INFRARED THERMOGRAPHY AS A SUPPORT TOOL FOR DEVELOPING SHAPE-MEMORY POLYMER BIODEVICES

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Abstract: Infrared Thermography is a technique for carrying out inspections and non-destructive tests that can also be used as a support tool for developing medical devices based on the use of shape memory polymer materials. This paper sets out some of the opportunities and advantages provided by this technique for designing the heating systems associated with these shape-memory polymer based devices. Its application for developing an active pincer, whose geometry can be changed by heating, is explained in detail. Similar devices can be used as active catheter ends for minimally invasive surgery tasks.
These thermography tests can also be used as a validation tool for the heating simulations, linked to optimising this type of devices, and also during "in vitro" tests aimed at obtaining safer active implantable devices.

1 INTRODUCTION TO INFRARED THERMOGRAPHY

Infrared (IR) Thermography is a technique for carrying out inspections and non-destructive tests which has multiple applications in the development of machines and products, equipment and facilities maintenance, and troubleshooting.

Since all bodies emit (according to their temperature) infrared radiation, which increases in intensity as the temperature rises, variations in this intensity can be detected by using infrared sensors.

Thermal cameras can detect radiation in the infrared range of the electromagnetic spectrum (usually between a 900 and 14000 nm wavelength, instead of operating in the visible range of 450 to 750 nm) and can produce images of this radiation.

These cameras are fitted with a sensor matrix (called microbolometer) that is sensitive to this radiation. Depending on the intensity of the radiation more or less current is sent to the camera's control electronics, which with the aid of specific software enables temperature maps to be obtained.

The spheres of application range from Mechanical Engineering, Electrics, Electronics, Aeronautics, Architecture and Engineering in general, to Medicine or Veterinary Science and even Art and Archaeology. The last decade has seen enormous progress in the equipment available on the market as well as more affordable prices that have led to its expansion as a testing technique in all kinds of industry.

Some of the fundamental advantages of the technique are its speed and ease of use, easy to interpret temperature map-based results and the fact that it is a non-destructive technique that does not damage the systems under study (Schindel, 2007, Maldague, 2001).

Apart from these applications, its use as a support tool for developing medical devices, especially those based on the use of shape-memory polymer (SMP) materials, is detailed in this work.

The main objectives of the study, as exposed in the following chapters, are:

- To show the importance of validating FEM thermal simulations with trials.
- To explain how IR thermography can be used in such validating trials.
- To make clear how both techniques should be used in a combined way for improving SMP-based medical devices development.

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2 SHAPE-MEMORY POLYMERS AND POTENTIAL BIODEVICES

Shape-memory polymers (SMPs) are materials that show a mechanical response to external stimuli, usually to changes of temperature. When these materials are heated above their “activation” temperature, there is a radical change from rigid polymer to an elastic state that will sometimes allow deformations of up to 400%. If the material is cooled after manipulation it retains the shape imposed; the said structure is “frozen” and returns to a rigid but “unbalanced” state. If the material is again heated above its glass transition temperature or “activation temperature” it recovers its initial non-deformed state.

The cycle can be repeated numerous times without degrading the polymer and most suppliers can formulate different materials with activation temperatures of between –30 ºC y 260 ºC, depending on the application required. Of all the polymers developed that show shape memory properties, those most worthy of mention are epoxy resins, polyurethane resins, cross-linked polyethilene, styrene-butadiene copolymers, polynorbornene and other formulations (Lendlein, 2002, 2005, Liu, 2007).

They are therefore active materials that present thermomechanical coupling and a high capability for recovery from deformation, (much greater than that shown by shape memory metal alloys), which combined with their lower density and cost has favoured the appearance of numerous applications. Their properties permit applications for manufacturing sensing devices or actuators, especially for the aeronautics, automobile and medical industry.

