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New Biomedical Applications Approach using Shape Memory Polymers for Muscles Rehabilitation and the Accompanying Wounds after Severe Bone Fractures

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Abstract*:* This article introduces a new approach for modern applications of medical devices using shape memory polymers to aid in the rehabilitation of muscles and injuries attached to severe fractures. The group of heaters connected with the splint controls the temperature and humidity inside the affected area. Microcontrollers were attached to the polymer plate in order to directly control the required parameters and changes in addition to giving direct commands to the connected sensors. Because of the property of changing the outer shape of the polymer after being exposed to a certain temperature and returning to the normal shape after the removal of the external influence, the designed polymer plate applies light intermittent pressure on the wound area, muscles, and surrounding tissues, which helps to speed up the rehabilitation of these muscles, especially after She suffered from stiffness due to lack of movement during the period of treatment.

Keywords: Bone Fractures, Medical devices, Microcontroller, Shape Memory Polymers, Smart splint,

I. Introduction

Many types of polymers used in the clinical field these days are materials that have been developed initially for application areas other than biomedicine applications. On the other hand, biomedical applications need other different material properties and functionalities assortments.

With regard to the intrinsic properties of materials, the desired functions of the materials cannot be obtained directly but are produced depending on the method of polymer synthesis suitable for those properties. A common example of such cases is the properties of shape memory or in other words, the effect of thermally induced shape memory. The ability of a substance to recover its previous shape by exposure to an external stimulus (in our case, the temperature change) is known as the thermally induced shape memory effect. [1].

At the present time, the development of smart materials in addition to the high performance of these materials is one of the most important goals of modern polymer science [2]. These materials can be considered at the present time as partial machines or artificial muscles, as these newly developed materials have the ability to show appropriate sensitivity to various environmental changes such as heat or light, etc. [3,4].

The effect of shape memory is one of the most important vital applications used in medical device applications at the present time, especially in materials used for minimally invasive surgical applications [5], where the effect of the double shape enables the material to change from one case to another (as in the figure) [6].

Form A can be considered as a temporary form generated by the programming process, and form B is the permanent form obtained during the polymer's initial processing [7,8]. The material programming process consists of two parts, the first part is mechanical deformation, and the second part is the post-fixation of this deformation. As these polymers, when exposed to an external stimulus, restore (shape memory) their permanent shape. This programming and retrieval process can also be repeated more than once in different temporary forms at later levels.

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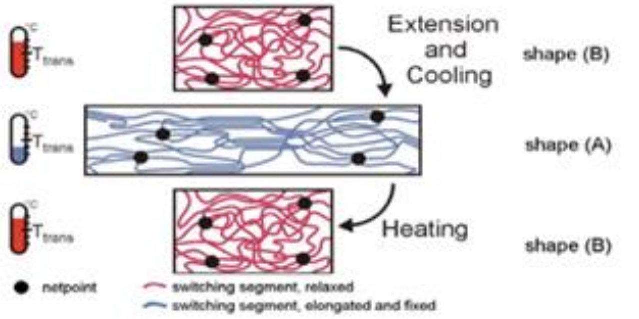

Fig. 1 The Molecular mechanism of the thermally generated shape-memory effect (dual-shape effect). where: Trans= thermal transition temperature related to the switching phase.

Embedded systems can be defined as dedicated devices equipped with an operating system and processor, designed to perform a specific operation alone or a group of pre-programmed operations at the same time. These systems contain a set of software and hardware designed to enable a special system consisting of mechanical and electronic components to serve a specific purpose through a microprocessor or microcontroller.

These systems operate interactively in real-time with limited resources and can perform its critical tasks from time to time in their respective areas of use [9].

The idea of designing an intelligent splint with different features has recently attracted many researchers because of its importance in developing methods and reducing the treatment period for patients with various fractures. In the following paragraph, we will present some of the essential previous literary studies in which researchers designed new systems on this topic.

