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RESEARCH ARTICLE

STERILIZATION EFFECT ON THE ELASTOPLASTIC BEHAVIOR OF GORE-TEX VASCULAR GRAFTS POLYMER

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Abstract

The study concerns with polymer material known commercially as GORE-TEX vascular polymer graft used in cardiac surgery, planting Parties arteries which show after a period of cultivation their tightness. Among the causes of this problem is the sterilization of the material as it is noticed by some Surgent at the Heart National Center – Tajoura, Libya. Precisely, the sterilization for more than three times based on the need and use which is contradicted with the manufacturer recommendation. The study would deal with the effect of sterilization types and frequency on GORE-TEX strength as an elastoplastic factor property. The mechanical properties are analyzed through uniaxial tensile tests, after each type and cycle of sterilization effect on GORE-TEX vascular graft polymer properties as elastoplastic behavior for two different routes of sterilization methods named the formalin & steam sterilization with the reference of the manufactory company sterilization process and condition. The sterilization effect on the mechanical behavior is evaluated. Data from uniaxial tensile tests are analyzed and discussed using the multi variant statistical tool (ANOVA) and the Post hoc Tukey HDS test in light of previous data on the commercially GORE-TEX vascular graft polymer used in cardiac surgery in order to highlight the correlation between the sterilization type and frequency of GORE-TEX vascular graft polymer with the elastic modulus and material resilience properties variation. The effect of formalin and steam sterilization and their frequency on the GORE – TEX polymer mechanical parameters are studied to be evaluated as a function of initial and final elastic modulus and the material resilience. Steam sterilization up to five times is recommended to use before deploying the implant in the living body. Formalin sterilization shows statistical significate difference compared to the manufacture sterilization data. So, it is not recommended to be used especially at high level of frequency.

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I- Background

GORE-TEX is the main constituent of vascular grafts which is a Tetrafluoroethylene polymer being inert in nature polytetrafluoroethylene and somtetrafluoroethylene copolymers known as PTFE: polytetrafluoroethylene [1]. The combination of mechanical properties and biocompatibility of bio-polymers make its application in medical applications is promising. Significant challenges are in place in the manufacturing and characterization of this type polymers for biomedical applications, especially addressing their reliability and stability [2]. The mechanical and physicochemical properties of biomedical polymers, which are exposed to physiological conditions, must remain constant in the living body [3]. The interaction of biopolymer with water and active environment can potentially lead to difficulties in implanted devices leading to dangerous consequences as explant and replacement [4]. Degradation of polymers may be induced by several factors, [5, 6] including sterilization [7, 8] which is commonly carried out on medical devices. Steam sterilization, which is conducted in an autoclave (100% relative humidity) at temperature above 115 °C [9], is a very frequently used method. The polymer properties may be changed during the sterilization process due to the combined effect of temperature and humidity [9]. The consequences of sterilization on the micro-phase structure and mechanical properties of biomedical polymers were investigated in an earlier work [8]. Some thermoplastic elastomers are used in vascular grafts, components of artificial hearts, drug delivery vehicles, micro-arrays and microfluidic devices [10-12]. The use of GORE-TEX vascular polymer graft for the manufacturing of biomedical devices is mostly related to their mechanical stability and durability in use conditions as microstructural and chemical properties. Therefore, mechanical properties of these polymers significantly change after sterilization, depending on the microdomain structure variation. In this work, the investigation of the mechanical behavior of GORE-TEX vascular polymer graft before and after sterilization is extended to figure out the difficulties of using this type of biopolymer raised by surgical specialists at the Heart National Center – Tajoura, Libya.

II- Materials and Experimental Design

2.1 Materials

GORE-TEX is the main constituent of vascular grafts which is a Tetrafluoroethylene polymer being inert in nature polytetrafluoroethylene and somtetrafluoroethylene copolymers known as ePTFE: expanded polytetrafluoroethylene. Fifty-five samples were made from a vascular graft material, divided into three groups of (five sample manufacturer sterilization, twenty-five for steam sterilization and twenty-five for formalin sterilization) divided into two groups of (5 samples each) according to each sterilization cycle. Samples were cut with the dimension (75x10x1) mm.

