine and Intralipid, where the stopcocks resisted the drugs for 24 hours but failed after 48 hours, as shown in Figures 1 - 3.

The Polysulphone stopcocks resisted 10 out of 11 drugs tested for 48 and 96 hours:

No cracks were observed after exposure to Heparin, Noradrenaline, Actrapid (insulin) and Vancomycin, and non-leaking cracks were observed after exposure to Fusid, Propofol, Nimodipine, Phenytoin Sodium, Intralipid and IPA. During exposure to Fusid and Propofol, cracks were observed only after 96 hours.

Breakages which caused leakage were found with exposure to Cyclosporine, as shown in figure 3.

Table 1

Type of drug tested - Test Results

Type of Stopcock	1 Fusid (Furosemide)	2 Heparin	3 Propofol	4 Nimodipine	5 Noradrenaline	6 Actrapid (Insulin)	7 Vancomycin	8 Phenytoin Sodium/ Natrium	9 Cyclosporine	10 Intralipid	11 IPA
A48-Tritan. Tested after 48 hrs	Intact	Intact	Intact	30% Non leaking cracks.	Intact	Intact	Intact	60% Non leaking cracks.	100% Non leaking cracks.	100% Non leaking cracks.	100% Non leaking cracks.
A96-Tritan. Tested after 96 hrs.	30% Non leaking cracks.	50% Non leaking cracks.	100% Non leaking cracks.	50% Non leaking cracks.	Intact	10% Non-leaking cracks.	Intact	40% Non leaking cracks.	100% Non leaking cracks.	100% Non leaking cracks.	100% Non leaking cracks.
B48-PC Tested after 48 hrs.	Intact	Intact	Intact	80% Non leaking cracks.	Intact	Intact	Intact	Breakages and leakage	Breakages and leakage	Leakage-resistant for 24 hrs. Breakages started after 48 hrs.	20% Non leaking cracks.
B96-PC Tested after 96 hrs.	Intact	Intact	30% Non leaking cracks.	50% Non leaking cracks.	Intact	Intact	Intact	Breakages and leakage	Breakages and leakage	Breakages. Not Intact.	30% Non leaking cracks.
C48-PSU Tested after 48 hrs.	Intact	Intact	Intact	95% Non leaking cracks.	Intact	Intact	Intact	95% Non leaking cracks.	Breakages and leakage	70% Non leaking cracks.	90% Non leaking cracks.
C96-PSU Tested after 96 hrs.	10% Non leaking cracks.	Intact	Intact	100% Non leaking cracks.	Intact	Intact	Intact	15% Non leaking cracks.	Breakages and leakage	80% Non leaking cracks.	60% Non leaking cracks.