In March 2020, Zaid Al-Sawaff et al., designed an electromagnetic field nickel-titanium (Ni-Ti) based smart splint. This splint contains three nickel-titanium wires of different diameters, each of these wires is connected to a constant current source. They proved through practical experiments that the electric current applied to the fracture area was effective in accelerating the healing process of the fractured area. In addition to the other unique specifications of the nickel-titanium wires, they were able to use them to reduce post-fracture symptoms such as atrophy of the surrounding muscles and stiffness of tissues and tendons in the fracture area[10].

In the same year, Burgo J. et al. Designed a smart splint using 3D printing techniques and based on microcontrollers [11]. This smart splint can monitor vital variables such as pressure, temperature, and humidity in the area around the fracture to control them in a short time in case of any emergency. This splint allows readings to be taken from the skin immediately after it is placed or the skin comes into contact with the splint [12]. In the same context, the authors presented another design for a smart splint based on 3D printing, where their design could add any electronic sensor that works by a battery in order to monitor several biological variables in the fracture area such as pressure, temperature, and change in the color of the surrounding tissue. They showed that it is possible in the future to link this cast with an algorithm that predicts future variables and compares them with previously stored data [13].

Also, K. Li, et al. presented a model of a smart splint manufactured using 3D printing techniques that can sense the changing pressure in the fracture area in order to detect the area of looseness in the cast and display the results on a screen attached to the splint. This splint can also measure the temperature in all cast areas through a temperature sensor that connects the cast to the patient's skin [14].

in This paper, we designed a smart electronic splint made of polymer shape memory alloy that can measure and detect vital variables in the fracture region such as temperature, pressure, and humidity. In addition, this splint has the ability to make stimulate the muscles and tissues of the area under the influence (the leg was taken as a case study) using the shape memory property of these polymers.

II. Materials and Method

The shape memory polymer (SMP) can be considered a smart material that has the ability to respond to an external stimulus by changing its molecular arrangement and then rebounding to its original shape from the temporary shape [15-18]; Fig.1 explains the changing procedure of a thermal reaction SMP using the heating process. initially, the temperature of the polymer is increased above the glass transition temperature (Tg), and then it is deformed by external forces or stresses in order to obtain a deformed shape. After that, the polymer is cooled, and the initial forces or stress are dismissed to get the temporary shape [19,20].

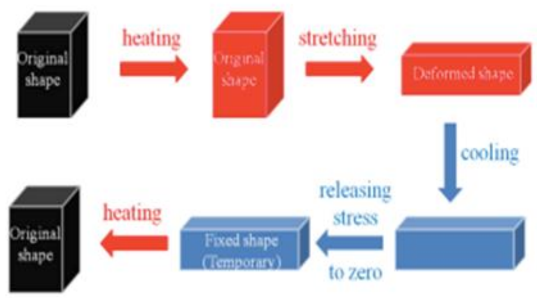

Fig. 2 Heating method for changing processes of the thermal-responsive shape memory polymer

The transformation is usually known as "martensitic transformation (MT)" while heating the sample from the low-temperature martensitic dimension, the transformation of solid solution into primary solid solution starts at the given

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temperature As (Austenite starting point) [21]. The transformation is ended at the known temperature Af (Austenite finishing point) [21]. At this known temperature, the complete sample is made over again into the first solid solution phase, in the same way [22], while cooling processes from the high-temperature austenite dimension, phase transformation austenite into martensite begins at the fixed temperature Ms (martensite start) and finishes at Mf (martensite finish) [23].
This is the basis for the work of the SMA polymers, as it returns to their original shape in which it was manufactured when they reached the appropriate temperature.
The heat transfer analysis [24] of the polymer was carried out using the heat transfer equation for convection with a mass coefficient and Brinson's model to describe the thermomechanical behavior of the SMAs, as the convection determines the equation of the heat transfer model and the average value of heating and cooling [24]. It is worth noting that the main parameters in this equation are applicable in engineering calculations and can also be easily determined by typical engineering experiments. First, we separate the volume fraction of martensite (ξ) into components due to stress (ξs) and temperature (ξT) such as: [25-30]

$$\xi = \xi_s + \xi_T \quad (1)$$

Also, the unit of elasticity (E) has been assumed as a linear function of the martensitic volume fraction:

$$E(\xi) = E_A + \xi(E_M - E_A) \quad (2)$$

Where ME and AE are martensite and austenite phase moduli of elasticity, respectively.

