World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:11, No:7, 2017

Investigation of Solvent Effect on Viscosity of Lubricant in Disposable Medical Devices

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***Abstract*—**The effects of type and amount of solvent on lubricant which is used in disposable medical devices are investigated in this article. Two kinds of common solvent, n-Hexane and n-Heptane, are used. The mechanical behavior of syringe has shown that n-Heptane has better mixing ratio and also more effective spray process in the barrel of syringe than n-Hexane because of similar solubility parameter to silicon oil. The results revealed that movement of plunger in the barrel increases when pure silicone is used because non-uniform film is created on the surface of barrel, and also, it seems that the form of silicon is converted from oil to gel due to sterilization process. The results showed that the convenient mixing ratio of solvent/lubricant oil is 80/20.

***Keywords*—**Disposable medical devices, lubricant oil, solvent effect, solubility parameter.

I. Introduction

TODAY, the disposable syringes are usually used for drug injections, and one of the important syringes in this category is three-part syringe [1], [2].

Three-part syringe are the syringes in which the connection between plunger and injection fluid is made by a piece of natural rubber or isoprene rubber.

For the better filling process of liquid and its injection in the syringe, a lubricant is used at the production and assembly stage in the barrel. Drug filling and injection without such lubricant is usually impossible.

Some properties of this lubricant due to its combination with injected drug are biocompatibility, degradation, and alteration of its chemical and physical properties after sterilization. Among these properties is the efficiency of its lubricancy characterization after sterilization [3].

Silicon oil is the most commonly used lubricant for medical devices because of its good properties such as stagnancy, highly hydrophobicity, viscoelastic properties, and good biocompatibility properties [4].

When silicon oil is sprayed in the barrel of syringe, it is placed on the surface as a thin film and it plays a lubricant role between gasket of plunger and wall of barrel [5]. Moreover, increasing the amount of lubricant causes accumulation on the surface of syringe barrel, and therefore, in addition to oily and poor appearance, a significant amount will be injected to patient's body and will cause unwanted damages. Hence, normally such lubricants which are usually silicone oil, get mixed with hydrocarbon solvents and are used as a compound and it is assumed that the solvent evaporates during sterilization and a thin layer of silicone oil will be left on the surface.

In this paper, the effect of solvent on physical properties of syringe before and after sterilization is investigated, and a good solution to this matter is proposed.

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II. Testing Methods and Materials

A. Materials

In this paper, a one-piece insulin syringe with the volume of 1 cc and a natural rubber gasket (donated by Bespar San'at Fakher Company) is used. Medical grade silicone oil with 12,000 mPa.s viscosity is used as lubricant. Also, n-Heptane and n-Hexane as solvent are used. Rate of mixtures of silicone oil and two solvents is shown in Table I:

TABLE I
Mixing Ratio of Silicon Oil/Solvent

SAMPLES	1	2	3	4	5
%SILICON	100	80	60	40	20
%SOLVENT	0	20	40	60	80

B. Mixing Procedure

First of all, the appropriate amount of silicon oil and solvents was weighted by digital balance with readability of 0.0001 g, and then, it was put in the closed container because of high evaporation of n-Hexane and n-Heptane. The mixture of two kinds of solvents and silicon oil was sprayed in the barrel of syringe, and then, the plunger and gasket and needle of syringe were assembled with syringe assembly machine. Finally, they were packaged with the paper and film packaging.

C. Sterilization Process

Sterilization process used which is identical to insulin syringe sterilization is as follows: at the first step, the steam was injected into the chamber to prepare the paper of packaging for entering the ethylene oxide gas, then ETO was entered to the chamber with concentration about 98%. The pressure was about +50 kPa, and the temperature was about 50 °C. The syringe was remained in the chamber for 8h then the EO gas was vacuumed.

D. Tensile and Compression Test

Tensile and compression test on syringes is done by using GT-TCS2000 Universal Testing manufactured by Taiwan GOTECH Company with modified grips.

III. Discussion and Analysis of Results

In Fig. 1, tensile and compression strength of piston movement in barrel to examine solubility of silicone and n-Hexane before sterilization is shown. As can be seen, when the amount of solvent in the mixture increases, resistance to movement reduces slightly. However, this reduction is not significant.

