ORIGINAL RESEARCH

Development of a Telemetric System for Postoperative Follow-up of Vascular Surgery Procedures: In Vitro Model

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Background**—**Because of the unique electromagnetic characteristics of the magnetoelastic microwire, the changes in the pressure of a fluid will provoke a variation of the mechanical pressure on the sensor, which will cause a variation of its magnetization that will be detectable wirelessly. Thus, a wireless system can be developed for following up vascular surgery procedures.

Methods and Results**—**The sensor consists of a magnetoelastic microwire ring, which was integrated into an in vitro model with pulsatile flow. Different degrees of stenosis were simulated in different locations both in bovine artery as well as in a polytetrafluoroethylene anastomosis. A Fourier analysis of the registered signals and a statistical analysis using Pearson test and receiver operating characteristic (ROC) curves were made. A Pearson index of 0.945 ($P<0.001$) was obtained between the invasive pressure of the fluid and the power of the signal transmitted by the sensor in bovine artery. The sensor obtained very good ROC curves upon analyzing the signals registered, both in the case of preanastomotic stenosis (area under the curve [AUC], 0.98; 95% CI, 0.97–1.00), of anastomosis (AUC, 0.93; 95% CI, 0.86–0.99), as well as distal (AUC, 0.88; 95% CI, 0.79–0.98), compared to the control group.

Conclusions**—**The magnetoelastic microwire has shown that it is capable of detecting, locating, and quantifying the degree of stenosis in bovine artery, as well as in a latero-terminal anastomosis, with a high statistical potency. For the first time, a wireless in vitro sensor has been developed for the postoperative follow-up of vascular surgery procedures. **(*J Am Heart Assoc*. 2016;5: e003608 doi: 10.1161/JAHA.116.003608)**

Key Words: blood pressure • diagnosis • dynamics • follow-up studies • peripheral vascular disease

Chronic ischemia of the inferior limbs is a range of signs and symptoms that are produced as a consequence of the progressive decrease of blood flow in the inferior limbs.

It is estimated that the prevalence of this pathology is between 3% and 18%, which that means more than 27 million people are affected in the world.[1–4]

Failure of surgical revascularization procedures, both open and endovascular, continues to be a challenge in the present-day clinical practice of the vascular surgeon and is associated with an elevated morbimortality rate, meaning that an exhaustive follow-up control is key to maintaining long-term permeability in these procedures, thus avoiding the amputation of the limb.

In view of the advanced age, high morbidity, and reduced mobility of many of the patients with critical ischemia of the limbs, optimizing the follow-up protocols, as well as offering out-patient attention to these patients, is fundamental to maintaining their quality of life. In spite of the importance of the follow-up procedure after arterial revascularization surgery, there is a lack of consensus in the relevant literature with regard to its efficiency, how it should be carried out, and for how long.

The growing number of patients needing care as a result of the aging of the population, and its subsequent economic impact, coupled with an increase in the incidence of chronic diseases, constitutes a powerful incentive to develop new strategies for the care of these patients, which has given rise to an increased interest over the last decade in investigating

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portable systems for the measurement of various physiological parameters.

Technological development has spurred the growing interest in the investigation of new biosensors aimed at simplifying present-day diagnostic methods, and thereby improve medical care, so that it improves the quality of life of the patients and allows for out-patient treatment for a number of pathologies, avoiding unnecessary hospital admissions.[5]

Magnetic sensors are at the helm of technological development seen in this field over the last decades, offering numerous advantages attributed to their elevated sensitivity, reduced size, systems without the need for an external source of energy, and wireless connections. The use of WSN (wireless sensor network) technologies offers the possibility of developing implantable biomedical sensors allowing for the monitorisation and follow-up of certain physiological parameters with precise and up until now, unthinkable measurements.

Therefore, the aim of this research is to develop a wireless magnetic sensor for postoperative follow-up procedures of vascular surgery.

Methods

Sensor Element

A magnetic microwire (MW) is a filament with an amorphous structure, whose nucleus is composed of an alloy of metals, the most frequent being iron and cobalt, with a pyrex covering as insulant, manufactured by means of an ultraquick cooling process resulting in MW with a maximum diameter of 100 μm. An amorphous magnetoelastic MW (MicroMag 2000, S.L.), composed of iron, cobalt, silicon, and boron, has been used for conducting this study.

MW possesses 2 unique characteristics, which convert them into an excellent sensor element. On the one hand, their high magnetostriction, together with their low anisotropy, makes them extremely sensitive to small changes in mechanical pressure, and that such changes be translated into changes in their magnetization when subjected to an external magnetic field. In addition, because of its high magnetic susceptibility along with its diameter in microns, it is able to modulate a high-frequency signal emitted by an antenna. Thus, changes in pressure of a fluid will cause a variation of the mechanical stress on the sensor, which will involve a variation of its magnetization and the emitted wave that will be detectable wirelessly through a receiving antenna.[6–9] It is therefore possible to use a ring made of this material as a wireless pressure sensor element.

The designed sensor consists of a MW ring bobinating 30 cm of this material (patent reference ES2524733).

Experimental Mechanism

Electromagnetic circuit

The sensor-artery/prosthesis unit is simultaneously subjected to a periodic low-frequency (0.1 Hz; BIAS magnetic field) magnetic field generated by some Helmholtz coils and to a high-frequency (1.29 GHz) electromagnetic wave from an emitting antenna. The BIAS magnetic field allows the modulation of the signal emitted by the microwire through its magnetization and demagnetization. Variations in mechanical stress on the sensor element will result in a variation of the emitted wave detectable by a second receiving antenna. Both antennas are connected to a vectorial analyzer (Agilent Technologies E8362B 10 MHz–20 GHz PNA Network Analizer; Lexington, MA) through 35-mm test-port 8513E HP cable so that we get a variation of power attributed to different pressures. To generate the magnetic field modulator of high-frequency signal, a function generator has been used (HP 15 MHz Function/Arbitrary waveform generator 33120 A) and an amplifier (Bipolar supply amplifier Kepco BOP 50 4M; Kepco, Inc., Flushing, NY). The intensity of the current circulating in the Helmholtz coils is detected using a multimeter (Fluke 45 Dual Display Multimeter; Fluke Corporation, Everett, MA).