The simplified form of Brinson's constitutive equation allows using a more compact form:

$$\sigma = E(\xi)(\varepsilon - \varepsilon_L \xi_s) + \theta(T - T_0) \quad (3)$$

Where:
σ = the stress,
ε = strain,
T = the temperature of the wire,
θ = the thermal coefficient of expansion,
T0 = the initial temperature, and
Lε = the maximum recoverable strain.

Material	Specific gratify	Tensile modulus [GPa (ksi)]	Tensile strength [MPa (ksi)]	Yield strength [MPa (ksi)]	Elongation at Break (%)
Polyethylene (Low density)	0.917-0.932	0.17-0.28 (25-41)	8.3-31.4 (1.2-4.55)	9.0-14.5 (1.3-2.1)	100-650
Polyethylene (High density)	0.952-0.965	1.06-1.09 (155-158)	22.1-31.0 (2.3-4.5)	26.2-33.1 (3.8-4.8)	10-1200
Poly (vinyl chloride)	1.30-1.58	2.4-4.1 (350-600)	40.7-51.7 (5.9-7.5)	40.7-44.8 (5.9-6.5)	40-80
Polytetrafluorethylene	2.14-2.20	0.40-0.55 (58-80)	20.7-34.5 (3.0-5.0)	----	200-400
Polypropylene	0.90-0.91	1.14-1.55 (165-225)	31-41.4 (4.5-6.0)	31.0-37.2 (4.5-5.4)	100-600
Polystyrene	1.04-1.20	2.28-3.28 (330-475)	35.9-51.7 (5.2-7.5)	---	1.2-2.5
Poly(methyl methacrylate)	1.17-1.20	2.24-3.24 (325-470)	48.3-72.4 (7.0-10.5)	53.8-73.1 (7.8-10.6)	2.0-5.5
Phenol-formaldehyde	1.24-1.32	2.76-4.83 (400-700)	34.5-62.1 (5.0-9.0)	---	1.5-2.0
Nylon 6,6	1.13-1.15	1.58-3.80 (230-550)	75.9-94.5 (11.0-13.7)	44.8-82.8 (6.5-12)	15-300
Polyester (PET)	1.29-1.40	2.8-4.1 (400-600)	48.3-72.4 (7.0-10.5)	59.3 (8.6)	30-300
Polycarbonate	1.20	2.38 (345)	62.8-72.4 (9.1-10.5)	62.1 (9.0)	110-150

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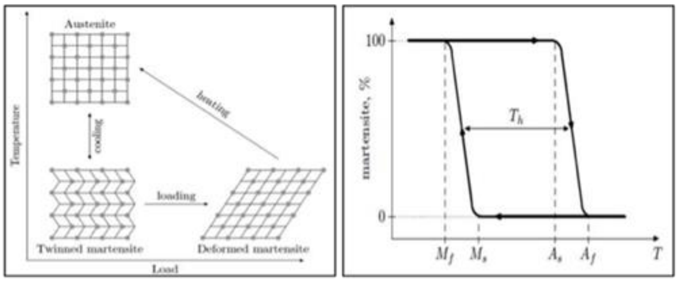

Fig. 3 temperature transformation curve for a specimen subject to one cooling-heating cycle, and four characteristic temperatures As, Af, Ms, and Mf of the phase transition process ate temperature rate from -50 to -110 C°

2.1 Monitoring system

Our goal in this research was to design an electronic splint that can monitor some vital variables important to the injured area during the healing process. For this, we used a microcontroller of the Arduino nano type because of its unique specifications and qualified at the same time for the proposed splint [32]. We also used pressure AMS 5812 AN02 sensor [32], temperature, and humidity DHT11 sensors [33] to monitor these important parameters during the healing process.

