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ASSESSMENT OF THE OPERATING LIFETIME OF COPOLYMER LINERS USING A NOVEL FORMULA

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Abstract:-
Preventive assessment of liners' lifetime is very important for the public health. Fatigue is the main reason of mechanical failure at least in 90 % of fractures during blood banks 'centrifuges operations. The aim of this study is to develop a formula to estimate lifetime of polymeric liners. The results from experimental and analytical study are pointed out in a diagram. Using our presented formula enables one to estimate approximately when a liner should be replaced before unwanted fracture might occur.

Key words: - *Prediction, lifetime, polypropylene liner, fatigue stress, blood centrifuge, Novel model system* Words: 3714 the authors declare no conflict of interest.

INTRODUCTION

One of the important parts in blood separation process that must replace on a schedule before fracture is polypropylene liner of blood centrifuges. Assessment of the lifetime of a part i.e. liners, is important for any expert and manager, who is working in blood banking center, and related companies that support instruments „supply, and preventative maintenance. Also, such estimated data could be used for anyone, who is involved in design and manufacturing different parts of centrifuges. Moreover, knowing the life expectancy of each part will directly help to reduce possible damage derived from small parts to the working machines. Beside such precautionary approach prevents cross-contaminations between involved personnel. Additionally, the blood supply chain has linked with human health, and any unwanted failure in blood processing system can interrupt this chain.

Generally the lifetime of a part like polypropylene liners is under dynamic pressures, and could be affected by multidiscipline phenomena especially fractures caused by fatigue. Fatigue is the main reason of mechanical failure at least in 90 % of fractures during operations, and it is dangerous, because it occurs without any previous warning or obvious signs.

Estimation of lifetime of any material is important but a difficult task and it seems as a black box that mainly is defined by direct cause-effect relation (figure 1). However, fatigue is the main cause of mechanical failure in different machines at least but not last causes 90% of fractures during operations. Any (unexpected) fracture in each part of centrifuge is dangerous, because it occurs without any previous warning or obvious sign (figure 1).

As in the application information manual from Beckman Coulter [1] is mentioned primary method for isolation of whole blood to cellular constitutions is differential centrifugation, because of its high throughput and versatility.[2] The separated blood components can subsequently be used for their respective clinical and scientific applications and investigations.[1] Continuously in blood centrifuge machines, the blood bags, liners and buckets are under centrifugal force, which is the main cause of separation of the blood components. The essential part in any centrifuge machine, which is used to protect plastic bags containing whole blood is a liner. In general a liner is produced from different components i.e. metallic, polymeric and mainly polypropylene materials. Besides co-polymers and homo-polymers both are used but in the case that is in our study analyzed, co-polymer is the material, which is used in our liner manufacturing.

Vinecenso and Francessco 2013 have shown[3] that 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, after braking function, the amount of stress on different parts (liners), decreases to the zero again. However, this process is a reversible process but causes irreversible erosion-like damage to the different fragile parts of machines, unremarkably.

Parker A.P 1982 [4] has proposed that to assess the amount of load conditions one should look at the dominant failure mechanism which might be caused by fatigue phenomenon.

Nihat Ozkaya et al. 2012 [5] described that loads 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 cycles, depending on the amplitude of the applied loads. Any fracture due to repeated loading is so-called fatigue, as well. 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 loading.[6]

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 signs.[7] According to Michael R et al. entries[8] it‟s possible for fatigue and creep phenomena to predict the lifetime analytically.

Loading condition in a certain centrifuge also point out as the dominant cause, this affects the lifetime of liners by means of fatigue. Richard G et al. 2011[8] proposed that the methods of fatigue-failure analysis represent a combination of the Engineering and Material Science.

The aim of this study is to find out a novel method to estimate the lifetime of liners and create an instruction/formula for preventive maintenance of the liners, timely. For any part of a device the designer must have an estimation of lifetime according to measured statistics and/or analytical data.

Materials and Methods

Two blood bank centrifuges from one of six blood bank centers of Iranian blood transfusion organization (IBTO) in Mashhad were considered to estimate the lifetimes of liners made in Sina Ebtekar Company (Mashhad, Iran) before use in blood separation process. The main reason for this selection was at first, the base of maintenance supply unit of Sina Ebtekar Company is localized in Mashhad, Iran. At second, the recording experimental results are a time consuming work. At third, data gathering and processing need the cooperation of all these units. Hence, 36 Polypropylene liners (n=36) of brand Sina Ebtekar Plus (SEP) were randomly selected from 2000 liners and the lifetime of these liners were studied for 11 months long. Data are presented are mean + SD and analyzed Using T-test. P –value more than 0.05% was considered as significant.