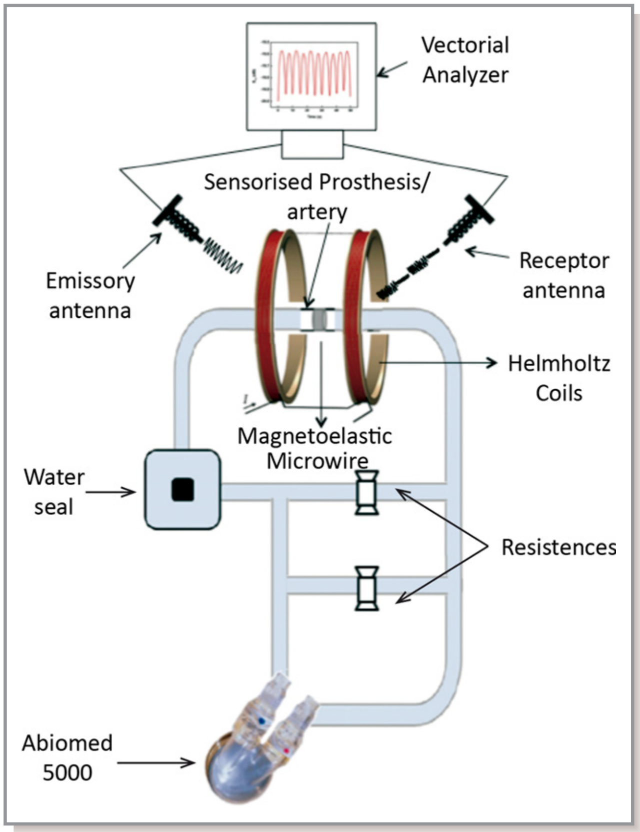

Figure 1. Scheme of the integration of the electromagnetic system and the pulsative flow system.

Pulsatile flow model

This model (sensorized artery/prosthesis) was included in a circuit with pulsatile flow connected to a ventricular assist system (Abiomed/AB5000; Abiomed Inc., Danvers, MA), and a water seal along with 2 resistors in parallel that allowed us to check the fluid pressure at all times by being able to modify the overall resistance of the circuit.

The fluid is a 0.33% dissolution of agar-agar to obtain a viscosity coefficient similar to that of blood of 37°C (0.04 Poise). The artery used is a 5- to 10-cm segment of bovine renal artery preserved in physiological saline solution for a period less than 48 hours. The prosthesis used is 6 mm polytetrafluoroethylene (PTFE; Maxiflo; Vascutek, Scotland UK). The procedures followed were in accord with institutional guidelines.

In order to be able to register the actual fluid pressure that passes through the artery or the prostheses at all times, 2 invasive pressure measurement systems, both distal as well as proximally to the sensor element, were connected. The pressure index (PI) is the ratio between both values. In Figure 1 we may see the integration of both models.

Measurements carried out

The investigation was divided into 3 parts, with clearly differentiated objectives. Each register of the wave emitted by the device lasted for 2 seconds.

To quantify the pressure of the fluid in PTFE and bovine artery. One-hundred twenty-eight determinations in PTFE and 96 in bovine artery were conducted, comparing the signal obtained by the sensor and the actual pressure of the fluid.

Localization and degree of stenosis in PTFE and bovine artery. Thirty-two registers without stenosis were made as a control group. Subsequently, 128 stenoses were simulated by means of a clip, which were then divided into 4 groups depending on the PI and their localization, which could be situated either in a previous position to the device or a posterior position to the same.

Localization and degree of stenosis in a PTFE latero-terminal anastomosis. The microwire was implanted proximally to the anastomosis (group A) or distal to the same (group B). Thirty-two registers without stenosis were made as a control group. Subsequently, 96 registers in each group were made, simulating stenosis of the graft, of the anastomosis, and distal to the same by means of a clip.

Analysis of frequencies. In order to analyze the information obtained, the Wolfram Alpha Mathematica computer program was used, applying the Fourier analysis (FA) of the waves obtained with the microwire.

Table 1. Average Invasive Pressures Registered in PTFE

Group	No. of Measurements	Average Pressure (mm Hg)	SD
1	32	58	5.9
2	32	85	25.5
3	32	154	38.9
4	32	182	35.1

PTFE indicates polytetrafluoroethylene.

In our case, we have worked with FA power, which is the square root of the sum of the squares of the real and imaginary part of FA, choosing the powers of both BIAS frequency (established at 0.1 Hz), as well as the frequency (around 0.7 Hz) in which the emitted wave was transmitted attributed to pulsatile flow obtained, called MW signal.

Statistical Analysis

Descriptive statistics included frequencies and percentages for categorical variables and means and SDs.

The Pearson correlation coefficient was used to study the association between the independent continuous variables and the continuous dependent variables.

The receiver operating characteristic (ROC) analysis was performed, using as dependent variable the presence of stenosis in the experimental mechanism. The area under the

Table 2. Results of Fourier Analysis

Group	BIAS Frequency (Hz)	BIAS Potency (AU)	MW Frequency (Hz)	MW Potency (AU)
1				
Average	0.1085	0.0275	0.73	0.0059
SD	0.0141	0.004	0.0768	0.0007
2				
Average	0.1032	0.0475	0.7168	0.0089
SD	0.0161	0.0253	0.0898	0.0029
3				
Average	0.1076	0.0285	0.8644	0.0165
SD	0.0135	0.0081	0.0797	0.0044
4				
Average	0.106	0.0369	0.891	0.0262
SD	0.0138	0.0073	0.0385	0.0077

AU indicates arbitrary units; MW, microwire.

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ROC curve (AUC) and the 95% CI were estimated to determine the discriminatory capacity of each continuous independent variable in predicting the presence of stenosis. An optimal cut-off value for each continuous independent variable was considered the one that maximized the sensitivity and specificity.

For all tests, a value of significance of 5% was accepted. Processing and analysis of the data was carried out by means of the SPSS statistic package (version 22.0; SPSS, Inc., Chicago, IL).

Results

Quantify the Fluid Pressure in Prosthesis and Bovine Artery

Measuring the fluid pressure in PTFE prosthesis

The minimum recorded pressure was 45 mm Hg and the maximum was 205 mm Hg with an average pressure of 120 mm Hg (SD, 27.3; Table 1).

