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Application of Shape Memory Alloys in Facial Nerve Paralysis

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RESEARCH

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Abstract

Background
The Facial Nerve can be damaged at a peripheral level by a stroke or, for example by trauma or infection within the face or the ear. In these cases the facial muscles are paralysed with little or no chance of spontaneous recovery. This research focuses on the potential utilisation of a Shape Memory Alloy (SMA) to replace the function of the Facial Nerve, which will allow in conjunction with passive reconstructive methods, a patient to regain limited but active movement of the mouth corner. Paralysis of the mouth corner is a very disabling both functionally and cosmetically, speech and swallowing are hampered and the patient loses saliva, with presents a social problem.

Methods
This work addresses the design activity by implementing a methodology utilising integrated methods for achieving successful product engineering. Research and development is related to the investigation of the utilisation of an SMA to supplement the "passive" technique. Operational design and development work has already been undertaken in relation to a SMA being controlled by a dedicated electronic control interface and power supply. The interface measures the active potential of the healthy Zygomatic muscle by means of electromyography (EMG) and produces a signal to control the actuation of the SMA. The research centres on the entire device ultimately being implantable, similar to a pacemaker or deep brain stimulator.

Results
To identify the key parameters of the EMG sensing device the system testing strategy needed to ascertain the output signal from the device for a range of facial movements. Data was collected relating to five different 'levels' of smile with a sampling period of 30 seconds for each 'level'. Experimental work confirmed that there is definite viability for the precise control of an SMA system based on EMG data. The next stage of development will address the issue of a 'tuneable' dedicated controller for this specific SMA control application and will also examine the potential integration and control of Electroactive Polymers (EAP's).

Conclusions
The first stages in assessing both the strengths and limitations of SMA's towards resolving biomechanical problems and relieving disability have been undertaken. Experimental work to date has confirmed there is definite viability for the precise control of an SMA system based on EMG data. A considerable amount of research and developmental work has still to be undertaken before the system can be considered effective for precise control. The research and experimental work undertaken to date provides a firm foundation for the further development of the EMG/SMA control system for an animatronic head and, in addition will potentially provide proof of principle for effective and real time EMG/SMA or EMG/EAP control.

Background
Facial paralysis caused by strokes and other medical conditions can have a very large impact on a patient both physically and mentally; individuals who have had severe facial nerve injury experience degraded self-image and loss of self-esteem. Although SMA's have been used extensively for a number of clinical and medical applications, the use of SMA's for corrective/cosmetic surgery is limited. Kang [1] described an SMA implant for corrective surgery to pin back a patients ears' suggesting that this procedure could be carried out with a local anaesthetic and completed in minutes by a nurse. Senders and Tollefson [2] suggest an approach utilising artificial polymer muscles as an implant to help patients regain control over partially or fully paralysed eyelids after suffering spinal injuries or nervous disorders such as Bell's Palsy. Senders and Tollefson stated; "The face is an area where natural appearing active prosthetics would be particularly welcome".

This work investigates the development of an interface system which controls the input from an Electromyography (EMG) muscle sensor into an output to control a Shape Memory Alloy (SMA) actuator. The proposed system would be used to regain limited control of the patients smile. Initial development focussed on gaining effective control of the SMA using the Merlin Robotics controller. Effective parameters were then found for different 'intensities' of smile based on outputs from the EMG sensor. Programme code was developed for the control handling input data received from the EMG sensor

and providing the relative outputs to the SMA. Experimental work to date has confirmed there is definite viability for the precise control of an SMA system based on EMG data. Further development utilising an animatronic head will provide the realisation of this application and confirm its potential viability in corrective surgical practise. This work provides a firm foundation for further research and development for the potential integration of SMA's within the human body by demonstrating that control of SMA's can be gained using an EMG interface.

Product Design Specification

A PDS is formulated from the needs of the product. Pugh [3] states that when a brief is clearly stated a PDS can be formulated "it acts as the mantle or cloak that envelops all the subsequent stages in the design core. The PDS thus acts as the control for the total design activity, because it places boundaries on the subsequent designs".

Throughout the initial development of the prototype system alterations and updates were made to the PDS; however it is acknowledged that a complete understanding of this device's specifications and limitations has to be determined for concept development.