Experimental measurement of the lifetime

In this study experimental results are based on considering the lifetime of 36 liners in 6 blood bank centers in Mashhad. And for analytical study of liners‟ lifetime, a chain of engineering steps were done. Normally the amount of load mass for each liner during a cycle was estimated around 500 gram, and the RCF was selected between 4500 to 5000 rpm. Simultaneously with experimental test and gathering the measurements of 36 liners‟ lifetime in field, the lifetime of liners were estimated scientifically. In this method by evaluating the loading condition, determining the initial and boundary

condition, liners" material characteristics, 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 2).
Then by using information of the stress-strain curves of nano-composite polypropylene (figure 3a adapted from ref [9]). The "Stress-Number of lifetime cycles data were extracted and is presented in figure 3b, and at the end the liners lifetime were estimated in cycles. And by mapping the maximum stress of liners from FEM analysis onto (S-N) fatigue life curve of the polypropylene material of liner as is shown in figure 4 [9].
Consequently first 3D-model system has developed by SolidWorks® modeling software according to its actual dimensions. During cyclic loading the Finite Element method (FEM) is used to obtain the maximum stress in part. The COSMOS software has been used for this method, and by simulation operating conditions of liners, stresses on the body of liner has been calculated.
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. The irregular geometric square was used as the modeling blood bags in the liner, by considering weight and volume of bags.
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, according to material characteristics of liners.
Loading was done as a centrifuge rotation with a rotational speed of 4000 RPM. The radius of rotor has been considered 280 mm. These conditions caused 5000 unit for RCF. It has been observed that maximum stress was approximately 18 to 20 MPa.

Analytical measurement of the lifetime

Briefly, for lifetime assessment based on fatigue analytically step by step, following phases were done as follow: The loading conditions were assessed. During this step the boundary and initial conditions were defined. The CAD model system was built in SOLIDWORKS software and exported in standard CAD format for FEM analysis. The FEM of system was built in COSMOS software. The Pyramid elements were used with four node and linear shape function. Then material characteristics, boundary and initial conditions were imposed to the FEM model, and the problem was solved by using default setting. The most important result of the FEM analysis was the maximum stress on liner part during centrifugation. Subsequently, based on the FEM"s results using fatigue data for material of liners (co-polymer polypropylene), the lifetime 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 supposed to be 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 forecast how many days the liners must be used? And according to own daily schedule, plan when do the liners need to be replaced with new ones?
6- Finally, according to the planning made routinely for blood bags that processed in each center, we developed a simple but applicable formula. This formula is useful to estimate lifetime of any single machine, because some centers have more than one machine for blood processing. So it"s possible to forecast how many days a liner could be used, under normal condition.

Results

Usually the lifetime of a part like polypropylene liners is under dynamic pressures, and could be affected by multidiscipline phenomena especially fractures caused by fatigue. Here we present a researched and developed formula that 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 developed by appropriate amounts of variables:

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

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

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

Or

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

After studying experimental data in upper and lower bound of lifetime the results were presented in table 1 and table 2.
In table 1 is the upper bound lifetime (2500 cycles) of "SEP" liners data processed and presented. Twenty two percent (22%) of these liners have lifetime more than this amount. Recall, it"s not advised that amount of lifetime be considered as the ultimate lifetime of liners.
In table 2 is the lower bound lifetime (1600 cycles) of "SEP" liners data processed and presented. Seventy five (75%) of these liners have lifetime between 1600 and 2500 cycles. It"s advised that this amount of lifetime be considered as the

ultimate lifetime of liners. By using the estimation and assumptions, which is developed by us, one can prevent 97% of unwanted failure. In figure 2 is the stress contour extracted from FEM analysis data shown that occurs in a liner during operation of blood centrifuge. The maximum amount (red sites) of stress is estimated about 18 to 20 MPa.

