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DYNAMIC TESTING ANALYSIS OF ARTERIAL BLOOD FILTERS

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Abstract. *A dynamic testing system (SEDin) has been developed in order to evaluate the physical integrity of medical devices. Forty one arterial filters, commercially available, of two local manufactures were submitted to dynamic testings. Those filters were from three different models coded as Type 1, Type 2 and Type 3. A nominal pressure of 100kPa, frequencies of 0.5Hz, 1.0Hz and 2.0Hz and 10,000 maximum cycles were the testing parameters used in this work. The complete study consisted of two phases: a) SEDin validation and b) device testings and SEDin evaluations. On the first phase, eighteen filters were tested, being six of them from Type 2 and twelve from Type 3, at 0.5Hz frequency. The others twenty three further filters, Types 1, 2 and 3, were submitted to 0.5Hz, 1.0Hz and 2.0Hz dynamic testings, completing the second phase. The environment temperature and humidity of all testings were monitored by a calibrated thermohygrometer. The testing data were processed using mathematical software (ARX model) making possible to identify the characteristic mathematical response models of SEDin and also of the medical devices submitted to dynamic testings. SEDin showed a first order overdamping step response for all frequencies. However, the medical devices showed a third order response due to the association of the SEDin first order response and their underdamped second order response. At this analysis, the SEDin obtained parameters were time constant,* τ, *for each frequency. On the other hand, time constant,* τ, *natural frequency,* ω_n, *damped frequency,* ω_d, *and damping factor,* ζ *were the obtained parameters for the medical devices. Moreover, it was possible to analyze root locus for each medical device, demonstrating its stability and the predominant behaviour of first or second orders according to its Type model.*

Keywords: *Cardiovascular implants, artificial organs, cardiopulmonar bypass, arterial blood filter, dynamic testing*

1. Introduction

The aim of this work was to develop a dynamic testing system (SEDin) which should perform the physical integrity evaluation of medical devices (Del'Vecchio et al., 2003; Del'Vecchio et al., 2004). The testing data were processed using a mathematical software (ARX model- autoregressive with exogenous inputs) in order to identify the characteristic mathematical response models of SEDin and also of the medical devices submitted to dynamic testing. The dynamic testing was performed in blood-gas oxygenators (Body et al., 1999) however only the physical integrity – leakage- was declared and no mathematical analyses for the device behavior was demonstrated. Moreover, the available standards, such as ANSI/AAMI/ISO 15675, do not refer any dynamic testing, only hydrostatic ones. The contribution of the present paper is to present a methodology to not only perform hydrostatic testing (leakage) but analyzing the dynamic behavior of the pressure inside the device under dynamic loading. The pressure data were mathematically analyzed and both, the system and the medical devices under testing, were evaluated.

2. Methodology

Forty-one arterial filters, commercially available in Brazil, from two local manufactures and presented in three different models coded as Type 1, 2 and 3. They were submitted to dynamic testing, following two studying phases: a) SEDin validation and b) medical device testing and SEDin evaluations. For the first phase a nominal pressure of 100 kPa and a frequency of 0.5 Hz were the testing parameters used for the SEDin validation.

Figure 1 shows a sketch of the main structure of the SEDin system. It could be seen that the SEDin consisted of hydro-pneumatic components and of a data acquiring/processing unit. Moreover, the compressed air line pressurizes the water existing at the chamber and consequently the medical device under testing. The control unit commands, in association with the exhaust and solenoid valves, the testing cycle according to the chosen frequency. In addition, the dynamic system has two pressure sensors that permit the inlet and outlet pressure measurement of the medical device. This pressure data and its related time were collected by a computer using Labview® software.

