

Evaluation of the Operating Lifetime of Co-Polymer Liners used in Blood Bank Centrifuges

Mohammad FallahTafti^{1*}, Reza Morshedlou² and Mehdi N. Zanjani²

¹Blood Transfusion Research Center, High Institute for Research and Education in Transfusion Medicine, Tehran, Iran; m.falah@ibto.ir

²Sina Ebtekar Company, Iran; rezamorshedlou@gmail.com, payafrrpart@hotmail.com

Abstract

Estimating the operation lifetime of rotating parts of the medical blood bank centrifuges is very important for designers, manufactures of medical equipment and also for the operators of medical laboratories. These rotating parts such as the buckets and the liners usually experience high mechanical stresses due to heavy dynamically loads of centrifuge process. It is well known that the fatigue phenomenon is a main reason for failure of these type parts. At this study the lifetime of the Polymeric liners produced by the Iranian Sina Ebtekar company, ISECo, that utilized by the Iranian Blood Transfusion Organization, IBTO, is evaluated experimentally and by modeling with the finite element method, FEM. Randomly, a number of 36 Polypropylene liners from 2000 liners produced by the ISE Company is selected and labeled as samples. The lifetimes of the samples are recorded for a period of 12 months while they were in service simultaneously. Also by an FEM analysis, the maximum stresses occurred within the liners due to rotating loads of centrifugation is calculated. Then the lifetime of the SE Company liners is calculated based on the maximum stress of the product and the S-N fatigue life curve of Polypropylene material. A good consistency is observed between the experimental and analytical results. Based on the results of the current research, a new correlation is presented for estimating the liners. This correlation can be implemented in a maintenance program for prevent of unexpected failure of the liners that may harms the safety and health of the machine's operators.

Keywords: Blood Bank Centrifuges, Failure Prediction, Fatigue Stress, FEM Analysis, Polypropylene Liners

1. Introduction

The aim of this study is to find a method to estimate the lifetime of blood centrifuge's liners and developing an instruction for preventative maintenance of them. For any part of a device the designer must have an estimation of lifetime according to measured statistics and/or analytical data.

As in the Application Information Manual from Beckman Coulter¹ mentioned because high throughput and versatility of differential centrifugation, it's a primary method for processing the blood. Separation of cellular constituents within blood can be achieved by this process². The separated blood components can subsequently be used for their respective clinical and scientific applications and investigations¹. An important part in

centrifuge machines is liner and the material that used for liners is polymeric material and mainly polypropylene materials. Co-polymers and homo-polymers both are used but in the case that is analyzed here, co-polymer is the material that used in liner manufacturing. As we know in blood centrifuge machines, the blood bags, liners and buckets are under centrifugal force and this force is the cause of separation of the blood components. As it's comprehensible from Vincenzo Vulla's entries³. During the blood processing, liners and others parts with rotational motion are under continuous loading, which starts from zero and reaches to a maximum stress, and stays in that stress limitation for a certain time. Subsequently, by braking function, the amount of stress in parts like liners decreases to the zero again. From this and Parker A. P.⁴ we can understand the assessment of load conditions indicates that the

*Author for correspondence

dominant failure mechanism is fatigue. Nihat Ozkaya and et al.⁵ explained that loads that may not cause the failure of a structure in a single application may cause fracture when applied repeatedly. Failure may occur after few cycles of loading and unloading, or after millions of cycle, depending on the amplitude of the applied load. Fracture due to repeated loading is called fatigue. In this mechanism fracture occurs under the stress caused by repeated loading and unloading, while the amount of this stress is lower than the yield stress in steady state loading⁶. Fatigue is the main reason of mechanical failure at least in 90 % of fractures during operating and it's dangerous, because it occurs without any previous warning or obvious signs⁷.

According to Michael R. et al. entries⁸ it's possible for fatigue and creep phenomenon to predict the lifetime analytically. Knowing the lifetime of a part like liners is important for experts and managers who work in blood bank centers, companies that support blood bank centers in instruments supply, preventative maintenance and design or manufacturing parts. Because knowing the lifetime of parts will help to reduce possible damage to peoples and decrease the loss of life. Moreover the blood supply chain has linked with human health and any unwanted failure in blood processing system can interrupt this chain. According to this need the study was done. Loading conditions in centrifuge machines indicate that the dominant cause determined the lifetime of liners is fatigue. Richard G.⁸ said the methods of fatigue failure analysis represent a combination of engineering and science. The combination of using standard material data for fatigue and stress analysis should be done to achieve the lifetime range. But like every analytical study the experimental results can confirm the analytical results.