Figure 1 **Results of stopcocks exposure to Intralipid**

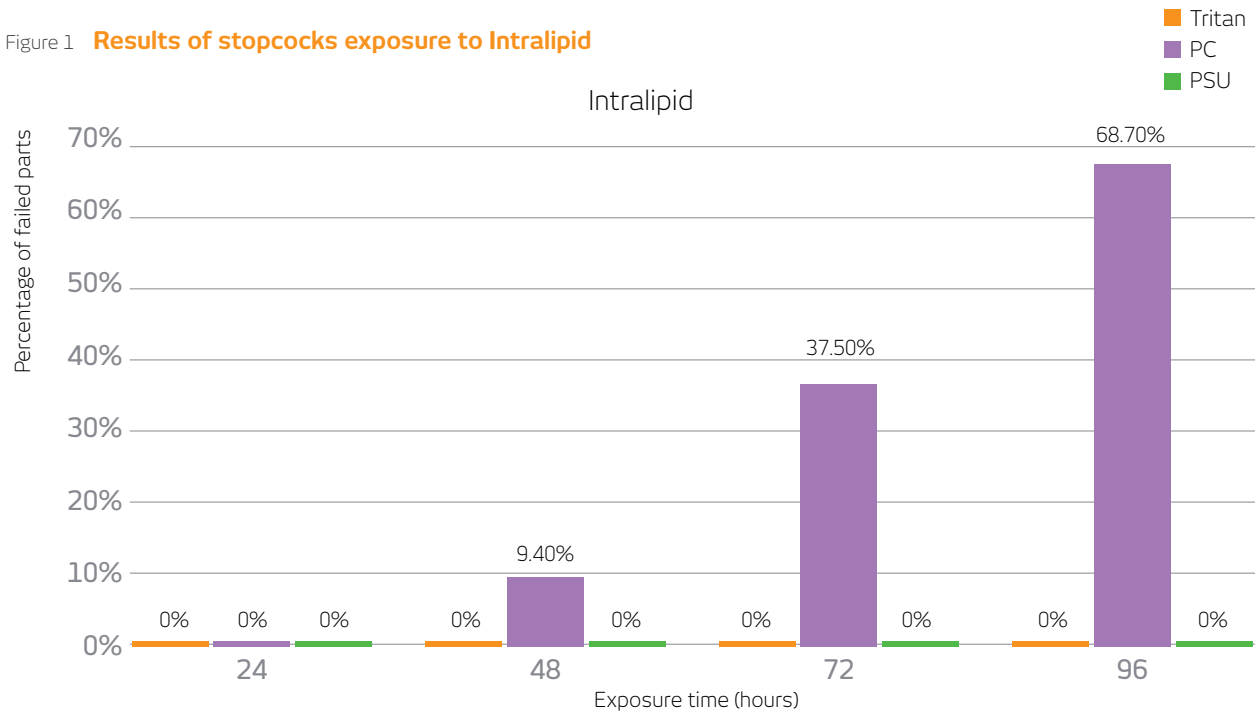


Figure 2

Results of stopcocks exposure to Phenytoin sodium

■ Tritan
■ PC
■ PSU

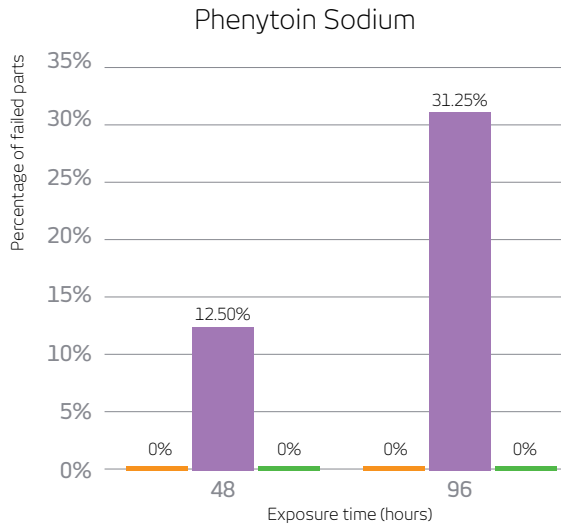
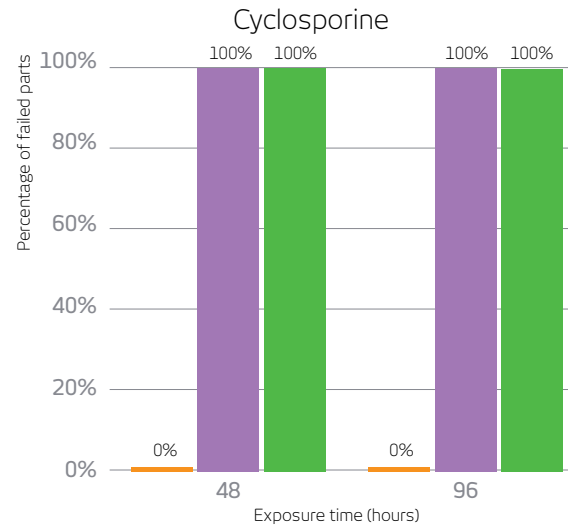


Figure 3

Results of stopcocks exposure to Cyclosporine

■ Tritan
■ PC
■ PSU



Conclusions

The Tritan stopcocks withstood exposure to all drugs and disinfectants tested in this trial.

The Polycarbonate stopcocks withstood all the materials except for Phenytoin Sodium / Natrium and Cyclosporine, and continue to be limited for use with Intralipid for up to 24 hours.

The Polysuophone stopcocks withstood exposure to most of the drugs and disinfectants during the trial, with the exception of Cyclosporine.

It can be concluded that under reasonable industrial conditions and clinical use the SafeT™ (Tritan integrated) Stopcock can be used for up to 96 hours , including for administration of lipid-based solutions and other aggressive drugs as detailed in this document.

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