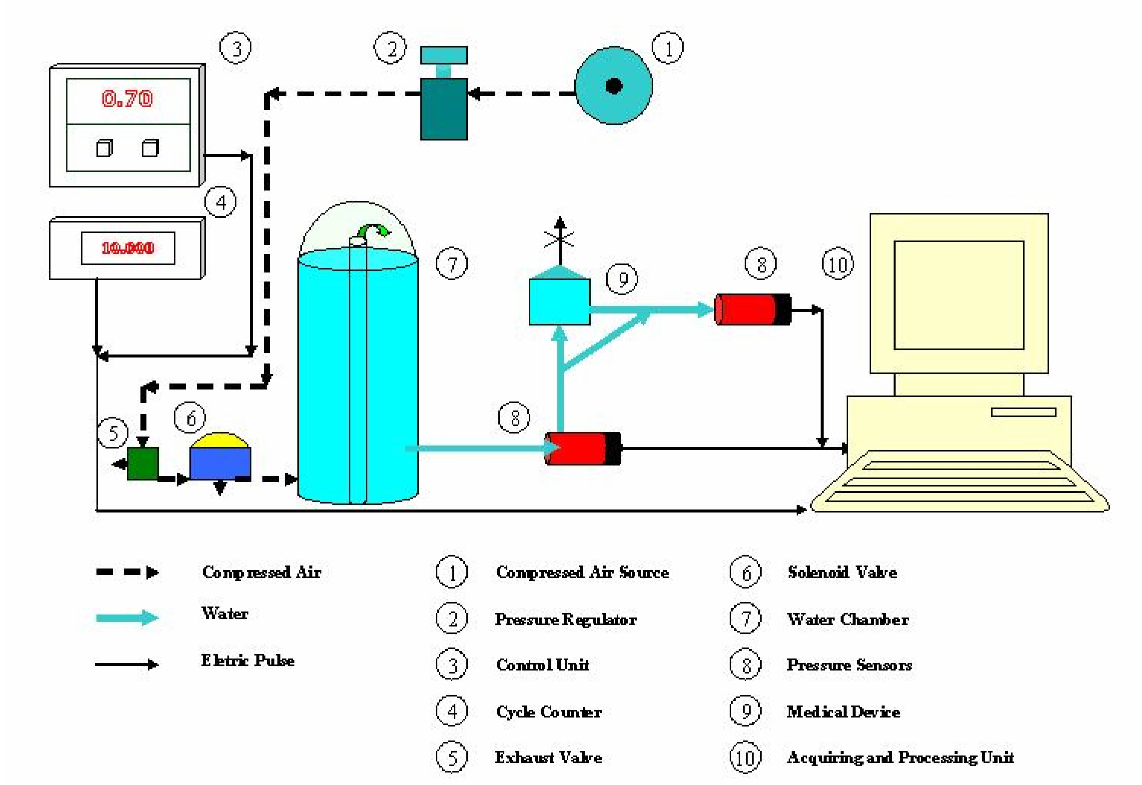


Figure 1. Sketch of the SEDin system.

On the SEDin validation (Del'Vecchio et al., 2004), eighteen arterial blood filters were used, being six of them from Type 2 and twelve from Type 3. The main objective of this phase was to evaluate the SEDin performance during all testings: maintenance, stability, accuracy. No detailed mathematical study was done on this phase. The leakage or cracking occurrence could be analysed which permitted the evaluation of the medical devices physical integrity. One third of samples have presented leakage. Only 11% of the tested devices did not have any kind of fissures. The SEDin was able to perform medical devices dynamic testing without any maintenance and demonstrated a good stability during validation.

For the second phase, medical devices were submitted to dynamic testing for 0.5Hz, 1.0Hz and 2.0Hz frequencies also under a nominal pressure of 100kPa. For both phases, the tests were performed until 10,000 maximum cycles or leakage occurrence.

In order to identify the SEDin behavior sixty tests with no medical device was used during testing.. Nominal pressures of 100kPa and 155kPa were used as a way of increasing the SEDin measuring range. During the SEDin evaluation two water chamber volumes were used: maximum water volume and standard water volume. Five tests for each frequency, both pressure and volumes were done. So, just one pressure sensor was used at the end of the water chamber in order to evaluate just the SEDin system. The environment temperature and humidity were monitored by a calibrated thermo-hygrometer.