2. Analysis Method

In this study experimental results are based on considering the lifetime of 36 liners in 6 blood bank centers in Mashhad. For analytical study of lifetime of liners a chain of engineering steps were done: a) Determining of loading conditions b) Modeling the system in a CAD software, c) Stress analyzing in a FEM software, d) Extract the rare results of lifetime from fatigue standard data based on maximum stress in liners and making and finally e) Using an innovative formula for constructing a sample instruction for predicting lifetime of liners in a blood bank centers an also determining when the liners must be replaced by new ones before unwanted failure.

To evaluate the lifetimes of liners made in Sina Ebtekar Company before use in blood separation process, two blood bank centrifuges from one of six blood bank centers of IBTO in Mashhad were considered. The main reason for this selection was that the base of maintenance supply unit of Sina Ebtekar Company is in Mashhad and the recording experimental results are a time consuming work and need the cooperation of these units. For this study 36 Polypropylene liners of brand Sina Ebtekar Plus were randomly selected from 2000 liners and the lifetime of these liners was studied for 11 months. Normally the amount of load mass for each liner during a cycle was about 500 gr and the RCF was between 4500 to 5000 rpm.

Simultaneously with the gathering the statistics of 36 liners lifetime, the lifetime of liners were estimated scientifically. In this method by reviewing the loading conditions, determining the initial and boundary conditions and material characteristics of liners and using the Finite Element Method (FEM) analyses, the maximum stress due to cyclic load (repeated loading and unloading of accelerating and braking) was extracted (Figure 1). Then by using information of the stress-strain curves of Nano-Composite Polypropylene (Figure 2)⁹ and by mapping the maximum stress of liners from FEM analysis onto (S-N) Fatigue Life Curve of the polypropylene material of liner (Figure 3)⁹ the "Stress-Number of Lifetime Cycles", were extracted and shown in Figure 4 and the liners lifetime were estimated (in cycles).

Therefore first, 3D modeling of system has done by SolidWorks® modeling software according to its actual dimensions. For obtaining the maximum stress in part during cyclic loading the finite element analysis is used. COSMOS software has been used for this method and by simulation operating conditions of liners, stresses on the

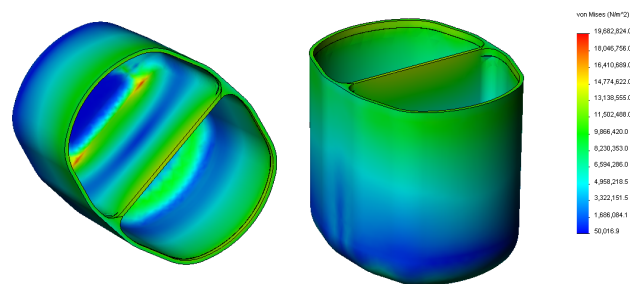


Figure 1. The FEM results of the stress contours occurred in a liner during centrifuge process. The maximum stress, Von Mises, was estimated about 20 MPa.

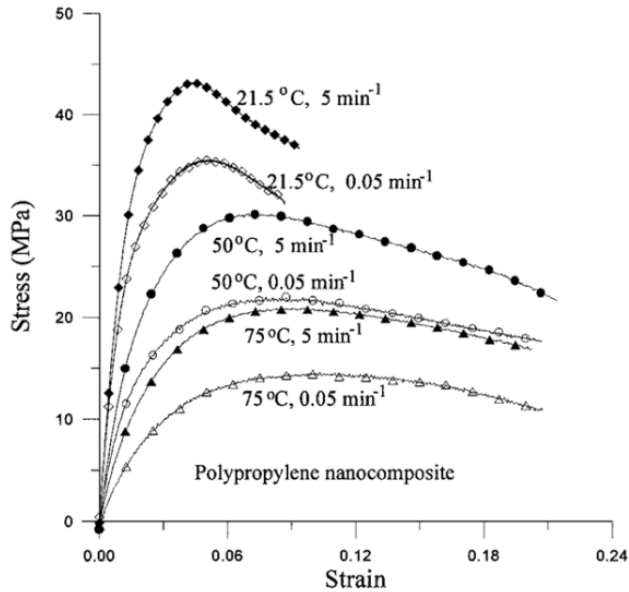


Figure 2. The stress-strain curves of nano-composite polypropylene materials in various temperatures and load rates⁹.