2.2 Samples Preparation

The GORE-TEX vascular grafts polymer cutting Dog-bone-shaped samples were produced by machine (ATS FAAR SPA MILANO/ITALIA), according to ISO 527-2 international regulation by dimension (75x10x1) mm, and putting into autoclave paper to be processed for sterilization. The cutting GORE-TEX vascular grafts polymer samples were done at (industry research center, Libya).

2.3 Formalin Sterilization Method

The GORE-TEX vascular grafts polymer samples were prepared with dimension of (75x10x1), for each sterilization cycle where they placed in bags for sterilization. The sterilization method was carried out using 2% formalin in autoclave under the conditions defined by the standard protocol in healthcare facilities and medical devices industries. The formalin sterilization process was performed using the machine “matachana 130LF”, made in Germany. In this method the sterilization was performed at 60°C, for 2 hr. Together with the heating and cooling time, every sterilization cycle took approx. 2 hours. These conditions were retained for 2 hours, then the autoclave was switched off and Samples were left inside the chamber for approximately 15 minutes. Afterwards, the samples were re-equilibrated under atmospheric conditions. The material was packaged in special, sealed paper bags, which were marked after each cycle. The formalin sterilization was done at (National Heart Center, Libya).

2.4 Steam Sterilization Method

The sterilization method was carried out to simulate the steam sterilization in the same conditions defined by standard protocols in healthcare facilities and medical devices industries, using machine steam sterilization machine (model matachana S1000, Germany). In this method the sterilization was performed at 121 °C, for 30 minutes. Together with the heating and cooling time, every sterilization cycle took approx. 30 minutes. These conditions were retained for 30 minutes, then the autoclave was switched off and Samples were left inside the chamber for approximately 15 minutes. Afterwards, the samples were re-equilibrated under atmospheric conditions. The samples

were wrapped in special sealed paper bags, which were marked after each cycle. The sterilization process was completely computer-controlled. The steam sterilization was done at (National Heart Center, Libya).

2.5 Tensile Test

Mechanical tests were carried out by using SATRA tensile testing machine (model STM466, England) through an average of five samples and each sterilization cycle equipped with a 5 KN tension load cell and mechanical side action grips. The test procedure was performed according to ISO 527-1 regulations. The tests were carried out at room temperature, at speed test (100mm/min). The tensile tests were done at (Industry Research Center, Libya).

2.6 Statistical Analysis Technique

Parametric tests such as analysis of variance (ANOVA) is potentially used. Since the study is designed to look at the impact of only one independent variable on the selected dependable variables, the one-way analysis of variance is selected due to its similarity to the t-test; where there is a significant mean difference among more than two groups on a continuous (metric) - selected dependent variable. The Siegel–Tukey test is used to determine if one of the two groups of data tends to have more widely dispersed values than the other.

III- Methodology:-

There are three types of vascular grafts polymer sterilization planned to be tested. These tests named company sterilization, formalin sterilization and steam sterilization. Number of samples prepared for this purpose and divided into three groups according to the type of sterilization process. Three subgroups were generated from each group. Subgroup one is not subjected to sterilization while subgroup two and three were subjected to sterilization methods. Finally, each subgroup divided into three classes according to the type of test (elastic modules and the material resilience). The experimental work will be conducted to answer the questions raised by the hypotheses as follow:

1. There will be a significant difference between the three sterilization methods of vascular grafts polymer regarding the elastic modules; therefore, hypothesis one formulated as: (i) The company sterilized samples will record a statistically significant difference in the initial elastic modulus values than the formalin sterilized samples cycles, while record no statistically significant difference in the final elastic modulus values than the formalin sterilized samples cycles. (ii) The company sterilized samples will record no statistically significant difference in the initial elastic modulus values than the steam sterilized samples cycles, while record no statistically significant difference final elastic modulus values than steam sterilization samples cycles.
2. There will be a significant difference between the three sterilization methods for the vascular graft polymer regarding the material resilience and the hypotheses are formulated as: (iii) The company sterilized samples will record no statistically significant difference in the material resilience values than the formalin sterilized samples cycles, While record no statistically significant difference in the material resilience values than the steam sterilized samples cycles.