During this second phase, twenty-three arterial filters, from Types 1, 2 and 3 were submitted to dynamic testing. The tested medical devices are listed on the following "Tab. 1". It was developed a detailed mathematical analysis of the SEDin and also of the devices under tests. Taking this in mind, the dynamic testing pressure data and its respective time were collected by a computer using Labview® software.

Using a mathematical software (ARX model), the testing data were processed in order to identify the characteristic mathematical models of SEDin and also of the medical devices under tests, (Aguirre, 2004). The SEDin time constant, τ, was obtained for all frequencies, 0.5 Hz, 1 Hz and 2 Hz, at nominal pressures of 100 kPa and 155 kPa. The time constant, τ, is related to the time value on which 63,2% of final testing pressure value is reached. For all arterial filters the time constant, τ, natural frequency, ω_n, damped frequency, ω_d, and the damping factor, ζ, were evaluated. The time domain data was converted to the frequency domain resulting on the above parameters.

Table 1. Number of arterial filters samples and testing frequencies.

Arterial Filter	Number of Samples	Frequency [Hz]
Type 1	3	0.5
	3	1.0
	3	2.0
Type 2	7	1.0
	2	2.0
Type 3	2	0.5
	3	2.0

3. Results

Table 2 shows the results for each testing condition. SEDin evaluation was performed by using the algorithm developed with the software based on ARX model. The time constant, τ, for all frequencies and nominal pressure of 100 kPa and 155 kPa, were calculated. Time constants for maximum water chamber volume for both pressures were lower compared to calculated value for the standard chamber volume which can be justified by the air compressibility effects.

Table 2. SEDin evaluation results.

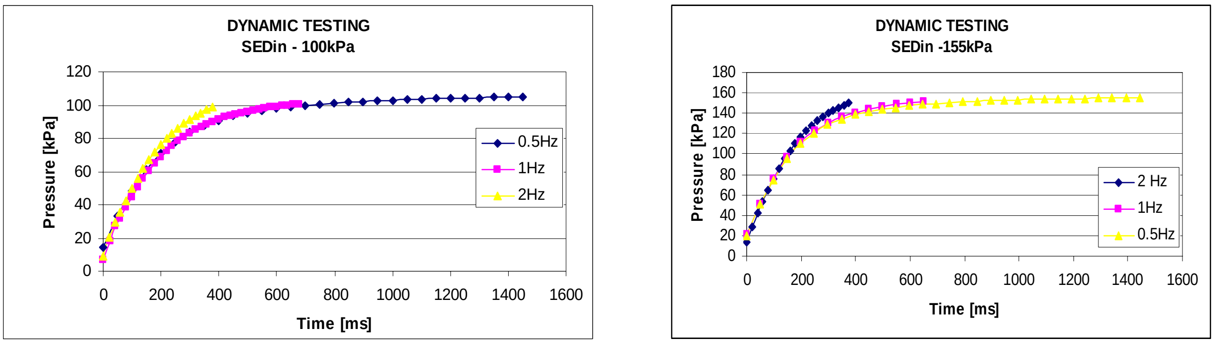
Pressure **[**Kpa]	**V**olume	Frequency [Hz]	τ [s]	
			Average	Standard Deviation
100	Maximum	0,5	0,12	0,01
		1,0	0,11	0,01
		2,0	0,11	0,01
	Standard	0,5	0,21	0,02
		1,0	0,21	0,02
		2,0	0,20	0,05
155	Maximum	0,5	0,10	0,00
		1,0	0,10	0,00
		2,0	0,10	0,00
	Standard	0,5	0,21	0,01
		1,0	0,21	0,02
		2,0	0,24	0,02

Figure 2 shows the testing pressure *versus* time graphic for all frequencies and both pressures. The observed curve shapes demonstrate the first order response obtained by SEDin for all testing conditions.