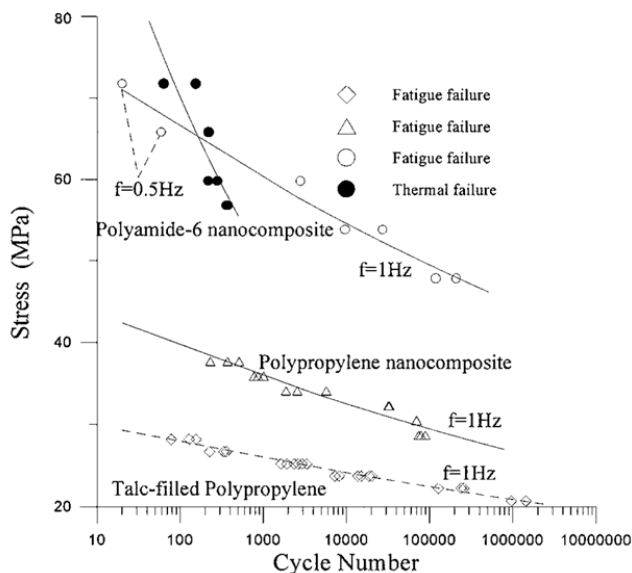


Figure 3. The fatigue characteristics of polypropylene material or the “Stress verses the number of cycles of lifetime”⁹.

body of liner has been calculated. According to decrease the amounts of unnecessary calculations, before starting mesh generation, provided 3D model was simplified in the region far from the stress concentration points. For modeling blood bags in the liner, by considering weight and volume of bags, the irregular geometric square was used. According to material characteristics of liners,

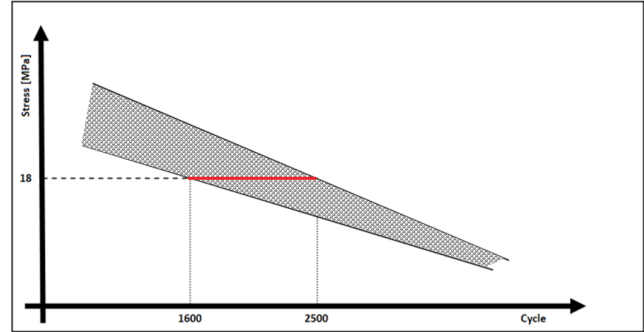


Figure 4. The fatigue analysis diagram.

the Mechanical property of liners for “Static Structural Characteristics” has been considered as “Linear Elastic-Isotropic” with elasticity modulus of 1.2GPa and Poisson’s ratio of 0.41. Loading has done as a Centrifuge Rotation with a rotational speed of 4000 RPM and the radius of rotor has been considered 280 mm. These conditions caused 5000 unit for RCF. It has been observed that maximum stress σ is approximately 18 to 20 MPa.

Briefly, for lifetime assessment analytically based on fatigue, following phases were done step by step:

- The loading conditions were assessed. During this step the boundary conditions and initial conditions were defined.
- CAD Model of system was built in SOLIDWORKS software and export in standard CAD Format for Finite Element analysis.
- Finite Element Model of System was built in COSMOS software. Pyramid elements with four node and linear shape function were used.
- Material Characteristics, boundary conditions and initial conditions were imposed to FE model and the problem was solved by using default setting. The most important result of FEM was the maximum stress in liner part during centrifugation operation.
- Based on results of FEM and using fatigue data for material of liner (co-polymer polypropylene) the life-time of liners was estimated in cycles (the number of repeated loading and unloading that liner can bear to show the first sign of fracture). This result is adequate for any designer. But in order to prevent unwanted failure and loss of life, every technician of preventative maintenance system or technical staff of blood bank centers needs to know how many days the liners must be used and according to their own daily schedule when liners need to be replaced with new ones.

- Finally, according to plan for daily blood bags that processed in each center, a simple but applicable formula was developed. It is useful for each machine, because some centers have more than one machine for blood processing. So it's possible to know how many days a liner could be used.

3. Results and Discussion

After studying experimental data in upper and lower bound of lifetime are presented Table 1. The present experimental and analytical results show that the most accurate predicted lifetime according to fatigue data of polypropylene have 97% true results about 3% of liners have lifetime lesser than predicted amount and 75% of liners have lifetime between lower and upper bound (1600 to 2500 cycles). About 22% of liners have lifetime more than predicted amount. This result has shown clearly in Figure 5, and indicates to prevent unwanted failure with 97% probability consider the lower bound of lifetime. If the upper bound is considered the probability of unwanted failing is 78% and it's not advised.

Here we presented a Hypothetical formula which could be used to estimate possible working time of copolymer liners in the centrifuges of any blood bank with the same circumstance.