The associated research and development work and complexity of this research project means that it is of fundamental importance to define a strong design methodology and ensure that it is followed as closely as possible. Total Design [3] contains an ideal design methodology used in this project. The "Total design activity model" [4] has the relevant inputs for such a detailed design process; it also takes into consideration the fundamental technical issues associated with this project.

A detailed Product Design Specification (PDS) was formulated, an abbreviated version of the full PDS is shown below.

Product Design Specification

Performance

1. The device must be able to pull the corner of the mouth at an accurate speed to simulate a patients 'full' smile;
2. Using electromyography the system has to accurately sense when the 'undamaged' side of the face is smiling;
3. The device must use the full potential of Nitinol wire to produce an appropriate force that will pull the mouth to create a realistic and symmetrical smile;
4. It must be compatible for implantation into different patients;
5. The anchor point connecting the corner of the mouth with the SMA must be at the most effective point to produce the appropriate amount of facial movement;
6. The device must ideally improve the patients' confidence and lifestyle.

Environment

1. The device must be able to operate successfully within the area underneath the skin on the face;
2. The normal temperate within the body (37 degrees Celsius) must not affect the performance of the device;
3. Selected materials must be safe to use within the human body, without causing a reaction between the materials and human tissue;
4. The electromyography sensor, SMA actuator and interface control must be compact enough to fit within the designated facial areas, without being externally visible and without causing any patient discomfort.

Safety

1. The device must be completely safe for implantation;
2. The build up of heat within the device must be kept within the appropriate limits to ensure no discomfort is suffered by the patient;
3. The device must adhere to all applicable medical safety guidelines and regulations.

Aesthetics

1. The device must be hidden when implanted within the face;
2. When in operation the device should correctly imitate and compensate to provide the patient with a full smile.

Maintenance

1. The device must have minimal or zero maintenance;
2. Because the device is within the face access to the main system components must be gained via simple and local surgery;
3. The lifespan must be appropriate for this type of medical device to be cost effective and to reduce patient hospital/surgery visits.

Legislation

1. If the system is to be fully developed then the appropriate medical regulations would need to be adhered to and the appropriate clinical trials would need to be conducted;
2. All materials and systems would need to adhere to the appropriate clinical trials and medical legislation before they could be approved for general medical applications.

The PDS provides the guidelines for the product and also an evaluation tool which can be used to assess the suitability of the final design. The PDS is a dynamic document and amendments are continually being addressed throughout the research and development stages.

Shape Memory Alloys and Electroactive Polymers

There are only a small number of alloys which undergo a shape memory transformation. These alloys can be heated and 'remember' their previous shape before being deformed. Shape Memory Alloys, such as Nickel Titanium (Nitinol), undergo a phase transformation in their crystal structure when cooled from the stronger, high temperature form Austenite to the weaker, low temperature form Martensite, thus combining the properties of shape memory and super elasticity. When a shape memory alloy is in its martensitic form it is easily deformed to a new shape, when the alloy is heated through its transformation temperatures it reverts to its

austenite phase and recovers to its previous shape with significant force. For this application the initial material investigated is an SMA.

As with SMA's, Electroactive Polymers (EAP's) are polymers which able to change shape when electrically stimulated. The shape change within an EAP is caused when electrostatic charge is created by an electrical charge. Electronic EAP's include ionic EAP's which also includes conductive polymers.

In numerous vascular treatments, guide wires and catheters are utilised to access and target specific areas inside blood vessels, these devices are usually reflexive, however by adding active control and allowing the device to be steered makes it simpler to reach the desired target area. The Creganna (Micromuscle) prototype guide wire [5] shown in figure 1 can be steered to the target location and has been developed as a guide wire with an EAP coating. By applying a small charge to the guide wire Creganna suggest that the position of the tip can be controlled.

Table 1.0 gives a basic overview and comparison of properties of SMA's and EAP's [6]. Potentially for this project the most significant property exhibited by an EAP when compared to an SMA is its ability to provide significantly faster response times, although the EAP's lower mechanical load capacity could be restrictive. The performance of EAP's to provide an alternative/improved control solution to SMA's will be tested and evaluated in the next stage of this research.

There are three different memory effects exhibited by shape memory alloy materials, the SMA for this application utilises the thermal memory effect, providing a repeatable, two way actuation. The SMA actuator would return to its original shape (length) after cooling, this is defined as an extrinsic two way effect due to the initial tension placed on the SMA as a result of it being anchored to the skull and ultimately causing it to return to its original shape.