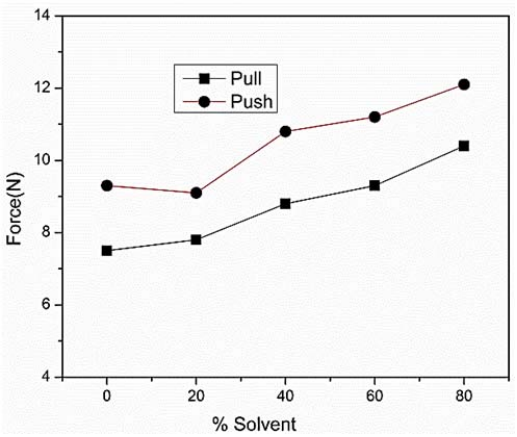

Fig. 1 Tensile and compression of syringe with n-Hexane before sterilization

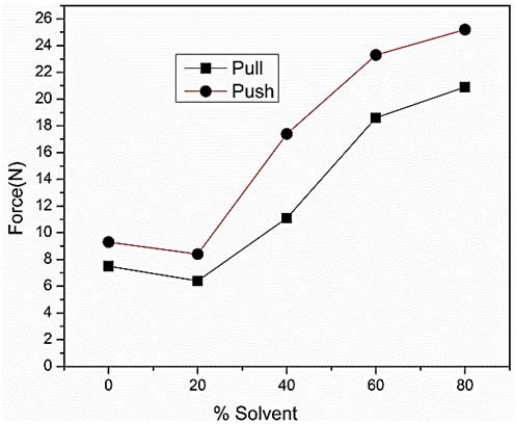

Fig. 2 Tensile and compression of syringe with n-Hexane after sterilization

In Fig. 2, tensile and compression strength of piston movement with n-Hexane is shown. As can be seen, movement resistance reduces with the reduction of the amount of solvent. This reduction is noticeable compared to the test done before sterilization.

As it is shown in Figs. 1 and 2, the pulling and pushing force for silicon oil without any solvent is not different before and after sterilization process. By increasing the ratio of solvent in the mixture of solvent/silicon oil, the resistance of movement of plunger in the barrel increased.

The difference of pushing force for mixture of n-Hexane/ silicon oil for 80% of solvent before and after sterilization process is about 100%. This difference for pulling force is about 90%. This increase in the resistance arises because of evaporation of solvent after sterilization process. When the solvent was evaporated after sterilization process, just a thin film of silicon oil is on the surface of barrel, so the resistance against movement increased.

The mentioned reduction which can be seen in Figs. 1 and 2 is due to solvent evaporation during sterilization process. In this case, a thin film of silicone forms on the barrel surface, and this layer causes piston slippage in the barrel and also movement resistance. It is clear that, with reduction in the amount of oil, the movement resistance increases tremendously and stays above optimum standard level.

The remarkable point in Figs. 1 and 2 is the higher level of movement resistance in pure silicone compared to the time when 20% solvent is used. This is due to the formation of a uniform film on barrel surface when 20% solvent is used as opposed to pure silicone which causes more movement resistance due to an uninform layer of silicone on the surface and accumulation of thick silicone particles in scattered locations. Also, it was observed that the form of silicon oil changed from oil to gel. It means that silicon in the gel form resists against the movement of plunger in the barrel.

Fig. 3 shows the resistance of plunger movement in the barrel with n-Heptane. As can be seen, with the increase of the amount of solvent, the tensile and compression strength increases quite unnoticeably, which results in reduction of piston slippage.

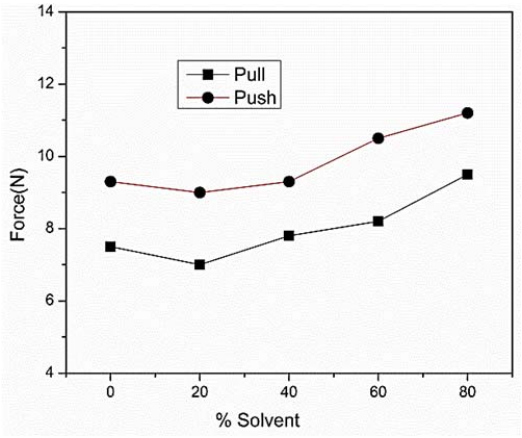

Fig. 3 Tensile and compression of syringe with n-Heptane before sterilization

Unnoticeable increase of tensile and compression strength can be caused by a little slippage because of the solvent itself.

Fig. 4 shows the resistance to slippage caused by different percentages of n-Heptane. As it can be seen in Figs. 3 and 4, the resistance to slippage increases by increasing the ratio of solvent in the mixture. The difference between pushing force before and after sterilization process for 80% ratio of solvent is about 72%. This difference for pulling is about 76%.

The lower difference between amount of pulling and pushing force for n-Heptane is an evidence for better solubility of solvent and silicon oil and also lower evaporation rate for this solvent. Because of higher molecular weight and near solubility parameter of n-Heptane versus n-Hexane, the movement of plunger in the barrel for n-Heptane is easier than

n-Hexane.

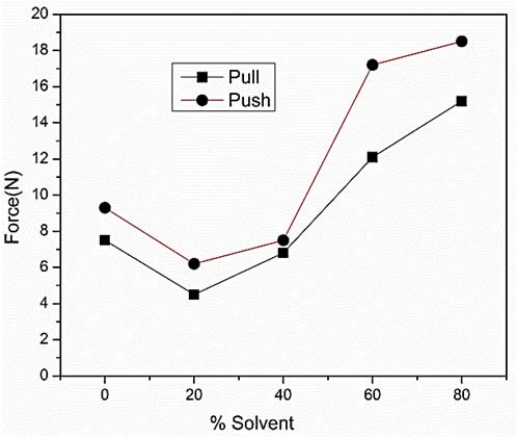

Fig. 4 Tensile and compression of syringe with n-Heptane after sterilization

Like the effects of using n-Hexane, the effect of solvent evaporation can also be seen here. As the amount of silicone oil reduces in the compound used, a significant reduction in piston slippage is seen.