The results obtained after FA of the 128 determinations carried out in PTFE are shown in Table 2.

A Pearson correlation index of 0.941 ($P<0.001$) between the invasive pressure of the fluid and the MW potency was obtained (Figure 2). A significant correlation with other dependent variables was not observed (BIAS frequency, BIAS potency, and MW frequency).

Measuring the fluid pressure in bovine artery

The minimum recorded pressure was 70 mm Hg and the maximum was 220 mm Hg with an average pressure of 143 mm Hg (SD, 32.6; Table 3).

The signals emitted by the MW were registered and an increase in the amplitude of the recorded signal was observed as the recorded invasive pressure increased (Figure 3).

The results obtained after FA are shown in Table 4.

A Pearson correlation index of 0.945 ($P<0.001$) between the invasive pressure and the MW potency was obtained (Figure 2). A significant correlation between the invasive pressure and the BIAS potency (Pearson index, 0.633; $P<0.001$) was also observed in bovine artery.

Localization and Quantification of the Degree of Stenosis in Bovine Artery

The average pressure in the control group was 56 mm Hg (SD, 0.1). Subsequently, 128 measurements divided into 4 groups were made as shown in Table 5.

The waves emitted by the MW were registered, and we observed that the stenoses located before the MW dampened its signal whereas those located after the MW caused the amplitude to increase. Moreover, this change is more accentuated the higher the degree of stenosis (Figure 4).

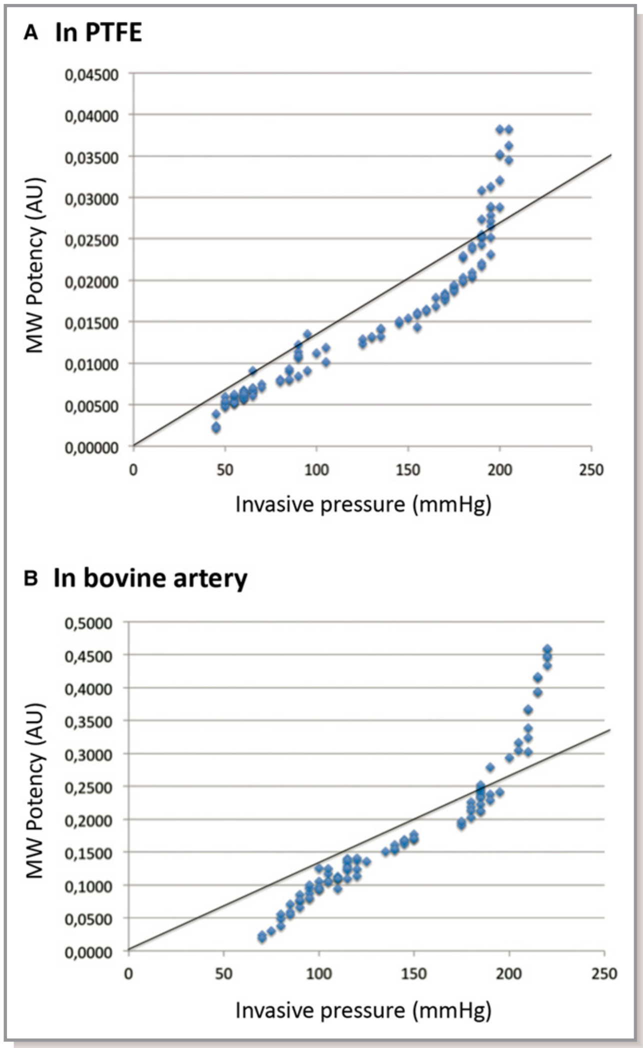

Figure 2. Scatter plot. Invasive pressure vs MW Potency in PTFE (A) and in bovine artery (B). AU indicates arbitrary units; MW, magnetoelastic microwire; PTFE, polytetrafluoroethylene.

Fourier analysis

FA was performed and its results are shown in Table 6. A decrease of MW potency was observed in cases where there was a stenosis before the sensor. This decrease is more

Table 3. Average Invasive Pressures Registered in Bovine Artery

Group	No. of Measurements	Average Pressure (mm Hg)	SD
1	32	101	13.2
2	32	138	36.9
3	32	189	35.2

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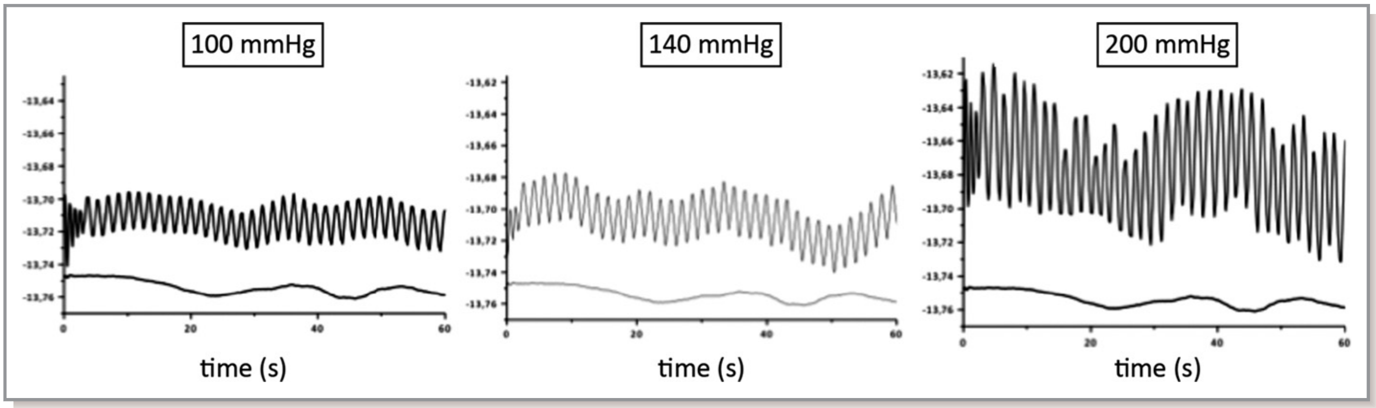

Figure 3. Signals emitted by the microwire in bovine artery submitted to increasing pressure.

accentuated the higher the degree of stenosis. Similarly, postwire stenosis caused an increase of MW potency, which is also higher the greater the degree of stenosis.