The Arduino Nano (Figure 4.a) features a new ATMega328 microcontroller and Arm's Cortex M0+ power-saving processor, which doubles the flash memory size and gives the processor a higher speed. Also, this type of Arduino is characterized by containing Microchip's Core Independent Peripherals (CIP), and its small size characterizes it compared to the rest of the other microcontrollers used in this field, which made it more suitable than others in our research project [33].

The AMS 5812 pressure sensors (Fig. 5) are high-precision sensors with two different outputs, the first one is analog, and the second one is 12C digital. The analog supply is from 0.5 to 4.5 volts and provides pressure measurement data. On the other hand, the digital output can take measurements of pressure and measurements of temperature. This output was not used in our research, where we used another sensor to measure the temperature.

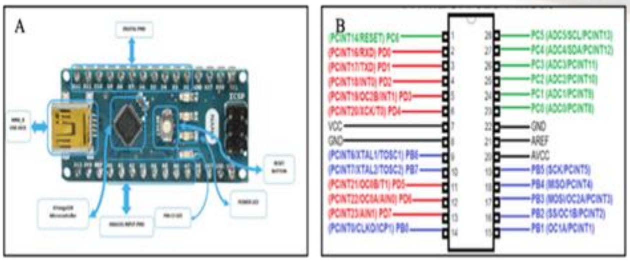

Fig. 4 A. Arduino every presentation. B. ATMEGA 328 pinouts

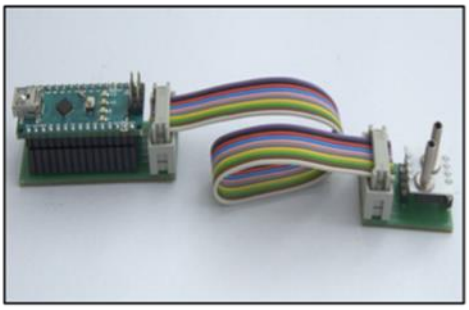

Fig. 5 AMS 5812 pressure sensor

The pressure sensors in the AMS 5812 series used in this project, combine a high-quality piezoresistive silicon sensing element with a modern mixed-signal CMOS ASIC for signal-conditioning on a ceramic substrate.

This enables a low total error band, excellent temperature behaviour, and high long-term stability, as in Figure 6A. The electrical connection of AMS 5812 sensors is typically made by soldering them directly on a printed circuit board or by mounting them on a suitable socket. To use the analog ratio metric voltage output only, it is sufficient to connect PIN2 (GND), PIN7 (VCC), and PIN8 (OUT). To read the digital output only, it is enough to connect PIN2 (GND), PIN7 (VCC), and the I2C-bus lines to PIN4 (SDA) and PIN5 (SCL), As in Figure 6B.

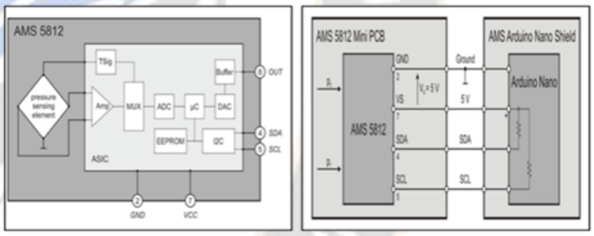

Fig.6 A. Functional description, and B. Electrical connection

Figure 7, explains the contents of the DHT11 temperature and humidity sensor with four pins- VCC, GND, Data Pin, and a not connected pin. this sensor consists of a capacitive humidity sensing element and a thermistor for sensing temperature

The pull-up resistor between 5k to 10k ohms is examined for communication between the sensor and the microcontroller.