IV- Results and Discussion

4.1 Formalin Sterilization Effect on Elastic Modulus

The company sterilized samples will record a statistically significant difference in the initial elastic modulus values than the formalin sterilized samples cycles, while record no statistically significant difference final elastic modulus values than steam sterilization samples cycles. Table 1 the mean values and standard deviation of steam and formalin sterilization processes effect on elastic modules and resilience materials. By using alpha level of 0.05, A one-way ANOVA between-cycles analysis of variance was conducted to explore the impact of sterilization levels of the vascular grafts, as measured by the sterilization processes effect on elastic modules and resilience materials. Samples were divided into five cycles for the sterilization processes effect on elastic modules and resilience materials cycles comparing the company sterilization step according to its sterilization condition. The finding revealed that, there was statistically significant difference at the $p < .05$ level in values for the sixth vascular graft sterilization cycle and $p < .05$ Post-hoc comparisons using the Tukey HSD test indicated that the deviation score for company sterilization, was significantly greater than the Initial elastic modules formalin sterilization cycles $F(5, 24) = 2.035$, $p = 0.110$, final elastic modules formalin sterilization cycles $F(5, 24) = 39.374$, $p = 0.000$ until fifth cycles compared company sterilization.

Figure (1) shows the mean and stand deviation of the initial and the final elastic modules of formalin sterilization cycles, which indicated that the Gore-Tex vascular grafts have higher strength compared to the one obtained from the company up to the fifth cycle.

For the formalin sterilization, the fourth cycle had the maximum elastic modulus (mean = 4.790) compared to other cycles, which is still higher than that of the sample obtained from the company. On the other hand.

Table 1:- Mean and Standard Deviation Values of Formalin Sterilization Processes Effect on Elastic Modulus.

Sterilization Cycles	Initial Elastic Modulus				Final Elastic Modulus			
	Mean ± Std	df*	F	P	Mean ± Std	df*	F	P
0 Cycle	3.632 ± 0.711	5	2.035	0.110	1.452 ± 0.152	5	39.374	0.000
1 st Cycle	3.740 ± 0.656				0.130 ± 0.223			
2 nd Cycle	4.280 ± 0.881				0.132 ± 0.031			
3 rd Cycle	4.080 ± 0.642	24	2.035	0.110	0.148 ± 0.025	24	39.374	0.000
4 th Cycle	4.790 ± 0.511				0.790 ± 0.651			
5 th Cycle	4.404 ± 0.521				0.146 ± 0.068			