They have been proposed to develop numerous medical devices such as self-expanding stents (Wache, 2003), intelligent sutures (Lendlein, Kelch, Langer, 2002, 2005), thrombectomy devices (Wilson, 2006), active catheters (Yackaki, 2007), drug delivery devices (Gall, 2004) or annuloplasty systems (Díaz Lantada, 2008).

As an example of the capability of these materials to recover their geometry Figure 1 shows the closure of a pincer manufactured in epoxy resin (whose trade name is Accura® 60) when its memory is activated by heating (under forced convection using a hot-air gun with air at 80 ºC).

Similar devices, introducing appropriate changes to their geometry according to the application, could be used as the active end of a catheter to remove harmful particles, clots and other elements.

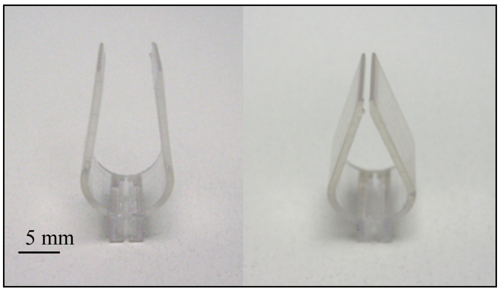

Figure 1: Shape-memory effect in an epoxy resin pincer.

The following section explains how infrared thermography can help optimise the development of shape memory polymer-based medical devices.

3 THERMOGRAPHY AND SMP BIODEVICE DEVELOPMENT

3.1 Operational Considerations

Generally speaking, the total power emitted per unit of area is given by Stefan-Boltzmann’s Law, which for a black body is expressed using the constant σ:

$$E_b = \sigma \cdot T^4 \tag{1}$$

It is important to point out that the concept of a “black body” is an ideal concept as the real objects are “grey bodies”, which means the concept of emissivity “ε” has to be taken into account, giving the equation:

$$E_b = \varepsilon \cdot \sigma \cdot T^4 \tag{2}$$

Where emissivity shows values in the $0 < \varepsilon < 1$ range and relates the radiation that would be emitted by an ideal black body at the same temperature. This constant is highly dependent on the material’s surface and its finish, and on the wavelength and surface temperature, and can have a marked influence on the results of the tests performed with infrared thermography equipments.

So, when conducting thermography tests, the value of the said emissivity needs to be selected depending on the material of the object or device under study. The camera itself incorporates typical values for different metals, polymers, ceramics and other materials.

For materials not included in the camera software, the emissivity of the material can be determined by painting a part of the object or device with black optical paint, for example Nextel Black Velvet, which gives an emissivity very close to 0.94.

Then the value of the emissivity in the camera can be changed for the original material surface until its reading is adjusted to the pre-measured value for the reference painted zone.

Figure 2 shows an example of the influence of surface colour on the emissivity of the pincer prototypes manufactured in shape-memory epoxy resin. It shows how the different emissivity leads to erroneous measurements of temperature, with differences of around 3 ºC, even though all the prototypes are the same temperature.

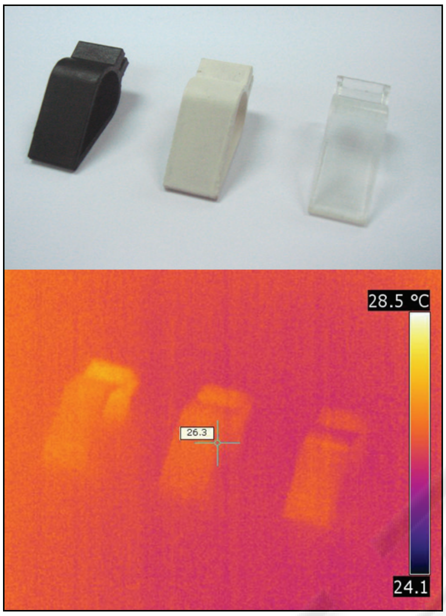

Figure 2: Importance of calibrating the emissivity of the material.

