Ultrasound welding device for reinforcement of the invasive textile mesh destined to the reconstruction of the thoracic wall

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Abstract. The assimilation of synthetic macromolecular compounds in the interdisciplinary fields represented by the medicine and therapeutics, must address the complexity of the problems imposed by the application field, mainly resulting from the temporary or long-term contact of the polymeric materials with the tissues and biological substances. In this context, polymeric biomaterials are defined as polymers or polymeric composite types certified as biocompatible in contact with the biostructures. Comparing to conventional procedures, ultrasonic welding is a domain with a lower overall weight, but with exceptional development and dissemination perspectives in different industrial branches (automotive, electrotechnical, electronics, microelectronics, medical devices), which involves techniques of combining new materials, biocompatible, intelligent composites, with shape memory, etc. Through their geometric, technical, bio functional and biomedical characteristics, the implantable medical devices must meet the imposed requirements, mainly represented by: chemical inertia, resistance to infections, adequate ratio between flexibility and dimensional stability, adaptability to the defect geometry and high bursting resistance etc.

1. Introduction
The process of thermal degradation of biomaterials in the stage of joining the constituent parts of the medical device is very important and can have a negative effect on its biomedical and bio functional properties [1].

In order to avoid this inconvenience, an innovative device was designed and accomplished in order to develop, through ultrasound welding, a reinforced knitted structure for reconstruction of the thoracic wall, in case of rejection of malignant/benign tumors in the sternum (figure 1).

The implantable medical device is intended for parietal stabilization in the case of anterior lateral defects, but also in cases in which a smaller defect (resection of two costal arches) resulted, which was considered as obligatory to ensure the stabilization especially due to the age of the patients or the alteration of the respiratory function (figure 2).

At the designing of the knitted textile structures, the following essential elements were considered:
- usage of raw materials suitable to the demands imposed by the destination, but also to the requirements for mechanical processing at a higher quality level;
- design of structures capable of providing bio functional and biomedical performance products suitable for the field of clinical application.
For the accomplishment of the knitted structure the PES 76 dtex/f34x1 yarns with tenacity of 3,5 cN · dtex$^{-1}$ and elongation at maximum break of 30% was selected.

In order to realize the invasive medical devices intended for the reconstruction of the semirigid wall of the thoracic cavity, two variants of knitting type were designed. These latters were realized in the chain structure with batting threads and executed with two bars with pastes. The difference between the variants is given by the height of the knitting ratio and the chain command.

![Figure 1. Clinical case study solved at Timisoara County Hospital, Romania, by using the invasive product for the reconstruction of the semi-rigid tissue.](image1)

![Figure 2. Medical device with textile structure implanted at Timisoara County Hospital, Romania.](image2)

**2. Material and methods**

The device was designed so that through its components and mechanisms the following operations would be ensured (figure 3):

- the desired displacements, characterized by certain sequences and durations, generated by the task programming system, in accordance with the requirements or commands transmitted. This operation is done by the microcontroller.

- comparing the current motion parameters with those required and making the necessary corrections through the sequence/motion controller.

- amplification of the control signal, usually of low power, in accordance with the requirements of the actuator, by using a power amplifier. Frequently, the power amplifier also performs galvanic separation functions between the low power and the power control circuitry, effective, high power drive.

- the actuator transforms the corrected signal into the input signal (moment, force, speed) in accordance with the requirements of the process.

- adaptation of the actuator parameters to the requirements imposed by the technological process, mechanical mechanisms and transmissions.

- sensor processing of the process parameter information and transmission of the corresponding signals to the motion controller.

The mechanical execution elements in this complex mechatronic system for moving in horizontal and vertical planes, rotating, etc. requires actuation systems powered by different types and forms of energy, that were placed on all three Cartesian coordinates, as follows:

The X-axis actuator is located on the metal frame (chassis) of the machine. The guide axes are located inside the metal frame, being supported at three points in order to avoid the loads that appeared during the ultrasound welding process. The axes are positioned in the same plane, being parallel both with each other and with the frames that form the chassis of the whole system (figure 4).
The Y-axis actuator has the role of ensuring the sliding and alignment of the ultrasonic welding electrode support (sonotrode). It is based on sliding elements on guide axes and linear bearings with mobile balls (figure 5).

**Figure 3.** General assembly of the ultrasonic welding device for the accomplishment of the reinforced mesh destined to the thoracic wall reconstruction.

The Z axis actuator consists of: mechanical support; mobile frame guidance system; transmission system; drive element; race limiting elements (figure 6).

**Figure 4.** The X-axis actuator.

**Figure 5.** Drive motor, sliding axes, end brackets, Y-belt tensioner.

**Figure 6.** Mobile frame of Z-axis

All the functional modules of the electrical installation are interconnected and placed in an electrical control panel.

The electrical installation is composed of the following functional modules:
- Electricity protection and distribution module: ensures the distribution of electricity to all other functional modules. The distribution and protection of the modules supplied from the single-phase electric power network is realized with the help of specialized devices of circuit breaker type.
- Automation module: for the control of servomotors and the sequences tracking step by step, an application based on a state-of-the-art microcontroller has been developed.
- Ultrasound generator module having the following components: - oscillator that creates the oscillation frequency itself; - amplifier for the signal level from the oscillator element; - piezoelectric element that receives the electrical signal from the amplifier and transforms it into a mechanical oscillation; - booster with role in the mechanical amplification of the amplitude of the mechanical
oscillation coming from the piezo element; - sonotrode - the final element that comes into contact with the welding surface and has the shape of the contact surface depending on the welding material and the shape of the splice and the power supply that distributes electricity for all component modules of the generator.