Statistical analysis

Upon analyzing prewire stenoses (moderate and severe) and comparing the signals emitted by the sensor when compared to the control group, the MW potency obtained an ROC curve with a very good discriminatory diagnosis capacity (AUC, 0.93; 95% CI, 0.88–0.98), with 92% sensitivity and 79% specificity for the cut-off point of 0.0086 AU (arbitrary units). To differentiate the degree of stenosis proximal to MW, severe stenosis groups were compared with moderate, obtaining 100% sensitivity and specificity in the power cut-off point 0.005 AU.

On the other hand, upon studying postwire stenoses (moderate and severe) and comparing the signals of microwire registered when compared to the control group, the BIAS potency obtained an excellent discriminatory capacity (AUC, 99; 95% CI, 0.97–1.00) with 100% sensitivity and 88% specificity for the cut-off point of 0.017 AU. To differentiate the moderate postwire stenosis when compared to severe, a cut-off point of 0.1173 AU of BIAS potency as well as MW potency of 0.0779 AU obtained a 100% sensitivity and specificity.

Therefore, given the cut-off points obtained in the ROC curves performed, we may follow the algorithm described in Figure 5, to classify a stenosis according to the data obtained with the MW.

Table 4. Results of Fourier Analysis

Group	BIAS Frequency (Hz)	BIAS Potency (AU)	MW Frequency (Hz)	MW Potency (AU)
1				
Average	0.0894	0.0249	0.6470	0.0986
SD	0.0066	0.0064	0.0711	0.0293
2				
Average	0.1045	0.0380	0.6631	0.1533
SD	0.0175	0.0084	0.0712	0.060
3				
Average	0.1107	0.0558	0.6663	0.2937
SD	0.0290	0.0083	0.0714	0.1130

AU indicates arbitrary units; MW, microwire.

Localization and Quantification of the Degree of Stenosis in a Lateral-Terminal Anastomosis With PTFE

The average pressure of the control group was 155 mm Hg (SD, 0.1). There were no significant differences either in the average pressure or in the degree of stenosis produced in the different groups, quantified according to the PI (Table 7).

Waves corresponding to different groups were recorded observing major morphological similarities in waves

Table 5. Classification Into Groups Depending on the Location and Degree of Stenosis Produced

Group	No. of Registers	Stenosis	Pressure Location	SD Index	Average Invasive Pressure Pre-/Poststenosis (mm Hg)
Severe stenosis					
1	32	Prewire	0.13	0.01	56/7
2	32	Postwire	0.21	0.01	56/12
Moderate stenosis					
3	32	Prewire	0.56	0.02	56/31
4	32	Postwire	0.59	0.03	56/33

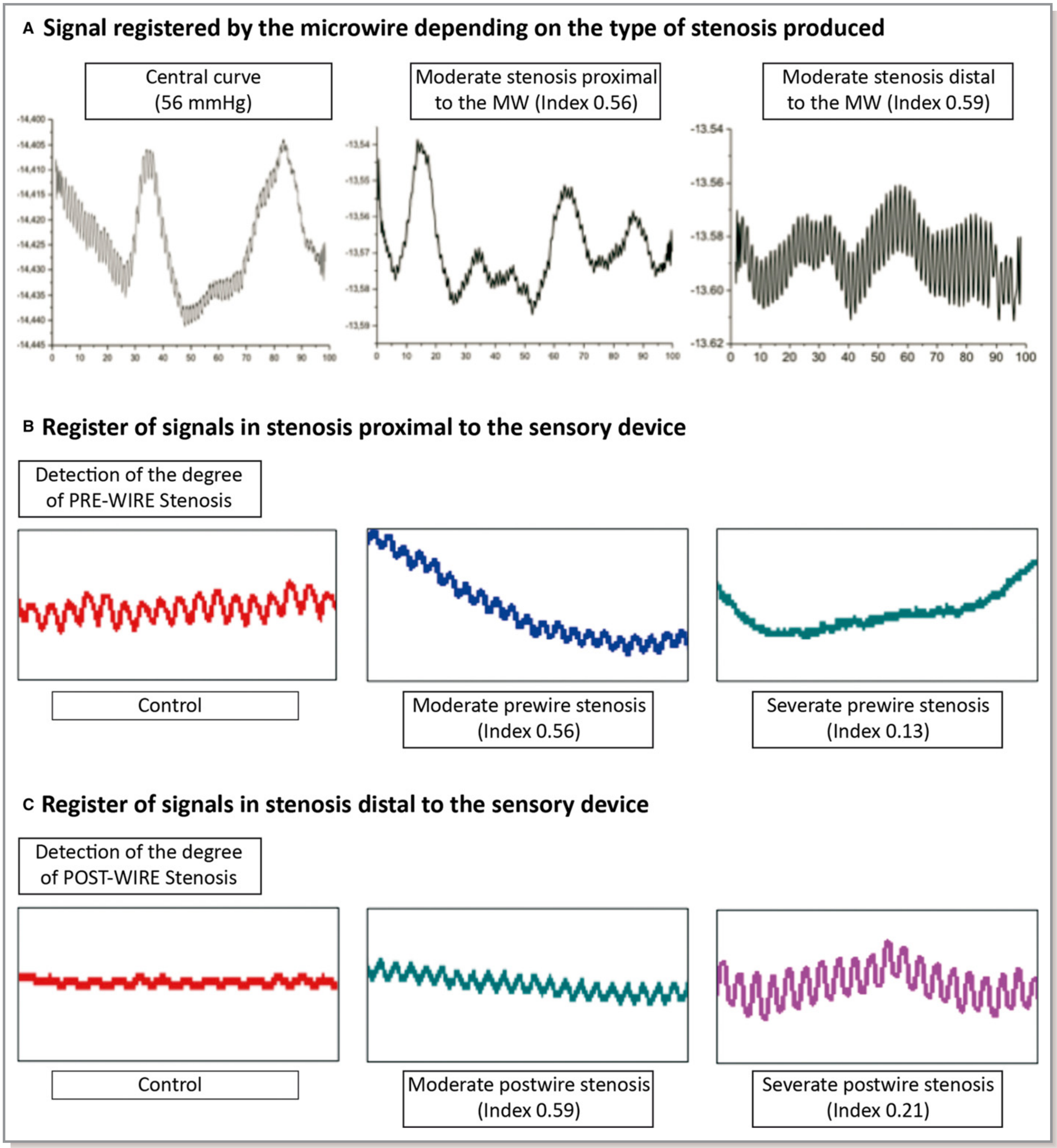

Figure 4. Signals registered by the microwire depending on the type of stenosis produced (A). In stenosis proximal (B) and distal (C) to the sensory device.

corresponding to the same type of stenosis between both groups (Figure 6).