Although publications related to the potential use of SMA's in connection with passive reconstructive surgical methods are limited there are numerous publications relating to the general implementation, operation and limitations of SMA's. Hodgson and Brown [7] give a good overview and limitations of SMA's including a number of examples where the shape memory effect can be used for actuators and proportional motion devices. A good introduction to shape memory alloys including their suitability as active materials for actuators is given by Kumar and Lagoudas [8] and also includes a brief overview of their use for medical applications.

SMA Actuation

For this work the bio capability of an SMA provides an advantage, with SMA's already being utilised for smaller medical applications, including forceps, stents and artificial muscles. SMA actuators have also been utilised in robotics applications and space structures due to their ability to generate relatively high forces in ratio to their overall weight However there are also some negative aspects of the material, including its non-linear response. Hysteresis is a characteristic of SMA's which causes their control to become imprecise and problematic. Hysteresis relates to the history dependence of a material, when a material is deformed the amount of spring return will depend on the 'history' of the forces applied to the material. If the material springs back then it exhibits hysteresis. The difference in the transformation temperatures when heating from martensite to austenite and cooling from austenite to martensite creates a delay in this transformation. This difference is known as the transformation temperature hysteresis, the problem which can occur in shape memory alloys is that sporadically a complete transition does not take place between the two states. This can become cyclic between transformation phases damaging the alloy and rendering it ineffective. By utilising a Pulse Width Modulation (PWM) controller for this application it is anticipated that Hysteresis will be minimised.

Whilst a basic DC current can activate Nitinol this can easily overheat the alloy causing potential damage using pulse width modulation (PWM) enables the current to be switched very rapidly. Using PWM control with Nitinol wire has major advantages, the oscillating current allows more even heating of the material by allowing cold spots in the wire to be heated whilst also reducing localised heating. More proportional control over the Nitinol wire contraction can be generated by varying the duty cycle of the square wave, this is due to the duty cycle of the square wave output being altered from fully activated to fully deactivated. These factors allow for improved control over Nitinol activation for longer periods of time without damaging its crystalline structure.

Initial development work has focussed on the design of an interface system between the EMG sensor and the SMA. The SMA connects to the output from the Merlin controller board, when a current is passed through a SMA material it retracts due to its microstructure transition. It is proposed that ultimately one end of the SMA wire will be anchored to the back of the patients' skull whilst the other end will be attached to the area around the Zygomatic Major.

Methods

Merlin Controller Board

The Merlin Multi-Valve Control Board (MVB) shown in figure 2 is a board-level interface subsystem designed to control multiple Merlin Air Valves [9]. The MVB was designed to control a group of Merlin Proportional Air Valves by contracting small lengths of SMA wire. Outputs from the MVB are current-controlled with a maximum output drive of about 0.75A. They also incorporate fold-back current limiting to avoid overload situations. The MVB is normally configured to drive Merlin Air Valves from a 5.0V input rail with outputs being driven by a smoothed PWM signal running at about 100Hz.

The PicoScope 2000 series PC Oscilloscope was used to monitor, display, record and provide the appropriate control outputs for the system. This device is a relatively low-cost, high performance instrument that is USB 2.0-capable and was utilised for analogue to digital (A/D) and

digital to analogue (D/A) conversion within the control system. At high sampling rates, the PicoScope collects data much faster than it can actually be processed by the PC. A real time continuous mode is also provided for use at low sampling rates when immediate data transfer without intervals is required but timing accuracy is not critical.

The Biometrics SX230W Surface Electromyogram (EMG) sensor [10] used for initial testing is shown inset in figure 2. The EMG sensor is connected to the appropriate PicoScope port transferring data via the internal amplifier within the EMG sensor pad. The amplifier is easily affected by movements in the connecting wire when reading small output values, therefore to reduce noise the amplifier is combined with the sensor.

Results

EMG Sensor Testing

To identify the key parameters of the EMG sensing device the system testing strategy needed to ascertain the output signal from the device for a range of facial movements. This data was used to identify the control parameters in the design of the interface control program. Once the most suitable parameters were set for each degree of smile and the associated facial movement the data could be linked to the relevant power percentage needed to produce a contraction to mirror the smile.