Therefore, for the above prototypes, according to the data in Figure 2, the emissivity values would be:

Black pincer.- 0.94
White pincer.- 0.92
Translucent pincer.- 0.86

This calibration of material emissivity is particularly important when the device has to fulfil its mission inside the human body, where differences of 2 to 3 ºC can be decisive for avoiding damage to tissue surrounding the end device.

Other environmental factors such as wind, rain or snow, whose influence is usually listed in the correction tables supplied by the thermography equipment manufacturers, may be omitted if the characterisation tests are conducted in a laboratory.

3.2 Characterization of Materials and Applications

As already explained, in order to produce geometric changes in active implantable devices based on shape-memory polymers the temperature of the material needs to be raised above its glass transition temperature. In the development process of these devices infrared thermography can be used as a support tool for other characterization and design technologies, particularly regarding:

- Determining the activation temperature in the different candidate materials.
- Designing and optimising the heating system to activate a change in the device geometry.
- Validating thermal simulations so that design decisions can be made more quickly.
- Carrying out the shape memory training process at the most suitable temperatures.
- Carrying out “in vitro” tests, as a prior step to tackling “in vivo” tests.

The last four points put forward are set out in the following sections, since determining the activation temperatures of the different candidate materials is usually performed with DSC or DMTA tests (Mather, 2002, Volk, 2005).

3.3 Designing the Activation System

To make the preliminary design for the heating system the number and value of the heating resistors can be pre-selected (in case of Joule effect based activation) in line with the following calculation procedure.

If the resistors in the active device are required to reach a steady state temperature above shape-memory activation temperature, the power generated must be equal to the leakage at that temperature. It must be thus verified that:

$$q = n \cdot R \cdot I^2 = C \cdot S \cdot (T_{biodevice} - T_{body}) \qquad (3)$$

With the following notation:

q.- Heat generated [W].
n.- Number of resistors connected in series.
R.- Resistance [Ω].
I.- Intensity through the resistors [A].
C.- Heat transfer coefficient [W/(m^2·K)].
S.- External surface of the device [m^2].

Having selected the heating resistors the transient state can also be evaluated and the time estimated that the device will take to reach activation temperature, as will now be explained:

$$q = n \cdot p = m \cdot c_p \cdot dT/dt + C \cdot S \cdot (T - T_{body}) \quad (4)$$

With the following notation:

m.- Device mass [kg].
c_p.- Specific heat of the SMP [J/(kg·K)].
T.- Device temperature [ºC ó K].
p.- Power generated by each resistor [W].

The differential equation is integrated between the initial temperature, usually 37 ºC, and the final temperature required for activation, which gives the necessary activation time.

However, in order to optimise the design of the heating system required to activate the geometric change in a shape-memory material based device, the combined use of infrared thermography tests and simulations made applying the finite element method is highly valuable.

This procedure will be explained below for the shape memory pincers already mentioned, which could be used as an active catheter end in minimally invasive surgery tasks.

The properties of the epoxy resin used for manufacturing the prototypes are listed in Table 1 and have been used when designing the device as well as for the simulations performed.

Table 1: Properties of the material used.

Accura® 60 Epoxy Resin	
Density	1.21 g/cm^3
Tensile Strength	58 – 68 MPa
Tensile Modulus	2690 – 3100 MPa
Glass Transition (T_g)	58 ºC
Hardness, Shore D	86

It is important to emphasise that although its activation temperature of around 60 ºC could not result in a safe intracorporeal device, there are several shape-memory polymers whose activation temperatures are closer to human body temperature and which could be subjected to a procedure similar to that set out in this work.

A heating resistor of 4.7 Ω was chosen for the tests and it was fitted into the device in an specifically designed housing, which was finally filled with additional epoxy resin. The prototype is shown in Figure 3.