In the case of group A, as noted in the previous records, the stenoses proximal to sensor produce a decrease in the amplitude of the emitted wave, whereas the distal stenoses for the same produced an increase in the amplitude of the signal.

However, in the case of group B, as the position of the MW changes with respect to the anastomosis, it could be observed how the stenosis in the anastomosis caused a

Table 6. Results of Fourier Analysis

Group	BIAS Frequency (Hz)	BIAS Potency (AU)	MW Frequency (Hz)	MW Potency (AU)
Control				
Average	0.1200	0.0098	0.6616	0.0111
SD	0.0253	0.00454	0.0469	0.0031
1. Severe stenosis prewire				
Average	0.1034	0.0163	0.9015	0.0028
SD	0.0178	0.0044	0.0321	0.0009
2. Severe stenosis postwire				
Average	0.1027	0.2511	0.6634	0.2567
SD	0.0174	0.0343	0.0343	0.0540
3. Moderate stenosis prewire				
Average	0.1197	0.0158	0.7179	0.0091
SD	0.0097	0.0059	0.0758	0.0089
4. Moderate stenosis postwire				
Average	0.1018	0.0294	0.6644	0.0176
SD	0.0172	0.0092	0.1242	0.0065

AU indicates arbitrary units; MW, microwire.

decrease in the amplitude of the signal similarly to the stenosis in the graft.

By comparing the signals, it could be observed how the waves registered in the stenosis in the graft were morphologically similar in both groups. In the case of distal stenosis, an increase in the amplitude of the signals was produced, more pronounced in the case of group B. However, in the case of anastomotic stenosis, signals between both groups were morphologically different. In the case of group A, the stenosis was distal to MW; therefore, it produced an increase in the amplitude compared to group B, in which the stenosis was before the sensor.

Fourier analysis

After FA of 192 registered signals, the results stated in Table 8 were obtained.

It was observed that both MW potency as well as BIAS potency increased in the stenosis produced distal to the sensor in both groups. On the other hand, these potencies decreased in the case of stenosis produced proximal to sensor. However, it is important to note that in the case of distal stenosis, the BIAS potency increased considerably in group B (sensor distal to the anastomosis). Similarly, MW potency is lower in the stenosis of the graft in group B compared to group A. Figure 7, summarizes the results obtained in the FA.

Statistical analysis

Overall, the position of MW immediately distal to the anastomosis (group B) was able to better discriminate the different types of stenosis compared to control group as well as between them.

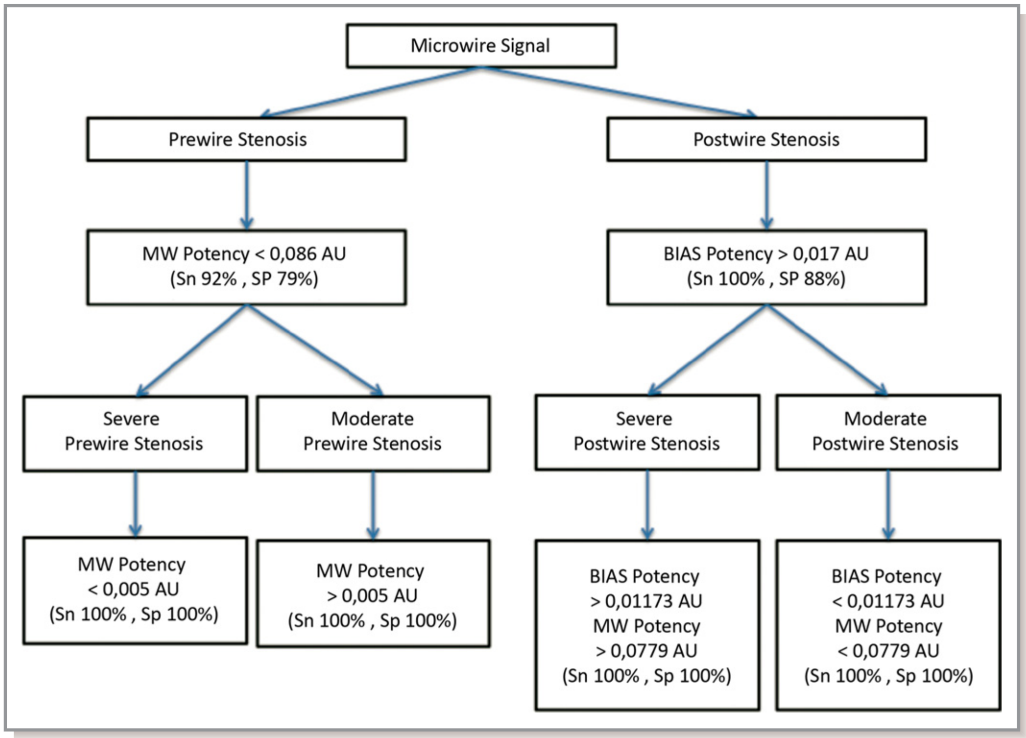

Figure 5. Diagnostic algorithm of stenosis depending on the signal of the magnetoelastic microwire. AU indicates arbitrary units; MW, microwire; Sn, sensitivity; Sp, specificity.

Table 7. Classification Into Groups Depending on the Location and Degree of Stenosis Produced

Position of Microwire	Stenosis Location	N	Pressure Index	SD	Average Invasive Pressure Pre-/Poststenosis (mm Hg)
Group A (microwire proximal to anastomosis)	Graft	32	0.41	0.02	155/63
	Anastomosis	32	0.52	0.01	155/80
	Distal	32	0.5	0.01	155/77
Group B (microwire distal to anastomosis)	Graft	32	0.52	0.01	155/80
	Anastomosis	32	0.52	0.01	155/80
	Distal	32	0.52	0.01	155/80

An MW potency greater than 0.0794 AU was able to diagnose the distal stenosis compared to control group with 85% sensitivity and 91% specificity (AUC, 0.88; 95% CI, 0.79–0.98).