The humidity sensing capacitor has two electrodes with a moisture-holding substrate as a dielectric between them. Change in the capacitance value occurs with the change in humidity levels. The process changed the IC measure's resistance values into the digital form [34-36]. This sensor uses a Negative Temperature coefficient thermistor for measuring temperature, which causes a decrease in its resistance value with an increase in temperature.

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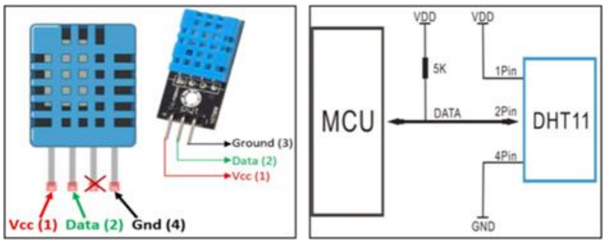

Fig. 7 DHT 11 Temperature and Humidity Sensor

After completing the process of manufacturing the memory shape polymer sheet, and attaching and connecting the temperature and humidity sensors to the plate, the process of programming the microcontroller board and designing the electronic circuits necessary to connect the sensors to the microcontroller begins. Taking into account that the data obtained from the microcontroller can be received by direct connection between the microcontroller and the PC or by using Bluetooth and Wi-Fi previously connected to the microcontroller. It is necessary to monitor the data coming from the temperature, pressure, and humidity sensors in the injury area during the period of use of the cast. Figure 9 illustrate the electronic connection of the proposed SMP cast.

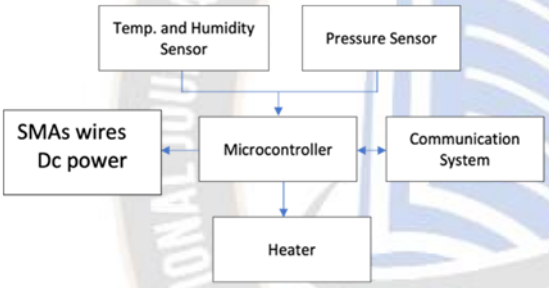

Fig. 8 the proposed smart SMP cast blog diagram

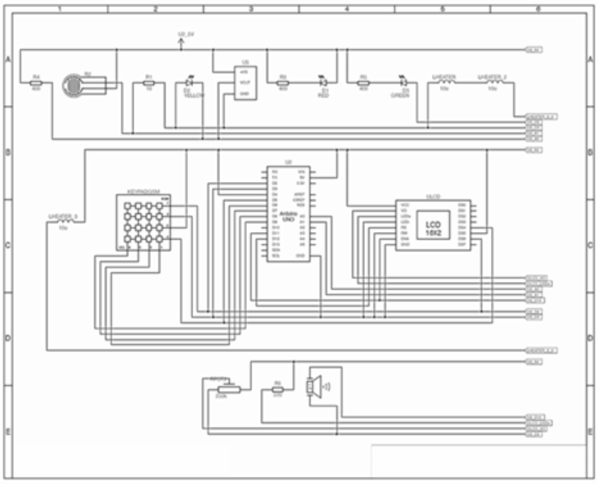

Fig. 9 The electronic connection of the proposed SMP smart cast

Figure 10 shows the relationship between the temperature taken from the temperature sensors attached inside and outside the splint during a specific period. The results showed that the temperature inside the splint was varied, where values were recorded between 36.8-38.4 C°. This discrepancy is because the sensor inside the splint was not in direct contact with the skin, as there was an air gap of 3 mm. On the other hand, the second sensor placed on the surface of the splint recorded values 2.4 C° lower than the first sensor. After taking the average temperatures between the first and second sensors, the change in the temperature of the splint can be measured, which is very necessary for the operation of the paper heaters connected to the cast in order to maintain a constant temperature throughout the treatment period.