Formula for lifetime of liners is used by appropriate amounts of variables:

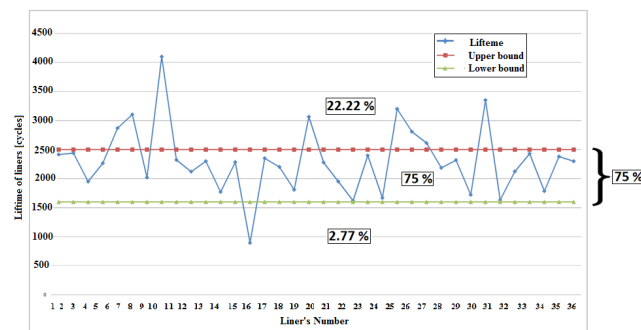


Figure 5. The lifetime of the 36 liners that measured experimentally. The numbers wrote on the figure show the percentage of samples in that bounds.

Table 1. The main instruction for replacement the liners of Sina Ebtekar Company in a preventative maintenance system.

Number of blood bags per day	50	60	80	100
Lifetime (day)	192	160	120	96

- The lifetime of liner in cycle = $L_{Cycles} = L_c = 1600$ (lower bound) or 2500 (upper bound)
- The number of liners that used in a blood centrifuge machine = $N_L = 6$
- The number of blood bags that processed daily in a blood bank center = $N_B = \text{variable}$
- The number of separating operations on each blood bag = $N_p = 1$ or 2 or 3 (in this study = 1)

By means of this amount could find the lifetime in days:

$$L_{D(\text{lower bound of lifetime})} = \frac{L_C \times N_L}{N_B \times N_p} = \frac{1600 \times 6}{N_B}$$

or

$$L_{D(\text{upper bound of lifetime})} = \frac{L_C \times N_L}{N_B \times N_p} = \frac{2500 \times 6}{N_B}$$

These functions are hyperbolic (Figure 6). Comparing between experimental and analytical lifetimes shows reasonably compatibility.

In Table 1 show the lower bound lifetime (1600 cycles) of “Sina Ebtekar Plus” liners. It can be seen that 75% of these liners have lifetime between 1600 and 2500 cycles. It's advised that this amount of lifetime consider as the ultimate lifetime of liners. By this assumption you can prevent of 97% of unwanted failure. The stress contour extracted from FEM analysis that occurs in a liner

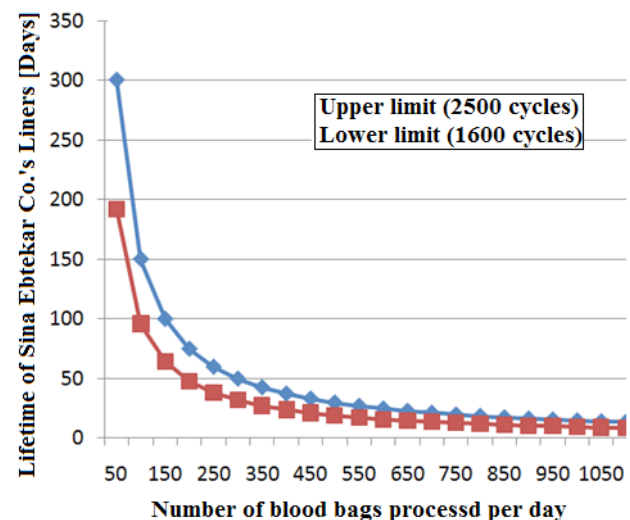


Figure 6. Upper and lower fatigue life of liners in days respect to the numbers of blood bags that processed daily in a blood bank center.

during operation of blood centrifuge is shown in Figure 1. The maximum amount of stress is estimated about 18 to 20 MPa. In Figure 2 the stress-strain curves of Nano-Composite polypropylene in various temperatures and various load rates are shown⁹. Figure 3 show the fatigue characteristics of polypropylene. In this diagram the “Stress-number of Cycles of Lifetime” (S-N curves) for polypropylene (Nano-Composite and Talc-Filled) are presented⁹.

The fatigue analysis diagram is presented in Figure 4. It is based on mapping of the maximum stress of liners from FEM analysis onto the curves of fatigue characteristics of liners material in Figure 3.

In Figure 5, the lifetime of 36 liners that measured experimentally are presented. The results show that if the lower bound lifetime (1600 cycles) is considered that unwanted failures will not occur with 97% probability.

In Figure 6, the curves of “upper and lower fatigue life of liners” in days upon “the numbers of blood bags that processed daily in a blood bank center” are shown. The analytical results show that the lifetime should be between 1600 Cycles (Lower Predicted Bound) and 2500 Cycles (Upper Predicted Bound). Curves are formed by output of the innovative formula with locating appropriate amount for variables.