To differentiate the stenosis of the graft when compared to the control group, the BIAS potency obtained an excellent discriminatory capacity diagnosis (AUC, 0.98; 95% CI, 0.97–1.00). The cut-off point of 0.0436 AU obtained 97% and 85% sensitivity and specificity, respectively. In addition, the MW potency obtained an ROC curve with AUC 0.86 (95% CI, 0.76–0.96). A lower value of 0.0473 AU was able to classify the stenosis of the graft with 81% sensitivity and 79% specificity.

Finally, the BIAS potency obtained a very good discriminatory capacity (AUC, 0.93; 95% CI, 0.86–0.99). A lower value of 0.0531 AU obtained 94% sensitivity and 85% specificity for classifying the anastomosis stenosis compared to the control group. The MW potency obtained an ROC curve with AUC 0.82 (95% CI, 0.71–0.94). A lower value of 0.0452 AU obtained 81% sensitivity and 78% specificity.

Hence, if we analyze only the MW potency in a latero-terminal anastomosis, we may classify the distal stenosis with higher reliability, whereas the signals emitted in the case of the other 2 types of stenosis would be similar as shown in Figure 8.

By comparing the signals registered in the anastomosis stenosis compared to the stenosis of the graft, we observed that BIAS potency obtained an ROC curve with AUC 0.85 (95% CI, 0.77–0.92). The cut-off point of 0.0378 AU classified these stenoses with 73% sensitivity and 79% specificity. Therefore, in those cases where the MW potency does not classify the stenosis type (MW potency less than 0.0473 AU), it will be the BIAS potency that will differentiate if it is an anastomosis stenosis or stenosis of the graft as shown in Figure 8.

The signals emitted in group A were analyzed, and it was observed that the sensor was able to classify the stenosis of the graft as well as the anastomosis stenosis, compared to the control group, and with the remainder stenosis with a high discriminatory diagnosis capacity. However, the sensitivity of the microwire decreased when the stenoses distal to the anastomosis were classified in comparison to the remainder stenoses of group A (AUC, 0.67; 95% CI, 0.57–0.78), and it was not able to differentiate the stenosis distal to the anastomosis compared to the control group.

Discussion

The continuing advances in science and technology, as well as the health care and social progress experienced in the past decades, have increased life expectancy in the world population, causing significant social and economic consequences. This fact, combined with the increase in the incidence and prevalence of chronic diseases, such as cardiovascular diseases,[10] has led to a change in health care organization in recent years, given that 5% of patients are responsible for 50% of health spending.[11] Thus, the increasing care and economic expenditure produced by these diseases is a powerful incentive to develop new strategies for the care of these patients.

The development of sensors applied to medicine has evolved dramatically in recent years. This may be seen from more than 4200 articles published in 2013 on new biosensors and their applications. The first article was published in 1958, and subsequently only 19 articles were published in the 1960s where the sensors were made of simple dielectric devices capable of detecting changes in water vapor pressure.[12]

In 2007, our group developed a high-sensitivity magnetic sensor for the early detection of the degeneration of biological heart valves, which was based on wirelessly detecting the movements of some MW fragments joined to the veils of a biological heart valve.[13]

In 2011, a Japanese group successfully developed a myocardial electrical activity sensor using an amorphous microwire as sensor element. It was based on the ability to detect the magnetic field produced by the electrical activity of the myocardium during the cardiac cycle in a completely wireless manner and with greater sensitivity than an electrocardiogram for the detection of cardiac arrhythmias and myocardial ischemia.[14]

Herrero-Gómez et al. recently developed a new amorphous microwire, with a high magnetoelastic coupling factor, with which excellent results were obtained without the need of an external magnetic field that facilitates the use of this material in small-sized biosensors and easier use in biomedical applications.[6]

Therefore, we can note how the field of magnetic sensors is in continuous evolution, having demonstrated numerous advantages in biomedical applications and still with a great potential yet to be discovered as shown in latest research.