Figure 3 shows the variation in smile output over a 10 second time period. These examples verify that there are definite parameters for the detection of different degrees of smiling, more extensive data readings were also collected enabling data sample averages to be calculated. Data was collected relating to five different 'levels' of smile; no smile, partial smile, normal smile, extended smile and maximum smile, with a sampling period of 30 seconds for each 'level' of smile. Approximately 300 samples were taken from the sensor during a 30 second sampling period.

Control limitations

The Merlin Multi-Valve Control Board (MVB) was specifically designed to control the Merlin proportional air valve and was not capable of supporting current outputs larger than those it was specifically designed for. The length of Nitinol calculated as an average length to achieve the required facial movement was 21cm [11], at this length the current loading for the board was too large and beyond its designed output parameters. An alternative method had to be investigated and implemented to address this limitation. This was achieved by dividing the 21cm SMA into a number of shorter lengths each being individually driven by the MVB. Although this was not ideal it was accepted that a dedicated SMA controller system was being utilised for a purpose for which it not been specifically designed. The next stage of development will address the issue of a 'tuneable' dedicated controller for this specific SMA control application. A simulated X ray image showing the location of proposed SMA and controller is shown in figure 4.

Conclusions and Further Development

Initial developmental work has successfully interpreted 5 different parameters of relative EMG facial feedback; this is quite limited in terms of overall parameter detection. Further work will expand the current range of detection and improve SMA control to produce a detailed and more realistic control system. Another consideration would be to divide the total length of wire over more control ports on the Merlin Multi-Valve Control Board. The system used by Fox [12] used 3 ports on the Merlin MVB, however with 8 ports available, and with 8 lengths of SMA more precise control is certainly achievable when compared to the current control system.

An animatronic head shown in figure 5 has been built and will be utilised for the next stage of development. The head uses DC servo motors to simulate various facial expressions including smiling and also control eyebrow movement.

The DC servo motors within the head are currently controlled with Phidgets [13]. Phidgets provide a set of 'plug and play' blocks for low cost USB sensing and control from a PC and have a high degree of accuracy. Further development will focus on developing the EMG interface and obtaining effective animatronic head smile control with a programmed phidget, finally the servo motor function will be replaced with SMA's to test for comparable control functionality.

A considerable amount of research and developmental work has still to be undertaken before the system can be considered effective for precise control. Future development is related to both short term and long term goals. The final goal will be the implantation of the device within the human body, to include a power supply and the control electronics to provide real-time and 'realistic' movement of the paralysed mouth. Ultimately it is anticipated that this system will not provide a complete solution to the damage caused by paralysis to the facial region. However the hope is that the proposed system will provide improvements at least cosmetically for the patient, in addition to providing improvements with speech and swallowing. The research and experimental work undertaken to date provides a firm foundation for the further development of the EMG/SMA control system for the animatronic head and, in addition will potentially provide proof of principle for effective and real time EMG/SMA or EMG/EAP control.

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AUTHORS' CONTRIBUTIONS

PB was responsible for the technological, materials and systems control implementation. MV was responsible for overall medical/clinical and technology interface advice. PB was responsible for the supervision of the associated research project students. MV was responsible for general related clinical/ medical advice and implementation. MV and PB were responsible for the research methodology to date. PB and MV jointly drafted the original draft manuscript; PB drafted the final version of the manuscript.