To drive the execution elements were used servomotor motors powered by DC power. DC motors are intended for the conversion of the electrical signal, in the form of an amplified voltage coming from a transducer, in a rotational motion of a shaft.

The advantages of such a motor consist in the processing of the input signals and the transmission of the initial power from the actuator, reducing the idle time, increasing the resolution and generating a higher maintenance torque.

Considering the intended purpose of the device, meaning the fabrication of the implantable medical, the following functional tests have been performed:

A. Drive control of the component mechanisms of the device and, implicitly, of the logic of the motor’s functionality ordered via a microprocessor dedicated to the application.

B. Control of the sequences and durations degree of precision, generated by the tasks programming system, in order to ensure the compliance with the requirements imposed by the designed commands.

Under static and dynamic testing conditions, the ultrasonic welding device has responded to the technical and functional requirements imposed by the final product destination area.

The technological tests was conducted under the conditions presented in the table 1: time of ultrasound welding: [4, 5 s; 8,0 s]; power: 800 W; energy: [800 J; 1300 J]; ultrasound initialization: at the contact with the surface ± 0,30 mm, before the contact with the surface up to : [1,0 mm; 5,0 mm]; amplitude: constant, decreasing, increasing.

### Table 1. Conditions of technological tests.

| No.of the functional test | Overall thickness (mm) | Time (s) | Power (W) | Energy (J) | Distance for ultrasound starting (mm) | Amplitude   |
|---------------------------|------------------------|---------|-----------|------------|--------------------------------------|-------------|
| 1.                        | 1,5                    | 8,00    | 800       | 1200       | at the contact with surface ± 0,30 mm | Constant    |
| 2.                        | 1,5                    | 6,50    | 800       | 1300       | at the contact with surface ± 0,30 mm | Constant    |
| 3.                        | 1,5                    | 5,50    | 800       | 1100       | before the surface contact with 1,0 mm | Increasing  |
| 4.                        | 1,5                    | 4,50    | 800       | 900        | before the surface contact with 1,50 mm | Increasing  |
| 5.                        | 1,5                    | 4,50    | 800       | 900        | before the surface contact with 5,0 mm | Decreasing  |

The distribution of the pressures when assembling the two components was evaluated using specialized CFD software.

During the experimental program, the structural analysis [2, 3] evidenced the following:

- for an exposure time of 8 s and increasing amplitude have been observed deformations of the base layer (knitted structure) caused by the thermal degradation of the material which can lead to the tears of the knitted fabric at the intersection points of the warp stitches;

- decreasing of the exposure time to ultrasound, leads to the removal of the accidental destruction effect of the assembled elements (monofilament and knitted textile backing);

- if the ultrasonic vibration is switched off at the moment of the contact with the assembled components and these are initialized five millimeters before contact with the polyamide monofilament, a better positioning of the assembled parts and consequently an appropriate stability of the assembly are achieved (figure 7);
- decreasing the exposure time to ultrasound up to 4.50 s, while changing the amplitude from constant to rising, leads to an increase quality of the welding;

The disadvantage, however, is that the assembled parts move from the original position. This inconvenience can be removed by changing the direction of the amplitude evolution (figure 8).

Based on the results obtained following the structural analysis, several ultrasonic reinforcement tests of the knitted textile support and monofilament yarns made of polyamide were performed and comparative physical-mechanical analyses for two variants of final medical devices were conducted in certified laboratories.

The physical - mechanical determinations aimed at: mass \( [g/(m^2)] \); thickness (mm); tear resistance (daN); breaking resistance (daN); elongation (%); impact resistance (kPa) and the results are presented in the table 2.

| Sample | Mass \( [g/(m^2)] \) | Thickness (mm) | Tear resistance (Kgf) | Braking resistance (Kgf) | Elongation (%) | Bursting resistance, (KPa) |
|--------|----------------------|----------------|-----------------------|-------------------------|----------------|------------------------|
| P1     | 98,1                 | 0,78           | 2,2                   | 7,60                    | 77,5           | 220,2                  |
| P2     | 101,20               | 0,8            | 1,8                   | 12,9                    | 29             | 462,5                  |

From the data analysis the following conclusions could be presented:
- There are no significant differences in mass and thickness for the two samples, which ensures that the functional tests were performed under the same conditions.
- Breaking resistance for sample 2 is on average 55% higher in both systems compared to the values obtained for sample 1 and burst resistance is 100% higher than in case of sample 1.

This highlights the stability of the structure and implicitly the balance of the two systems of the warp knit reinforced with polyamide yarns, the perfect positioning of the two ultrasonic assembled elements and the maintenance of the stability of polymers by avoiding degradative phenomena.

3. Results and discussion
The structural analysis of the phenomena that occur during the ultrasound welding process has evidenced that the increase of the assembly resistance and the imposed quality of the surface texture are ensured in the following situations: ultrasound exposure time: 4.50 s; power: 800 W; ultrasonic start: before contact with the surface; decreasing amplitude.

This conclusion was validated both by the results of the physical-mechanical analyses conducted in certified laboratories and clinical applications.
4. Conclusion
The functional, technological and experimental tests demonstrated the feasibility, functionality and suitability of the developed ultrasonic welding device for the medical devices with textile structures accomplishment.

The new innovative technological solution for the reinforcement of the knit textile support made up of polyester yarns with a polyamide monofilament using ultrasound welding equipment ensure the required level of dimensional stability of the product and adequate architecture that enable the semi-rigid neo tissue development.

The components of the implantable medical devices are perfectly ensembled, avoiding the undesirable specific polymeric degradation.

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