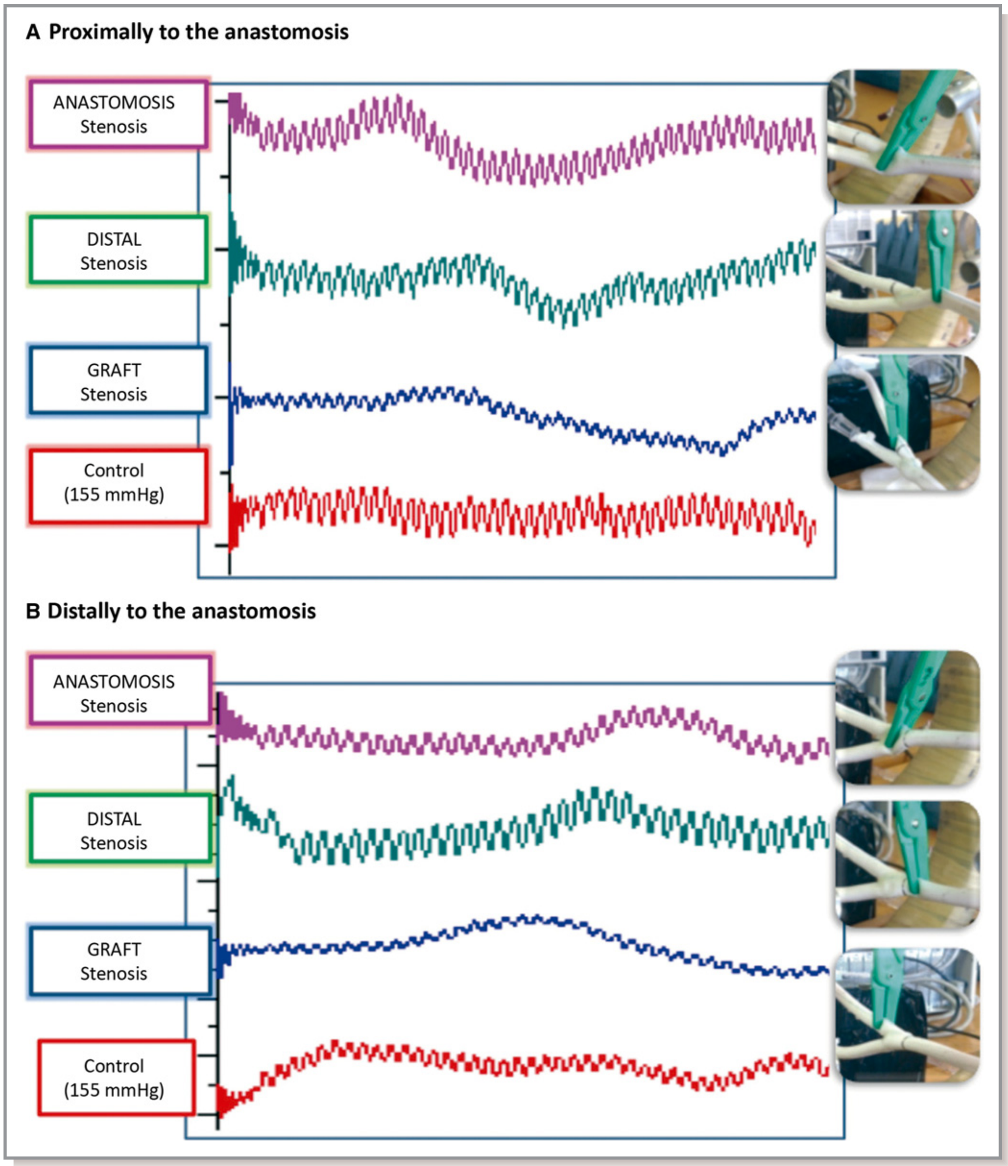

Figure 6. Waves registered by the microwire implanted proximally (A) and distally (B) to the anastomosis.

In this research, a wireless sensor has been developed, for the first time, for monitoring procedures in vascular pathology with which they have obtained excellent in vitro results, in terms of correlation between the MW potency and the registered pressures. On the basis of these results, the BIAS potency seems to change from a variation threshold of the MW potency. That is to say, for small MW potency variations, the BIAS potency is not affected, whereas for larger MW potency variations, the BIAS potency begins to vary in a proportional manner.

Therefore, the variation of the BIAS potency only in bovine artery may be attributed to its lower rigidity with respect to PTFE and to its greater compliance. According to Tiwari et al., the compliance of the healthy artery (0.059%/mm Hg) is greater than that of PTFE (0.016%/mm Hg); therefore, it is able to better emit a pulsatile flow. However, the compliance of the artery decreases with advancing age and evolution of arteria and sclerosis disease[15]; therefore, in the future, and to ensure reliable monitoring of vascular procedures, we believe that the position of the ring sensor in PTFE is more effective. In addition, the finding of prosthetic material would, in the future, enable to incorporate MW to the fabrication network, which therefore would increase the contact surface between the sensor and the graft, thereby probably increasing sensitivity. However, these findings should be confirmed in subsequent studies in experimental animals.

The magnetoelastic microwire has been able to locate and quantify the stenosis caused in bovine artery and in a latero-terminal anastomosis of PTFE with a high statistical power. It

Table 8. Fourier Analysis of the Signals Registered in the Model of L-T Anastomosis in PTFE

	Group	BIAS Frequency (Hz)	BIAS Potency (AU)	MW Frequency (Hz)	MW Potency (AU)
	Control				
	Average	0.1124	0.0427	0.07837	0.0959
	SD	0.0180	0.0242	0.0319	0.0274
Group A (microwire proximal to anastomosis)	Graft stenosis				
	Average	0.1007	0.0280	0.7710	0.0408
	SD	0.0089	0.0074	0.0457	0.0145
	Anastomosis stenosis				
	Average	0.1261	0.0632	0.7915	0.1210
	SD	0.1548	0.0252	0.0468	0.0305
	Distal stenosis				
	Average	0.1330	0.0489	0.08071	0.1039
	SD	0.1535	0.0082	0.0376	0.0210
Group B (microwire distal to anastomosis)	Graft stenosis				
	Average	0.1292	0.0275	0.7926	0.0358
	SD	0.1242	0.0132	0.1339	0.0125
	Anastomosis stenosis				
	Average	0.1088	0.0373	0.8131	0.0387
	SD	0.0354	0.0156	0.0480	0.0117
	Distal stenosis				
	Average	0.0969	0.0763	0.7903	0.1420
	SD	0.0183	0.0152	0.0472	0.0580

AU indicates arbitrary units; MW, microwire; PTFE, polytetrafluoroethylene.

has been found that the position of the stenosis with respect to the sensor causes a change in the morphology of the registered signal that is even more evident the greater the degree of stenosis. It is also important to note that based on the results above, we believe that the distance between the stenosis and the sensor affects the signal emitted by the sensor, which would increase the applicability and versatility of the sensor. This will be studied in future research.

The sensor has correctly classified a significant percentage of stenosis of any degree, both in position before sensor as well as distal to it, and has been able to properly diagnose 100% of severe stenosis in bovine artery. These results have been obtained under ideal laboratory conditions and thus may not be transposable to clinical practice and must be confirmed in future studies.

There are numerous articles that offer results of various telesurveillance programs. A review article that included 65 studies conducted in Europe and the United States that analyzed telesurveillance programs of different pathologies concluded that home surveillance of chronic diseases provided accurate and reliable data with minimal technical problems. It also influenced the attitude of the patient, increasing their commitment in the control of the disease, which potentially improves their medical conditions.[16]

Therefore, although the design, development, and implementation of WSN systems poses a difficult task with several issues with high technical difficulty, the benefits of its use for the prevention, early diagnosis, and management of diseases are multiple and widely documented.[16–21]

Currently, there are follow-up protocols for various procedures in vascular surgery with the aim of identifying those malfunctioning grafts, which need to be reoperated and thus maintain their permeability. However, there is a lack of consensus with regard to the tests to be carried out, frequency of evaluations in the postoperative period, as well as cost-effective impact of the various existing strategies.