Like the provided results on n-Hexane, combination of 20% solvent and 80% silicone oil provides best slippage in this case. A complete layer on the surface could be the reason for the results obtained. However, with further reduction of silicone oil, the tensile and compression strength of movement plunger in the syringe increases due to the less ticker layer of lubricant.

Figs. 5 and 6 are the comparison made between tensile and compressive strength for different percentages of two solvents, heptane and hexane. As can be seen, n-Heptane has better slippage in different percentages. As can be seen in Fig. 5, when 20% solvent is used in the mixture with silicon oil, the difference between pulling force of n-Heptane and n-Hexane is about 55%. While the rate of solvent is increased, the difference between pulling force of two solvents is reduced to about 33% for mixing ratio of silicon oil/solvent 80%. This phenomenon comes from better mixture of solvent and silicon oil with n-Heptane against n-Hexane.

The silicon oil has lubricant role in the syringe, so the viscosity properties of lubricant are more significant in this application.

When the mixing ratio of solvent and silicon oil is about 20%, role of solvent is more important than mixing ratio 80%. In the case of 20% solubility, parameters of silicon oil and solvent play an important role in the mixture because, when the solubility parameters of each phase are near the mixture, it will have better viscosity properties.

The solubility parameters of n-Hexane and n-Heptane are about 7.24 and 7.4. This parameter is about 7.3 for silicon oil [6].

In the case of 80%, the difference of pulling force of two solvents is lower because the viscosity of two solvents is the same and the ratio of silicon oil is about 20% in the mixture, so the role of solubility parameter is lower than 20%.

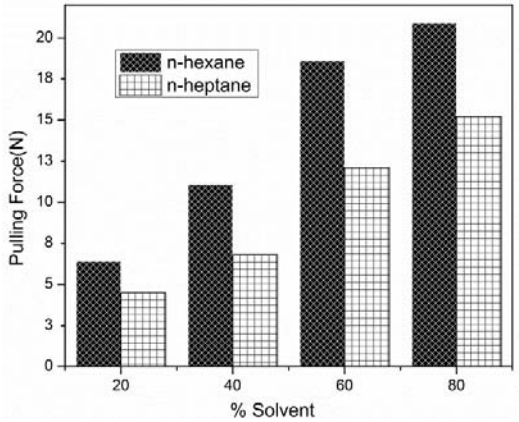

Fig. 5 Comparison pulling force of syringe between two solvents

Fig. 6 shows the pushing force results for all samples. As it can be observed, the same results are obtained. The difference between pushing force of two solvents is about 50% for mixing ratio 20%. This difference for mixing ratio 80% is about 26%.

In the all cases, n-Hexane shows a more desirable resistance to moving plunger in the barrel than n-Heptane. It means that the mixture of n-Hexane and silicon oil has lower effect on pushing force of samples because of lower solubility between them. As a result, they cannot make uniform film on the surface of barrel against n-Heptane.

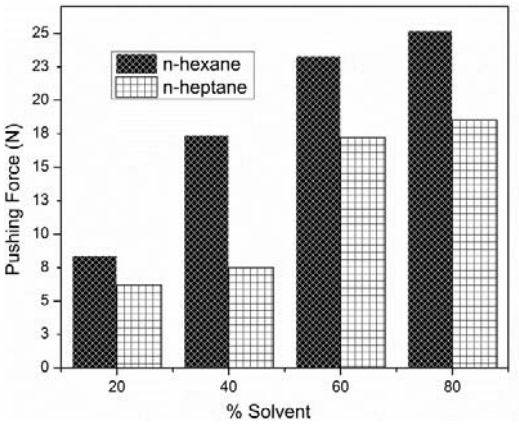

Fig. 6 Comparison pushing force of syringe between two solvents

This case could be the result of two factors:

1- The closer rate of solubility parameter of heptane with silicone compared to hexane results in better combination of heptane and silicone. This factor could be viewed as an important factor since better combination of solvent and silicone could cause a better and more complete layer of film on the surface of syringe barrel.
2- Higher molecular weight of n-Heptane causes reduction in evaporation during sterilization process.

IV. Conclusion

In this paper, the effect of adding the two solvents, Heptane and Hexane, to silicone oil used in lubrication of barrel in

three part syringes was examined. The results show that the sterile process increases the resistance against movement of plunger. Because, when the solvent was evaporated in the sterilization process, the thin film of silicon oil was remained on the surface of the barrel, so the resistance of movement will be increased.

Also by comparing the results, it can be concluded that n-Heptane is better and more effective on piston slippage in syringe barrel as opposed to hexane, which may be the result of slower n-Heptane evaporation in sterilization process and better combination of it with silicone oil.

The results from tensile and compression test also show that splash of silicone oil with 20% solvent has a far greater impact on slippery property than uniform pure silicone oil, and this factor could be the result of formation of a uniform and complete film on the surface of syringe barrel.

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