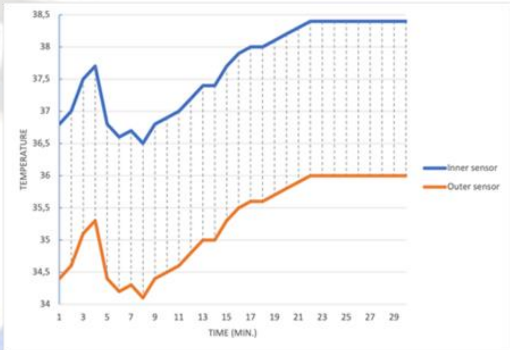

Fig. 10 the relation between the temperature taken from the temp. sensors and time in minutes

Knowing the amount of moisture inside the splint is very important, especially in cases that have undergone surgery or an injury in addition to a fracture, as humidity plays a significant role in the spread of pathogenic bacteria that cause many types of skin infections at injury site [37]. Figure 11 shows the humidity value inside and outside the cast taken from the humidity sensor [38] connected inside and outside the splint, the results showed a slight difference in the indoor humidity values over time, and these values are known to be changed according to the physiological nature of the human being in terms of sweating and other environmental conditions. In our research, it was also necessary to know the moisture value inside the cast in order to operate the attached paper heaters to stabilize the moisture value throughout the treatment period.

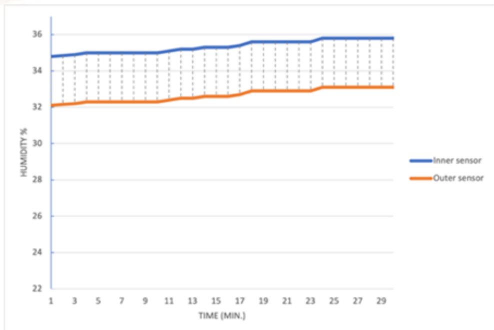

Fig. 11 the relation between humidity of the inner and the outer sensor with time in minutes

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In our research, we used an AMS 5812 pressure sensor with a surface area of 1 cm2. Figure 12 shows the average pressure inside the cast, where the graph shows that the value of the pressure applied to the fracture area by the cast is 58 gf/cm2, which is the pressure needed to stabilize the bone and joint that suffers from the fracture in its usual position without moving [39].

In order to know the effect of pressure inside the cast on the affected area, we simulated the presence of swelling in one of the affected areas and under the splint excitation. During the period between the 10th and the 15th minutes, we noticed that during the increase in the pressure inside the cast by applying an external force, the pressure exerted inside the cast changed to a value of 97 gf/cm2. By referring to the actual situation, the specialist can know the presence and location of swelling inside the injury area by taking advantage of the change in the internal pressure values inside the designed cast.