Currently, the echo Doppler is the most used test for the follow-up of revascularization surgery of the lower limbs. However, because it is an exploring-dependent test, it has several limitations, as is the case of calcified arteries or deep grafts. Despite the high sensitivity and specificity of the echo Doppler in the follow-up of the infrainguinal vein grafts, there is conflicting information regarding the benefit in terms of cost-effectiveness and salvation of the extremity.[22–28] In

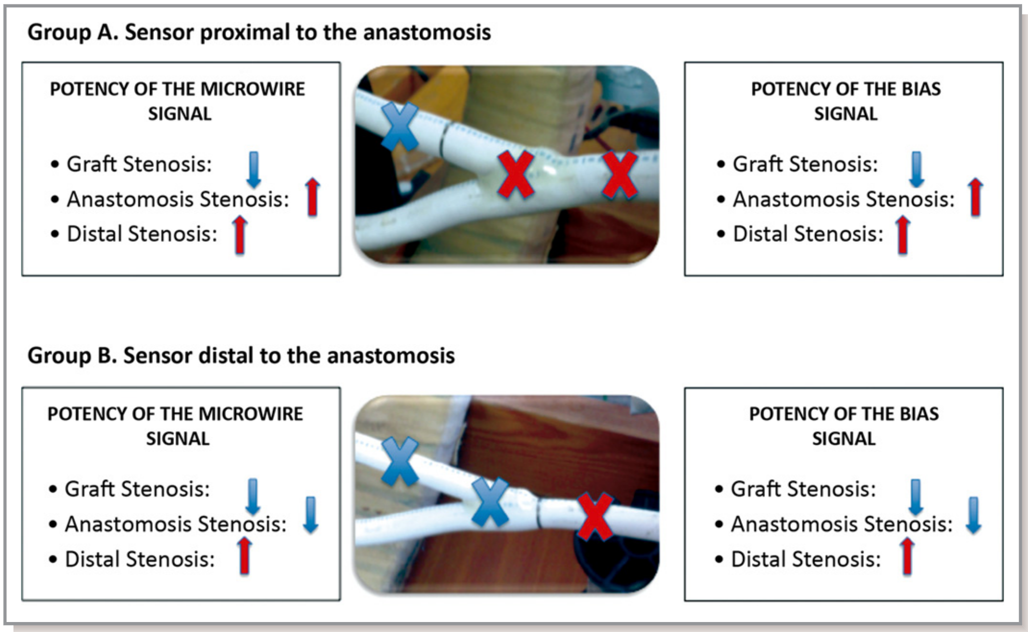

Figure 7. Variations on the signal emitted by the sensor after Fourier analysis with regard to the group A (sensor proximal to the anastomosis) and group B (sensor distal to the anastomosis). In blue, stenosis before the sensor; in red, stenosis distal to the sensor.

addition, tracking through echo Doppler has not shown to increase the permeability of the prosthetic grafts[29,30] nor of the endovascular techniques,[31,32] and therefore, on the basis of the results obtained in this study and the demonstrated efficiency of the new wireless methods of clinical assistance,[5] the establishment of a new surveillance protocol for the procedures in vascular surgery based on WSN technology could be of interest in the future.

Therefore, the development of new methods for wireless surveillance offers numerous advantages. In the first place, it allows to assess the pressure in an exact point with a high sensitivity and specificity. It also removes the explorer-dependent factor, in that, because it is a noninvasive and wireless test, it can be performed on an outpatient basis without the need for specialized personnel and could even be performed from the patient's home, which could modify the

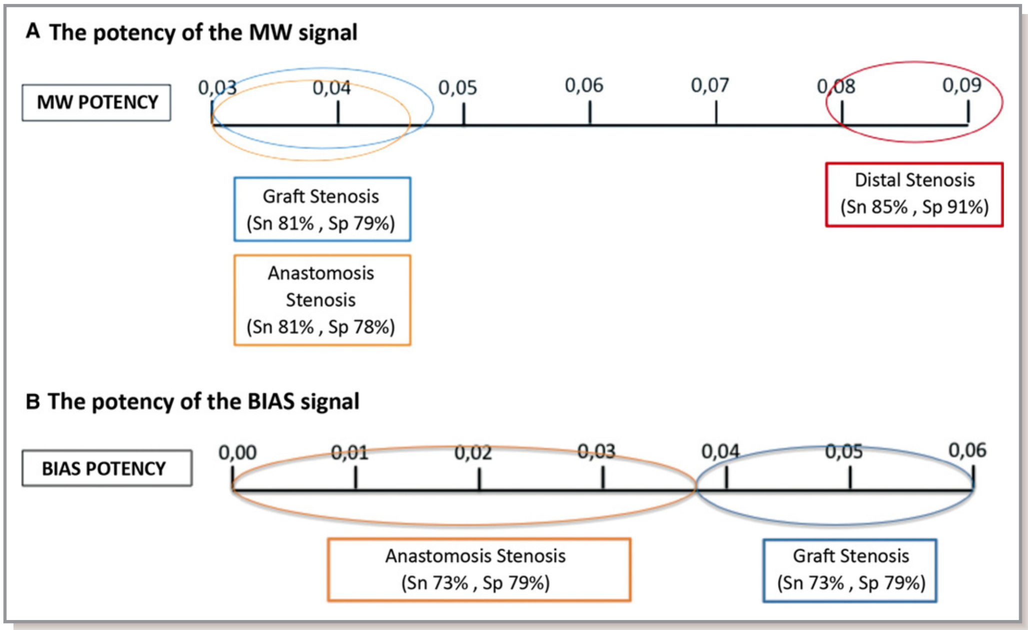

Figure 8. Classification of the type of stenosis depending on the potency of the MW signal (A) and the BIAS signal (B). MW indicates microwire; Sn, sensitivity; Sp, specificity.

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postoperative care to patients operated by vascular reconstructions in the future.

Conclusions

The magnetoelastic microwire has proved an excellent statistical correlation between the pressure of a fluid and the power of the signal emitted by the device in both PTFE as well as in bovine artery. It is also capable of detecting, locating, and quantifying the degree of stenosis in bovine artery, as well as in a latero-terminal anastomosis with a high statistical power.

For the first time, a wireless in vitro sensor has been developed for the postoperative follow-up of the vascular surgery procedures. However, the results obtained have to be validated in future research in animal models.

The resultant technological development allows for the possibility of developing new forms of surveillance of procedures in vascular surgery by telemetry with numerous potential applications in our speciality in the future.

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Disclosures

Hernando Rydings, Aragón Sánchez, Marín Palacios, Hernando Grande, and Serrano Hernando possess a patent related to the sensor described in this investigation (ES2524733). The other authors report no conflicts.

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