Table 3 shows all calculated parameters for the twenty three arterial filters submitted to dynamic testing. Arterial filter Type 1 did not present any leakage however one sample presented lower natural, damped frequencies and also damping factor compared to the same type samples. This fact can be explained by an internal crack occurrence. The high parameters values mainly for the frequencies can be analyzed taking into consideration that this kind of filter is made by a more resistant raw material and also because its design has lower compliance.

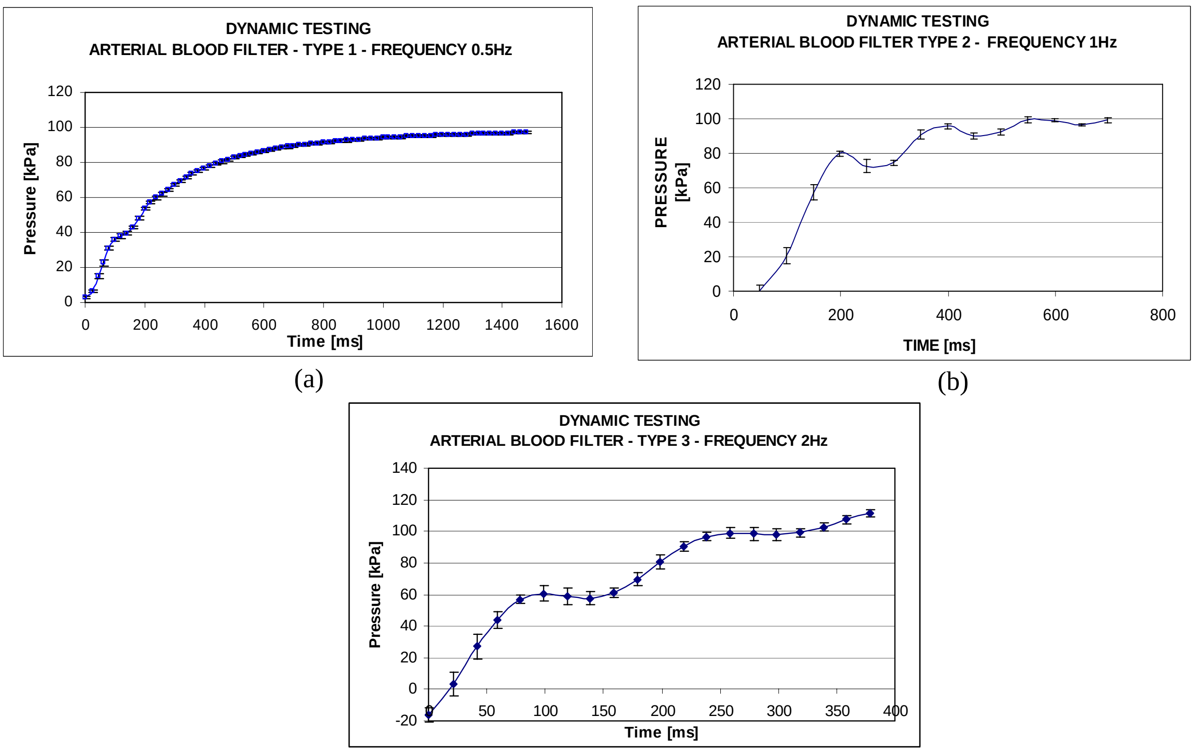
Arterial filters Type 2 and Type 3 also had their parameters calculated. Unless, Type 2 showed filters with leakage, the values for the calculated parameters did not differ so much, however the parameter values tended to increase when no leakage was observed. The great leakage incidence observed on Type 2 arterial filter, six samples at nine tested, might be justified by the raw material used during its manufacturing which presented a lower resistance. Type 3 was manufactured using a more resistant raw material. Despite the fact that less Type 3 samples were tested, it can be seen that they performed better than Type 2, reaching more samples without leakage, although the parameters values did stay at the same measuring range.