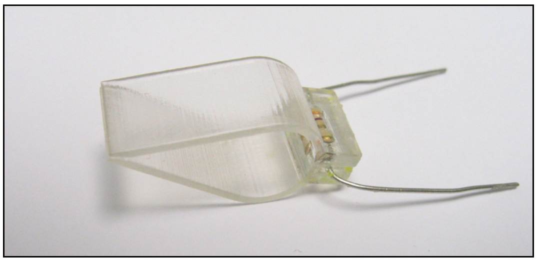

Figure 3: Epoxy resin pincer with built-in heating resistor for activation.

This prototype was heated above the glass transition temperature of the epoxy resin by using a hot air gun with air at 80 ºC for forced convection. The temporary shape was obtained by inducing opening using traction perpendicular to the middle plane of the pincer, just 2 mm above the resistor. In this way, most of the temporary deformation is produced in the zone near to the heating resistor, which means that the initial shape can be recovered by heating a small area of the device.

The low conductivity of the polymers means that the use of several heating resistors is usually required for devices with geometric changes in different zones. The way of giving our device its temporary shape means that the tests can be carried out with a single resistor.

Figure 4 shows heat activation of the shape-memory polymer based pincer. For the infrared thermography tests, shown in Figure 5, a variable voltage transformer was used. The first image shows the situation under a steady state with a 0.6 W heating power (geometric change activation is not reached) while the second shows the situation under a power of 1 W (which allows T_g to be exceeded and activates the device).

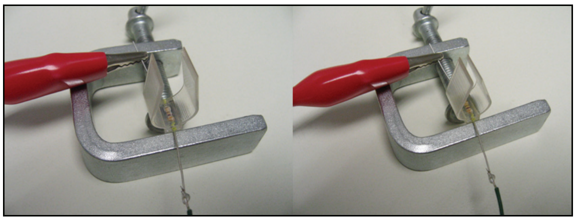

Figure 4: Activation by heating the pincer and recovery of its geometry.

The ANSYS 9.0 finite element calculation program was used to carry out the heating simulations. Heating powers of 0.6 and 1 W were used, similar to those used in the thermography tests, with the purpose of comparing the results.

Additional data on the material and boundary conditions used in these tests are set out in Table 2.

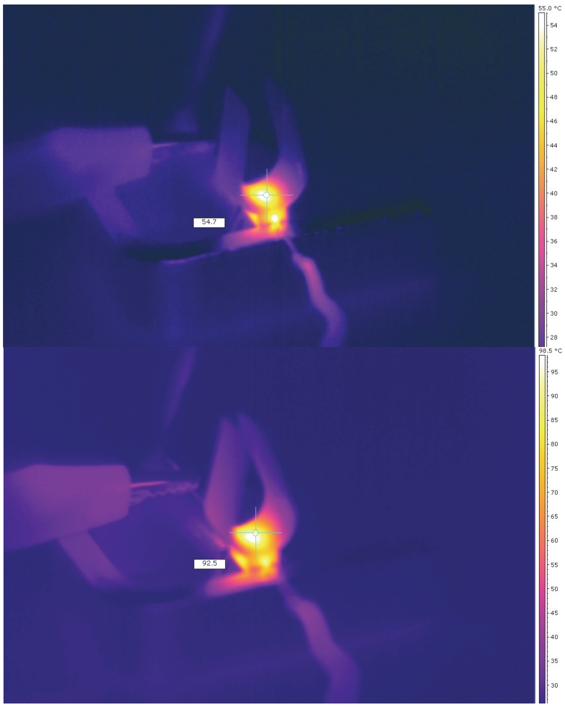

Figure 5: Infrared thermograph of the pincer during the heating process, below (54.7ºC) and above (92.5ºC) activation temperature.

Table 2: Additional data for finite element simulations.

Thermal conductivity	0.2 W/(m·K)
Specific heat	1.6 J/(g·K)
Emissivity	0.86
Convection coefficient	15 W/(m^2·K)
Ambient temperature	26 ºC
Isotropic material hypothesis	

The results of the simulations carried out are shown in Figure 6 as steady state temperature maps and its relation with the thermography tests performed is also explained.