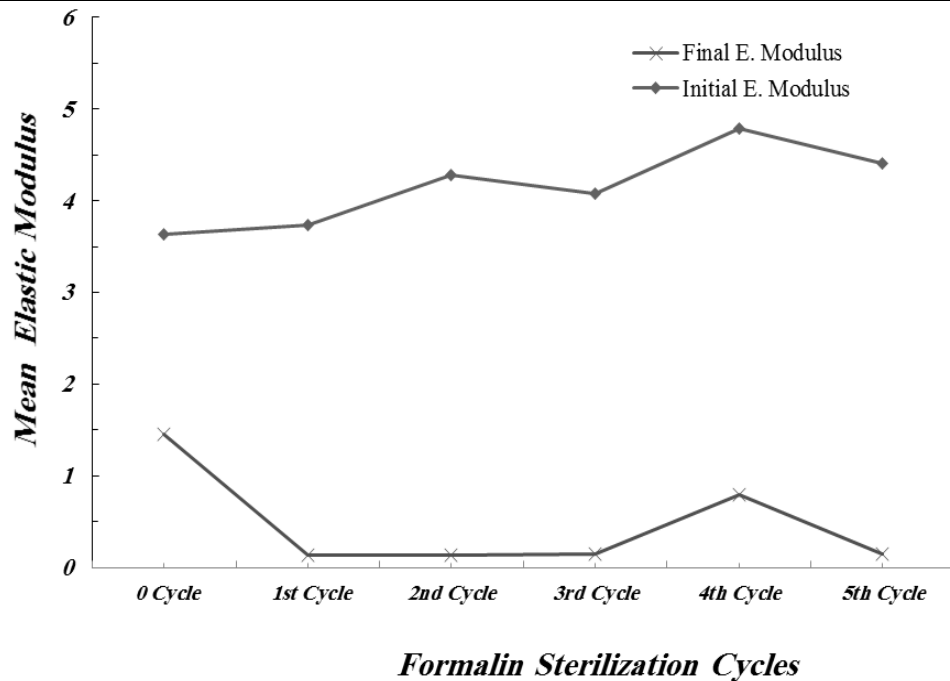


Figure (1):- Line graph showing one-way anova comparison of effects of formalin sterilization cycles on elastic modules of the tested Gore-tex vascular grafts.

4.2 Steam Sterilization Effect on Elastic Modulus

The company sterilized samples will record no statistically significant difference in the initial elastic modulus values than the steam sterilized samples cycles, while record no statistically significant difference final elastic modulus

values than steam sterilization samples cycles. Table 2 the mean values and standard deviation of steam and formalin sterilization processes effect on elastic modules and resilience materials. By using alpha level of 0 .05, A one-way a nova between-cycles analysis of variance was conducted to explore the impact of sterilization levels of the vascular grafts, as measured by the sterilization processes effect on elastic modules and resilience materials. Samples were divided into five cycles for the sterilization processes effect on elastic modules and resilience materials cycles comparing the company sterilization step according to its sterilization condition. The finding revealed that, there was statistically significant difference at the $p < .05$ level in values for the sixth vascular graft sterilization cycle and $p < .05$ Post-hoc comparisons using the Tukey HSD test indicated that the deviation score for company sterilization, the initial elastic modules and final elastic modules was no significantly different from were recorded initial elastic modules steam sterilization cycles $F(5, 24) = 0.565$, $p = 0.726$, final elastic modules steam sterilization cycles $F(5, 24) = 60.533$, $p = 0.000$.

Figure (2) shows that the initial and final elastic modules of steam sterilization cycles of the Gore-Tex vascular grafts (with few differences between them) were strongly higher than those obtained from the company. The second cycle had the maximum elastic modulus (mean = 4.600) compared to other cycles, which is higher than that obtained from the company.

Table 2:- Mean and Standard Deviation Values of Steam Sterilization Processes Effect on Elastic Modulus.

Sterilization Cycles	Initial Elastic Modulus				Final Elastic Modulus			
	Mean ± Std	df*	F	P	Mean ± Std	df*	F	P
0 Cycle	3.632 ± 0.711	5	0.565	0.726	1.452 ± 0.152	5	60.533	0.000
1st Cycle	4.260 ± 0.465				0.186 ± 0.045			
2nd Cycle	4.600 ± 0.406				0.142 ± 0.028			
3rd Cycle	4.180 ± 0.492	24	0.565	0.726	0.178 ± 0.019	24	60.533	0.000
4th Cycle	4.128 ± 0.491				0.428 ± 0.602			
5th Cycle	4.540 ± 0.413				0.320 ± 0.238			