Figure 3 shows the testing pressure *versus* time graphic for three chosen samples: (a) for Type 1, (b) for Type 2 and (c) for Type 3 at 0.5, 1.0 and 2.0 Hz, respectively. It could be noted that, for these samples, Type 1 filter presented a first order response predominance, similarly to the SEDin behavior. On the other way, Type 2 and Type 3 showed a second order behavior which was expected as they had a lower damping factor and so more oscillations at lower amplitudes. A complement to this analysis is the root locus, "Fig. 4 and 5", which demonstrates the arterial filters models stabilities during the testing. Type 1 showed a first order predominance in the most of tested samples, except on the sample which had low ω_d, ζ, and ω_n, exhibiting a second order predominance, confirming the crack occurrence. Type 2 and Type 3 had both first and second order predominance.



(a) (b)

Figure 2. SEDin dynamic testing evaluation: (a) - at 100kPa and (b) - at 155kPa.



(a) (b)

(c)

Figure 3. (a). Type 1 arterial blood filter, (b). Type 2 arterial blood filter and (c). Type 3 arterial blood filter.

Table 3. Calculated parameters of tested arterial filters, submitted to a dynamic testing.

Type	Pressure [kPa]	Frequency [Hz]	Leakage	Time Constant [s]		Natural Frequency [rd/s]		Damped Frequency [rd/s]		Damping Factor	
				τ	S.D.	ω_n	S.D.	ω_d	S.D.	ζ	S.D.
Type 1	100	0.5	No	0.24	0.01	32.33	1.42	32.19	1.41	0.09	0.02
Type 1	100	0.5	No	0.27	0.01	50.71	1.61	48.80	1.06	0.27	0.05
Type 1	100	0.5	No	0.20	0.002	48.99	3.08	47.09	2.75	0.27	0.04
Type 1	100	1.0	No	0.22	0.004	51.42	12.18	44.29	4.89	0.33	0.22
Type 1	100	1.0	No	0.22	0.003	56.29	2.51	53.34	1.85	0.31	0.04
Type 1	100	1.0	No	0.22	0.002	59.91	17.24	52.52	9.41	0.38	0.21
Type 1	100	2.0	No	0.23	0.01	48.92	0.98	48.11	0.92	0.18	0.01
Type 1	100	2.0	No	0.22	0.02	46.91	3.53	46.02	3.12	0.19	0.04
Type 1	100	2.0	No	0.23	0.01	48.82	0.94	48.00	0.89	0.18	0.01
Type 2	100	1.0	Yes	0.19	0.01	33.46	0.83	33.32	0.83	0.09	0.01
Type 2	100	1.0	Yes	0.20	0.02	32.79	0.72	32.53	0.73	0.12	0.03
Type 2	100	1.0	No	0.13	0.01	32.64	0.23	32.55	0.23	0.08	0.01
Type 2	100	1.0	Yes	0.17	0.02	34.21	1.59	34.06	1.54	0.09	0.01
Type 2	100	1.0	Yes	0.18	0.003	34.37	0.66	33.88	0.74	0.16	0.02
Type 2	100	1.0	No	0.20	0.02	37.38	3.78	36.60	2.86	0.18	0.08
Type 2	100	1.0	Yes	0.20	0.01	35.26	1.13	34.98	1.16	0.13	0.01
Type 2	100	2.0	Yes	0.14	0.03	38.81	0.81	37.57	0.46	0.25	0.04
Type 2	100	2.0	No	0.22	0.06	40.21	0.85	38.71	1.41	0.25	0.12
Type 3	100	0.5	No	0.18	0.01	38.88	0.59	38.14	0.56	0.19	0.05
Type 3	100	0.5	Yes	0.20	0.004	35.11	0.22	34.94	0.20	0.10	0.01
Type 3	100	2.0	No	0.15	0.01	39.69	0.57	39.13	0.44	0.16	0.04
Type 3	100	2.0	No	0.18	0.02	41.53	0.64	40.65	0.61	0.20	0.02
Type 3	100	2.0	No	0.23	0.03	41.19	0.60	39.99	0.64	0.24	0.03