3.1 Fatigue Study

In this paper, fatigue effects of centrifugal stresses on polymer liners of blood bank centrifuges was considered for determining the operating lifetime. By considering the number of permissible cycles until fatigue fracture of the liner's material, the number of the operating days of liners determined by using the maximum stress cycles which calculated from finite element static analysis.

3.2 Liner Lifetime Calculation

The liners of blood bank centrifuges has been used daily routine and variable with blood bank center and day to day, so counting the number of times a liner has been used is difficult or perhaps impossible. If the mean value of daily input of a blood bank center is considered as a constant, then the following procedure can be useful. When you have the lifetime of liners (in cycles) by using fatigue analysis, it should convert to the lifetime of liner (in days) according to the daily mean value input of blood bank centers. For this an innovative formula was developed and presented.

In result section can see that by putting appropriate value to variables ((L_c , N_L , N_p)) a function was built that in it:

$$L_D = f(N_B)$$

According to the operating lifetime curves obtained shown in Figure 6, the replacement time for liners of blood bank centrifuges was presented for each liner of blood transfusion center. For example, maximum operating lifetime of a liner used in a blood bank centrifuge machine which centrifuges 100 blood bags per a day is 96 days or 3 months.

3.3 Fatigue Characteristics of Liners' Material

On the contrary of polymeric material in metals, theoretical fatigue basis and failure are relatively developed topics¹⁰. According to Maxwell entries¹¹ it's clear that mechanical characteristics of polymers are so sensitive to changes in temperature, strain rate, thermal conditions and chemical nature of environment, like presence of water, oxygen and organic solvents. William D.¹² has mentioned in his book the behavior of polymers according to the frequency is more sensitive than metals. Cycling Polymers at high frequency and /or relatively large stresses can cause localized heating consequently; failure may be due to a softening of material rather than as a result of typical fatigue processes¹². In order to increase mechanical properties such as increasing the Impact resistance and economical production of polymers, the polymer science researchers succeeded to make a group of polymers called copolymers.

In this structure two or multi different monomers with regular or irregular sorts form a copolymer. Polypropylene is one of the thermoplastic polymers. Polypropylene homopolymer has higher submission stability than polypropylene copolymer and is comparable with high-density polyethylene. Polypropylene copolymer is more flexible than polypropylene homo polymer¹³. In this study two aspects of polypropylene characteristics are needed; “Static Structural Characteristics” and “Fatigue Characteristics”. These data was used according to references^{14,15}. For liner production either homo polymer or copolymer could be used. But the liners which were used for experimental tests were copolymers.

3.4 Load Conditions for Fatigue Study

Assessment of external and internal forces due to centrifugal forces that imposed on liners provides condition

for analytical method. After 3D modeling of system and using FEM analyses according to method explained in previous section are done. It has been observed that maximum stress σ is approximately 18 to 20 MPa. This is the sign of sensitivity of this part and it shows the prediction of starting fracture from this part. Centrifugal force during accelerating and braking make a cyclic loading with this maximum stress. Therefore this maximum stress is critical stress for fatigue analysis.

3.5 Fatigue Analysis

In order to determine the number of operating cycles that could be beard by liners until fatigue failure the Fatigue Analysis must be used. According to the results of the finite element analysis that maximum stress is 18 to 20 MPa and by using S-N curve can find endurance cycles of liners. The procedure determines that numbers of fatigue fracture cycles are in a bound between 1600 to 2500 cycles. This bound selected for conditions that operating temperature was 2 to 20 °C because the temperature affects the all characteristics of polypropylene more than anticipation¹⁵ and the safety factor was between 2 and 3⁹. For other operational temperatures and safety factors changing operation lifetime is indispensable.

4. Conclusion

Taken together, our hypothetically presented formula is working when the liners of model "Sina Ebtekar Plus" of copolymer polypropylene are taken under centrifugal force with RCF between 4500 to 5000 unit and temperature must be between 2 to 20 °C. Also other destructive factors like solvents and humidity was not considered. For fatigue characteristics, the material grade and filers that during plastic product injection can be used are very important. Dimension scale of plastic product that affects the cooling time during plastic product injection is a factor that can change fatigue behavior of a plastic product. Surface smoothness of liners is also important. According to these situations in this study, fatigue effects of centrifugal stresses on polymer liners of blood bank centrifuges of model "Sina Ebtekar Plus" was considered for determining the operating lifetime of them. Also experimental tests were done to validate the analytical results. The results of this study are applicable both for designers and staff of preventative maintenance system.

5. Acknowledgement

The authors should appreciate from the Sina Ebtekar Company and the Iranian Blood Transfusion Organization for their supports of this research.

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