PEER REVIEW

Not commissioned; externally peer reviewed

CONFLICTS OF INTEREST

The authors declare that they have no competing interests

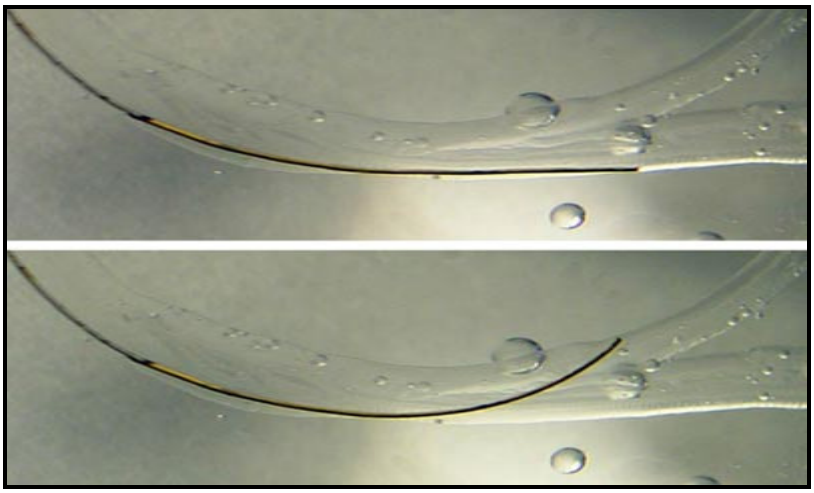

Figure 1: Creganna (Micromuscle) EAP coated steerable guide wire

Property	EAP	SMA
Actuation Strain	> 10%	< 8%
Force	0.1 - 3 MPa	Approx. 700 MPa
Reaction Speed	µ second to seconds	Seconds to minutes
Power consumed	mW	W
Fracture toughness	Resilient, elastic	Elastic

Table 1.0: Property Comparison - EAP and SMA

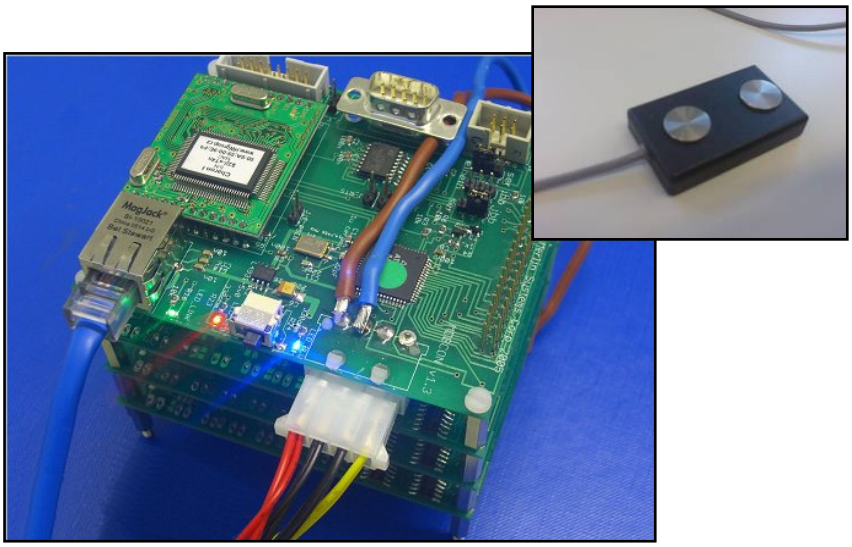

Figure 2: Merlin SMA control board with inset showing Biometrics surface EMG sensor