In figure 3A the stress-strain curves of nano-composite polypropylene is shown which is affected at different temperatures, and various load rates [9]. Compared to higher temperature a decrease in temperature and strain increases the stress, however. The stress decreases when the strain of nano-composite polypropylene increases. At higher strains than 0.1 the effect of temperature on stress disappears. In figure 3B is shown the fatigue analysis diagram when you map the maximum stress of liners from FEM analysis onto the curves of fatigue characteristics of liners‟ material that for instance is depicted in figure 2. As is assessed and indicated in figure 3B when production per day would be between 1600 and 2500 cycles is the maximum stress around 18 MPa. Moreover, the "stress-number of cycles of lifetime" (S-N curves) for polypropylene (nanocomposite and talc-filled) have an inverse correlation based on fatigue and thermal failure. Total stress in Talc-filled polypropylene was lower than polypropylene nonocomposite-liners (data not shown).

In figure 4A is a prediction of stress-cycle number relation depicted that is adapted from Ullman DG 2005. The present experimental and analytical results illustrates that the most accurate predicted lifetime according to fatigue data of polypropylene had 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. The fatigue analysis diagram when one plans the maximum stress of liners from FEM analysis onto the curves of fatigue characteristics of liners‟ material as is indicated in figure 2. Although all preventive assessments should be adjusted when i.e. environmental temperature, usage volume and pressure varies significantly (figure 4B).

In figure 5 is the lifetime of 36 liners (n=36) shown that is processed from measured data experimentally. The results confirm that if the lower bound lifetime (1600 cycles) is considered that unwanted failures will not occur with 97% probability. If the upper bound is considered the probability of unwanted failing is 78 %, and it‟s not recommend by authors.

These functions are hyperbolic (figure 6). Comparing between experimental and analytical lifetimes shows reasonably compatibility. In figure 6 is the curves displayed of "upper and lower fatigue life of liners" in days upon "the numbers of blood bags that processed in a blood bank center daily. The curves are formed from the output of our developed „innovative formula‟ after locating appropriate amount for variables.

Discussions

In this paper, to predict the operating lifetime, fatigue effects of centrifugal stresses were on polymer liners of blood bank centrifuges considered. Based on the FEM‟s results using fatigue data for liners‟ material (co-polymer polypropylene), the lifetime of liners was in cycles estimated. By considering the number of permissible cycles until fatigue fracture of the liner‟s material occur the number of the operating days of liners determined. Furthermore, by using the FEM static analysis the maximum stress cycles was calculated.

Based on the FEM‟s results using fatigue data for material of liners (co-polymer polypropylene), the lifetime 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 supposed to be 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 do the liners need to be replaced with new ones?

According to the planning made routinely for blood bags that processed in each center, we developed a simple but applicable formula. This formula is useful to estimate lifetime of any single 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 there.

Liners' lifetime calculation

Every day, the liners of centrifuges have been used during routine work, and sometimes variable in blood bank center, 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 one has 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 be seen that by putting appropriate value to variables ((L_C, N_L, and NP) a function was built that in it:

$$\mathbf{L_D = f\ (N_B)}$$

According to the operating lifetime curves obtained 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 day could be estimated on 96 days (3 months).

Fatigue characteristics of liners' material

On the contrary of polymeric material in metals, theoretical fatigue basis and failure are relatively developed topics [10]. According to Maxwell entries [11] it‟s clear that mechanical characteristics of polymers are so sensitive to changes in temperature, strain rate, and environment i.e. presence of water, oxygen and organic solvents. William D. [12] has mentioned in his book that 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 processes [12].

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 polymer [13].
In this study two aspects of polypropylene characteristics are needed; 1. "Static Structural Characteristics" and 2. "Fatigue Characteristics". These data was used according to ref. [14, 15]. For liner production either homo polymer or copolymer could be used. But the liners which were used for experimental tests were copolymers.

Load conditions
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 M&M section. It has been observed that maximum stress is approximately measured at 18 to 20 MPa. This is the sign of sensitivity of this part, and it shows the prediction of starting fracture from this part. The centrifugal force during accelerating and braking make a cyclic loading with this maximum stress. Therefore this maximum stress is critical stress for fatigue analysis.

Fatigue analysis
In order to determine the number of operating cycles that could be beard by liners until fatigue failure, the Fatigue Analysis model system 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. Procedure determined that numbers of fatigue fracture cycles are in a bound between 1600 to 2500 cycles. This bound selected for conditions that operating temperature was measured/observed from 2 up to 20 °C. Because the temperature affects the all characteristics of polypropylene more than anticipation,[15] and the safety factor was between 2 and 3 [9]. For other operational temperatures and safety factors changing operation lifetime is indispensable.
In the long run, our hypothetically presented formula is working when the liners of model "SEP" 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.
Taken together the results of this study might after more investigations be applicable for both designers and staff of preventative maintenance system.

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