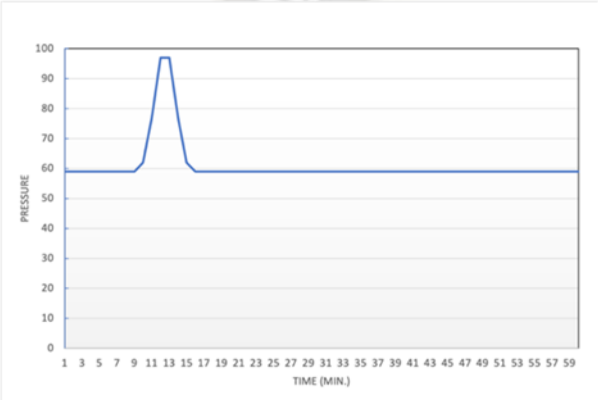


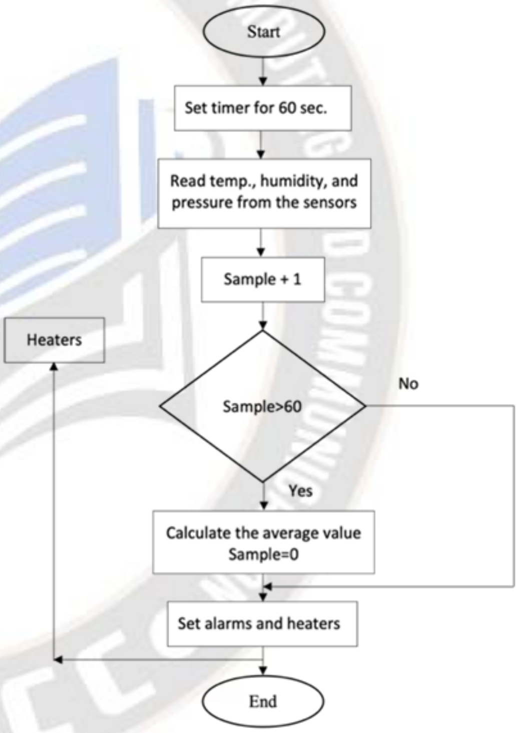
Fig. 12 The relation between the pressure applied on the designed cast over time

For more than half a century, research has been ongoing on humans and animals [40-42] in order to reveal the relationship between the change in temperature patterns and medical conditions, as the change in the temperature of any area of the body is usually caused by cell metabolism or local blood flow. On the other hand, with some disease processes or during the stages of new bone formation or repair of fractures, a noticeable decrease in the surface temperature of the affected area may occur [43].

In the case of using a traditional medical splint for any part or broken bone, the weight of this splint may lead to severe problems, in addition to the difficulty of washing and bathing, which may lead to pathological or physical problems of the skin in the area surrounding the broken bone. It is one of the most important daily problems that Orthopedic patients suffer from [44].

This study presents a design for an intelligent splint that can detect and sense the change in temperature, humidity and pressure applied to the affected area for a certain period determined by the doctor in order to discover potential problems in the area of injury during the treatment period, where the data taken from the sensors can be collected. Moreover, these data can be stored and then compared with the database to monitor the development of the situation.

In addition, the shape memory polymer, which is the backbone of the proposed splint, was used to activate and stimulate the tissues and muscles surrounding the broken bone through the ability of the memory of this alloy to restore its original shape, in addition to the group of paper heaters that are used to equalize the temperature or humidity inside the splint according to the need of the patient's needs. Furthermore, this proposed splint can be developed, and several other sensors added, as needed, to draw a thermograph or the like for the area under the splint and more accurate monitoring. The following structural diagram illustrates the working principle of the proposed smart cast.



III. Conclusion

The main objective of this study was to design an intelligent splint capable of monitoring different changes in some important parameters such as temperature, humidity, and pressure in the injury area in order to take a comprehensive picture of the development of the growth stages of the broken bone by using artificial intelligence.

The smart splint was designed and connected to an Arduino NANO microcontroller. This controller can monitor the change in the mentioned parameters with the help of special sensors for

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this purpose. In addition, the intelligent splint is designed from a shape memory polymer plate SMP.

This plate will stimulate the muscles and tissues surrounding the bone by taking advantage of the temperature change inside the splint, as the shape of the plate change according to the shape memory law throughout the treatment period. In addition, a group of paper heaters was attached along the inner surface of the cast to control the internal temperature and the amount of moisture inside the cast according to the general situation of the broken bone.

This smart splint is characterized by its lightweight due to the materials used in its manufacture and the possibility of updating it by adding other sensors or increasing the monitoring period during the healing process.

Author contributions

Warqaa Hashim: Conceptualization, Methodology, Software,
Tahani G. Al-Sultan: Field study, Data curation, Field study
Azza Alhialy: Writing-Original draft preparation, Visualization.
Zaid H. Al-Sawaff: Software, Validation. Investigation, Writing-Reviewing.
Fatma Kandimerli: Editing, making the final draft, and supervision.

Conflicts of interest

The authors declare no conflicts of interest.

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