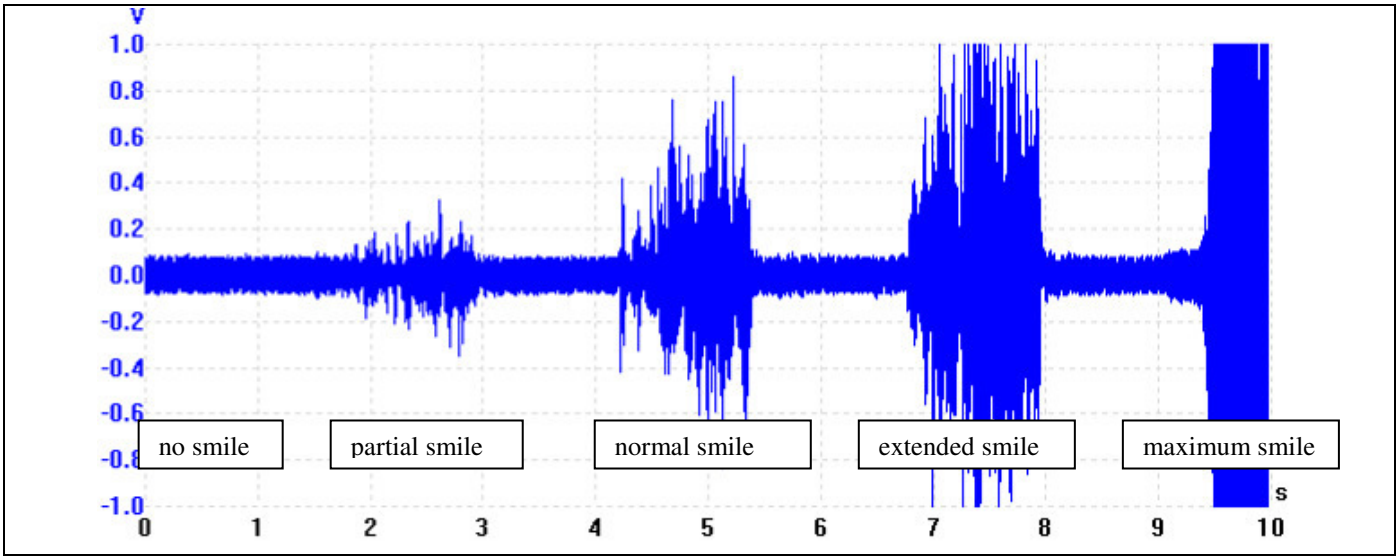

Figure 3: EMG output - Smile variation over a 10 second time period

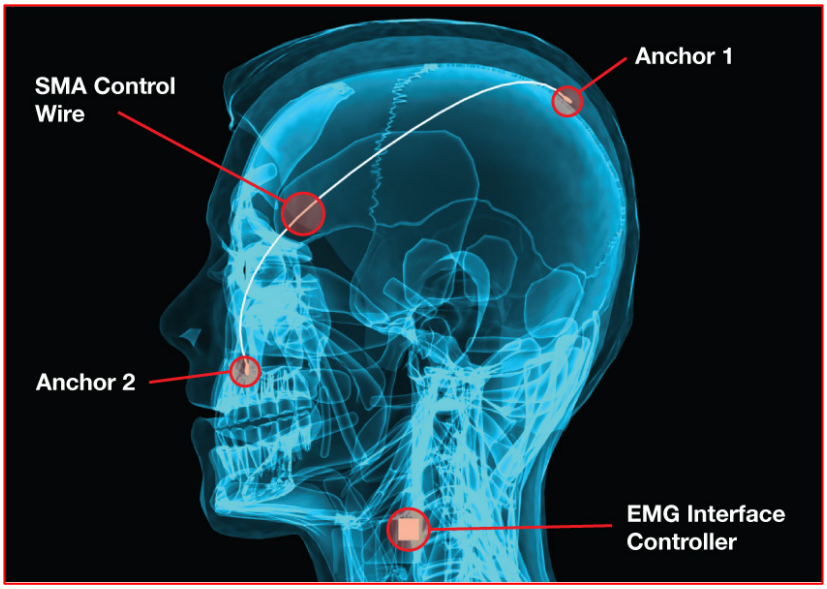

Figure 4: Simulated X ray image showing location of proposed SMA and Controller

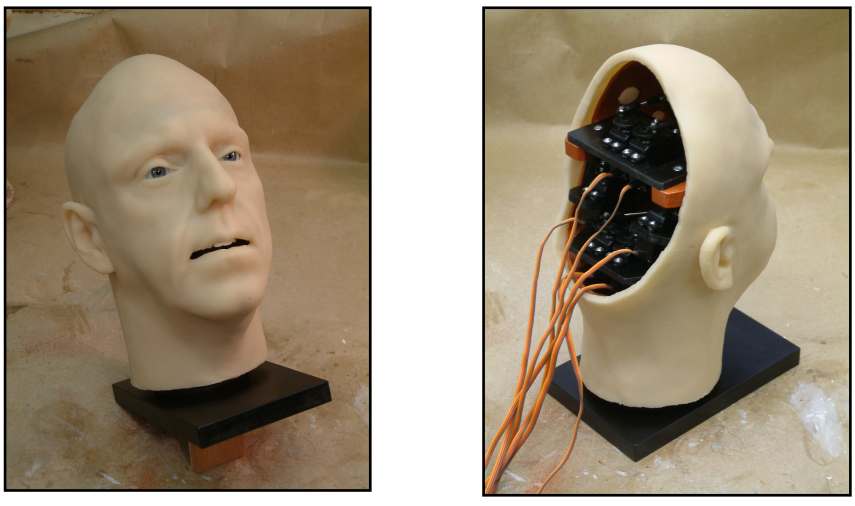

Figure 5: Animatronic head built for initial testing