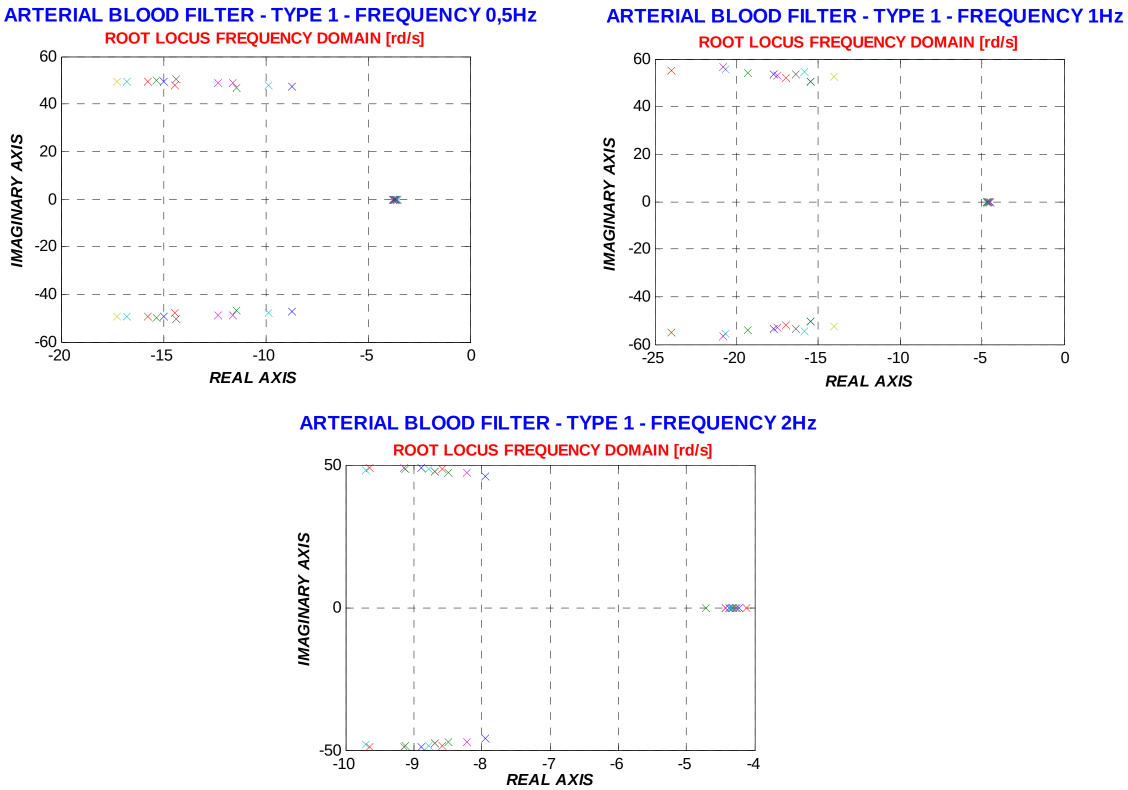
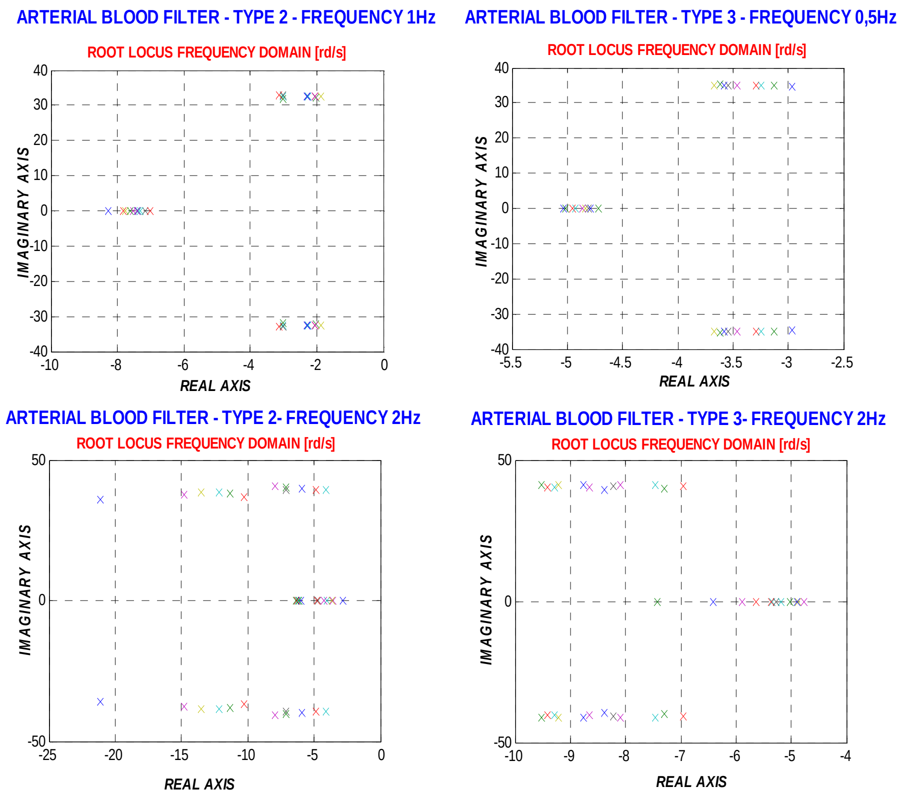