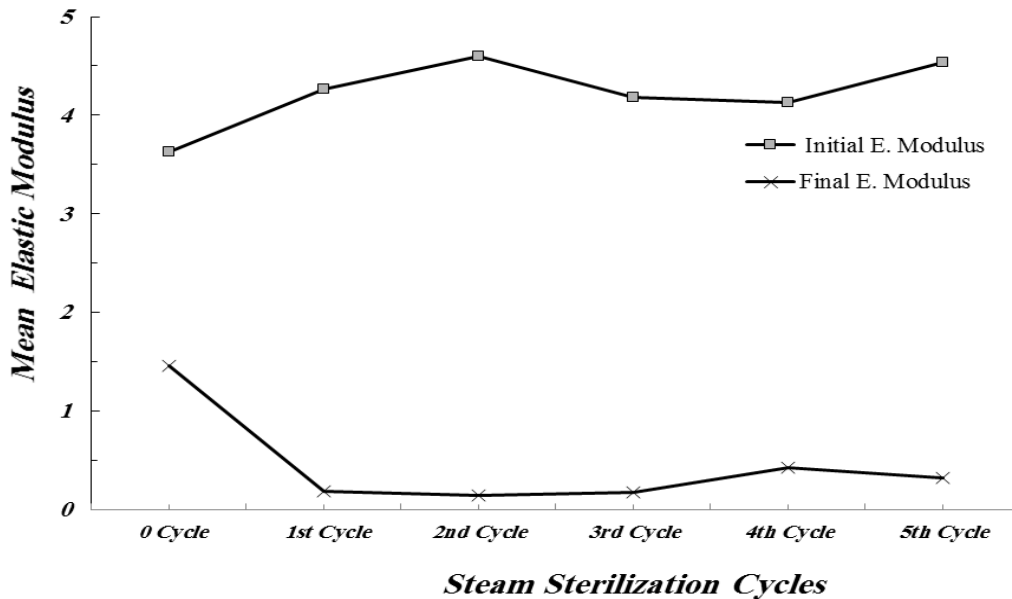


Figure (2):- Line graph showing one-way anova comparison of effects of steam sterilization cycles on elastic modules of the tested Gore-tex vascular grafts.

4.3 Sterilization Method Effect on the Material Resilience

The company sterilized samples will record no statistically significant difference in the material resilience values than the formalin sterilized samples cycles, while record no statistically significant difference in the material resilience values than the steam sterilized samples cycles. Table 3 the mean values and standard deviation of steam and formalin sterilization processes effect on elastic modules and resilience materials. By using alpha level of 0 .05, A one-way a nova between-cycles analysis of variance was conducted to explore the impact of sterilization levels of the vascular grafts, as measured by the sterilization processes effect on elastic modules and resilience materials. Samples were divided into five cycles for the sterilization processes effect on elastic modules and resilience materials cycles comparing the company sterilization step according to its sterilization condition. The finding revealed that, there was statistically significant difference at the $p < .05$ level in values for the sixth vascular graft sterilization cycle and $p < .05$ Post-hoc comparisons using the Tukey HSD test indicated that the deviation score for company sterilization, was statistically no significant difference the resilience using the steam sterilization $F(5, 24) = 9.623, p = 0.000$, strongly high strength than formalin sterilization $F(5, 24) = 4.623, p = 0.003$, until fifth cycles compared company sterilization.

Figure (3) shows the resilience of the steam and formalin sterilization cycles. The steam sterilization cycles of the Gore-Tex vascular grafts had higher strength than the formalin sterilization cycles, which is also higher than those obtained from the company. The second cycle if the steam sterilization had the maximum resilience (mean = 5.400) compared to other cycles, while the second cycle of formalin sterilization had the maximum resilience (mean = 4.488) compared to other cycles.

Table 3:- Mean and Standard Deviation Values of Sterilization Cycles Processes Effect on Resilience.

Sterilization Cycles	Formalin				Steam			
	Mean ± Std	df*	F	P	Mean ± Std	df*	F	P
0 Cycle	4.736 ± 1.977	5	4.623	0.003	4.736 ± 1.977	5	9.623	0.000
1 st Cycle	3.928 ± 1.019				4.638 ± 0.510			
2 nd Cycle	4.102 ± 0.872				5.400 ± 0.484			
3 rd Cycle	4.488 ± .331	24			5.240 ± 0.581			
4 th Cycle	4.152 ± 1.085				4.300 ± 0.800			
5 th Cycle	4.404 ± 1.220		4.672 ± 0.220					