It is important to point out the similarity of the results given by simulations and tests, which makes us specially confident in the usefulness of our simulations for future heating system optimisations. For a 0.6 W heating, the steady state temperatures of the hottest zone given by testing and simulation are 54.7 ºC and 52.8 ºC respectively. For 1 W of heating, these temperatures reach 92.5 ºC in the test and 92 ºC in the simulation. The temperature distribution is also similar, with errors of less than 5% overall.

So, infrared thermography can be used as a tool in non-destructive tests for validating the results of simulations performed as part of the design process for shape memory polymer-based devices.

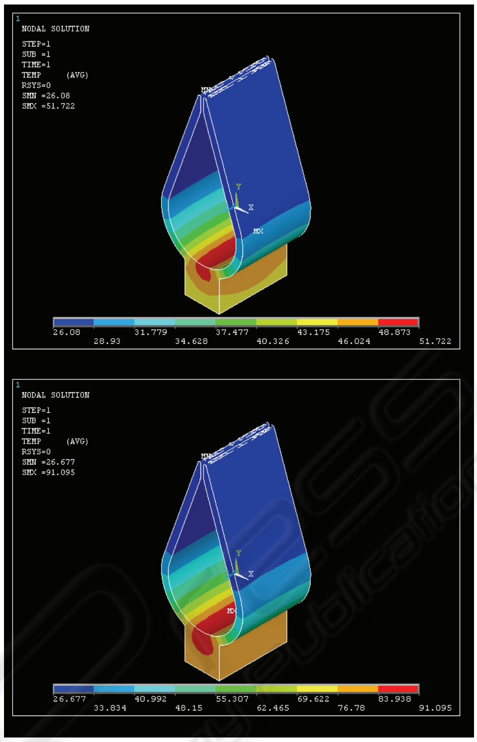

Figure 6: Heating simulations. Solution of steady state temperatures for heating powers of 0.6 and 1 W.

3.4 The "Memory" Effect Training Process

To enhance the process of obtaining the temporary shape of the shape memory polymer device, instead of using oven convection heating or the help of a hot air gun, the resistors in the activation system of the device itself can be used.

In this way, with the help of associated control electronics, the glass transition temperature can be exceeded in specific zones of the device where the geometry could be mechanically changed.

The use of thermography devices can be useful for controlling and limiting the heating of the device so that it will only exceed the T_g in the zone whose geometry is wished to change temporarily, the rest of the structure remaining unaltered.

3.5 Carrying Out "in vitro" Tests

Infrared thermography is also useful when it comes to carrying out "in vitro" tests for validating the device before going on to the "in vivo" tests.

In a similar way to the examples shown, the temperature reached by the surface of a prototype of a SMP-based implantable device during activation can be checked. It can be checked whether this temperature is harmful for the tissue that will be in contact with the device. In addition the effectiveness of using protective coatings can also be studied.

Indeed, by implanting the device “in vitro” and taking a thermograph during the activation process, the temperature of the tissue surrounding the device can be measured at any time to ensure that no harmful heating is being produced.

4 CONCLUSIONS

The work presented shows the use of infrared thermography as a support tool for the development of medical, surgical or implantable devices based on the use of thermally activated SMPs.

This technology is extremely helpful for designing the activation system of these devices and for validating heating simulations aimed at optimising their development. As an application, tests and simulations carried out with active pincers obtained by rapid prototyping are shown. With slight changes to their geometry and size, such devices could be used as active catheter ends for minimally invasive surgery.

Thermography is also extremely useful for carrying out “in vitro” tests and obtaining safer end implantable devices, which would not potentially harm the surrounding tissues by heating, as a result of optimising the heating and isolating system using combined FEM simulations and thermography trials.

As future challenges it would also be interesting to apply such a procedure to medical devices based on other active materials that can be thermally activated. It could therefore be applied to improve the response of actuators manufactured with shape memory alloys or sensors based on pyroelectric materials.

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