Figure 4. Type 1 root locus at 0.5Hz and 2.0Hz.



(a) (b)

Figure 5. (a). Type 2 root locus at 1.0Hz and 2.0Hz and (b). Type 3 root locus at 0.5Hz and 2.0Hz.

4. Conclusions

The time constant, τ, obtained for the SEDin system for each frequency, demonstrated that its performance shows a characteristic first order response for both 100kPa and 155kPa. On the other hand, medical devices showed a third order response, although with a first or second order predominance, due to the association of the SEDin first order response with their second order response. All tests showed a very good stability based on root locus graphics. For medical devices parameters obtained were time constant τ, natural frequency, ω_n, damped frequency, ω_d, and the damping factor, ζ. Arterial blood filters Type 1 demonstrated a first order domain showed on its root locus graphic, having lower oscillations than Type 2 and Type 3, except on the sample which had low ω_d, ζ, and ω_n, exhibiting a second order predominance, confirming the crack occurrence. Type 1 presents natural frequencies higher than Type 2 and Type 3. Moreover, Type 1 design is less complacent than the other types. This can be proved by low oscillations and higher frequencies.

Type 2 and Type 3 arterial filters have a different design showing lower frequencies and presenting more leakage than Type 1. In addition, Type 2 and Type 3 have more underdamped behavior than Type 1 arterial blood filter that means that they are more complacent filters. All arterial blood filters showed low damping factor, according to the material characteristics (polymers).

The results prove that the goal of this work of demonstrating the importance of using a dynamic testing to perform a detailed mathematical analysis of the medical devices under testing. At this direction, it was showed that the SEDin system can be recommended to perform dynamic tests. Moreover, the medical devices analysis is a very important tool for design devices that are less traumatic for the patient. In addition, new medical devices design can be evaluated by the dynamic testing system SEDin. Also, the system can be adapted to test others medical devices like dialyzers and cardiovascular prosthesis (heart valves, tube vascular prosthesis and others).

5. Acknowledgements

Authors would like to acknowledge the financial support from CNPq and CAPES. The contribution of Vladimir A. Macedo of TechSteel Automation Ltda is gratefully acknowledged.

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