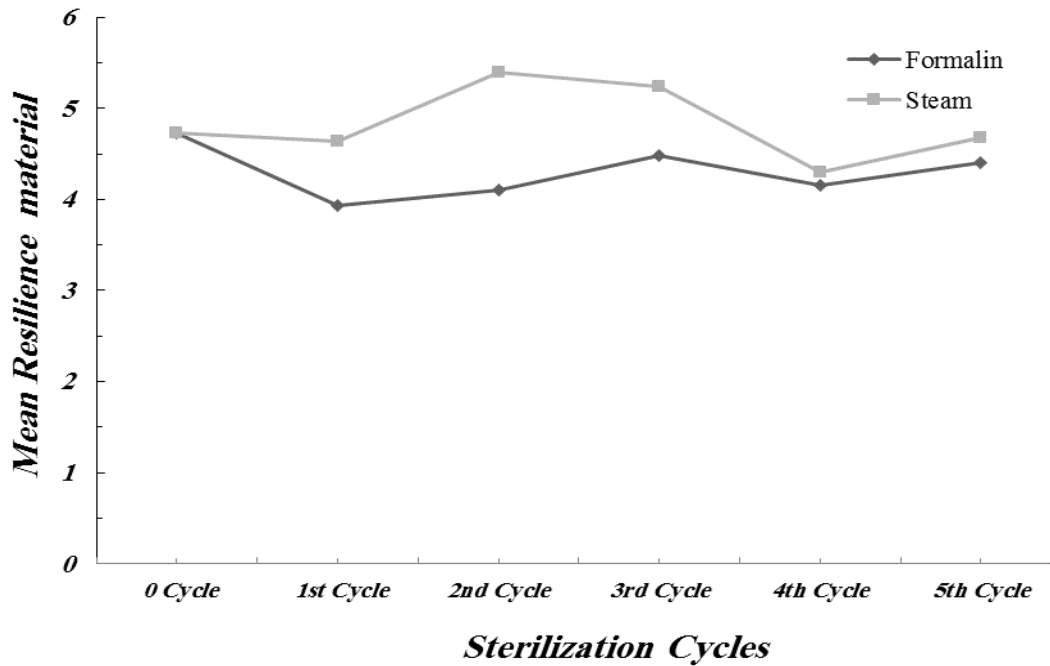


Figure (3):- Line graph showing one-way anova comparison of effects of sterilization cycles on resilience of the tested Gore-tex vascular grafts.

Affect the physical properties of the polyester weaken the graft By Autoclave sterilization at 134 °C it is known that hydrolysis the reverse reaction of the polyester synthesis, it causes to degeneration of polyester grafts in the human body after years of implantation. It could also be showing the hydrolysis of polyester vascular grafts is extremely accelerated in boiling water [13, 14].

Advantageous of PTFE's qualities its biocompatibility, non-degradation and strength. But prone to thrombosis in low flow states. To reducing the hydrophobicity of a material by covalently bond hydrophilic groups to its surface. Heparin is hydrophilic, contributing to its anti-platelet adherence properties and reducing the hydrophobic nature of collagen [15] similarly the used of compliant silicone rubber as a vascular conduit has been hampered by its hydrophobicity, affording it high affinity for platelets and fibrinogen Julio et al [16]. For future observations the record of the implant material employed must be take into account the re-sterilization of the implant.

Conclusion:-

In this work, the initial and final elastic modulus as well as the resilience properties of GORE-TEX vascular graft polymer as a function of sterilization process type and frequency is studied. The mechanical properties of these polymers have been investigated through tensile tests before and after each sterilization process, type and frequency which commonly performed on biomedical devices.

The steam sterilization had greater effect on the elastoplastic properties, than that caused by the formalin sterilization. This could be attributed to the fact during the steam sterilization higher temperature of 121 °C was used for 30 min, while for the formalin sterilization relatively lower temperature (60°C) was used for 2 hr. This means that the steam sterilization method provided a higher degree of safety, which comply with the sterilization protocol. In addition, this method is economically better than the formalin method used in Gore-Tex vascular grafting in heart surgery. Contrary to the recommendations provided by the company, our results showed that steam sterilization for five times, which is a necessity in Libya (due to availability issues) does not affect the properties of the Gore-Tex vascular grafts.

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