DELIVERABLE REPORT

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D4.1, First prototype of electrode liner (M10)
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WP4, Task 4.1 4.2 4.3, Liner/Socket for multichannel EMG recording, Otto Bock HealthCare

1 DESCRIPTION OF THE TASK

Task 4.1 Electronics for EMG recording (OBG (24), M01 - M24):

This task deals with the development of multichannel EMG amplifiers (circuit design, layout etc.) which are small enough to integrate them in a prosthetic system. One possibility could be that those amplifiers will be integrated in the distal end of a liner. It needs to be investigated how this could be done. The connection of the electronics will be a main topic here. Another important work will be the development of shielding concepts, as the separation of electronics from electrodes could lead to a system which is more prone to electromagnetic interferences and cable movement artefacts. This includes noise sources such as power line noise, cell phones or electronic anti-theft devices. E.g. active shielding of the cables has been applied successfully in preliminary tests to reduce the influence of power line noise. This work is based on an already existing desktop amplifier which was developed to record EMG from dry electrodes in the EU funded project AMYO (Grant No. 251555, 2011-2014).

Task 4.2 Liner/Socket for multichannel EMG recording (OBG (22), UMG-GOE (2), M01 - M24):

A new liner/socket interface for EMG recording will be developed. Focus is on the combination of conductive and nonconductive materials. Experience showed that this is a critical point to record high quality EMG which is not prone to artefacts such as electrostatic noise

- Conductive polymers to have a consistent liner/socket surface to the skin will be investigated. One key is to find a polymer which does not tend to movement artefacts
- Moreover the likelihood of lift offs will be decreased by exploring special shape and/or flexibility of electrode material and new socket designs.

Task 4.3 Design validation and iterative development (OBG (34), M06 - M48):

All activities in this work package will be carried out according to an iterative, agile research and development process. This task was specifically introduced with a run time over almost the entire project duration to reflect this agile development, while keeping the other Tasks of this WP focused and concise. Already starting with the first design concepts and mock-ups we will integrate orthopaedic technicians and end-users (amputees) into the process in order to understand their needs.

The evaluations comprise laboratory as well as clinical tests and the results will continuously guide the development progression of the electrode liner/socket interface.

2 Description of Deliverable

The goal is to develop a novel and robust liner/socket interface to reduce the influence of orthopaedic technicians on the quality of a prosthesis fitting. The interface should provide reliable multichannel EMG (in daily life). This includes:
• Eliminating the requirement to place the position of electrodes very accurately by introducing a large number of (redundant) EMG electrodes.
• Reducing the costs of EMG electrodes by

- Using conductive polymers
- Automated in-factory electrode integration in the liner rather than manually by the orthopaedic technician a separation of electrodes and amplification
- Eliminating the influence of external artefacts by proper guarded shielding
- Effectively reducing the risk for electrode-lift off by using socket designs and material

3 Implementation of Work

3.1 Liner development

This Chapter gives an overview over material combinations and selection. Furthermore the development and manufacturing of a first electrode liner and the signal acquisition system will be shown.

3.1.1 Material evaluation and selection

The biggest challenge is to find the best material combination for robust signal acquisition. Some material combinations are prone to artefact into the superficial EMG (sEMG) signal. This is caused by electric charges induced by mechanical friction and contact. The triboelectric properties of materials and combinations can describe the magnitude of these artefacts. Electrode shifts can cause artefacts as well.

Figure 1 shows the parts of the electrode liner. The base for the liner is the matrix material. An experimental test showed the most robust matrix material is polyurethane. Furthermore, different embedded electrodes were evaluated. A combination of conductive fabric and conductive silicone performs the best signal quality and artefact robustness. For the transmission of the electrical signals through wires, conductive silicone was evaluated as the best option, because of its flexible and stretchable properties. The evaluated and preferred surface treatment of the liner is parylen. The distal mechanically and conductive connection was created with spring contacts in combination with a pin lock system.

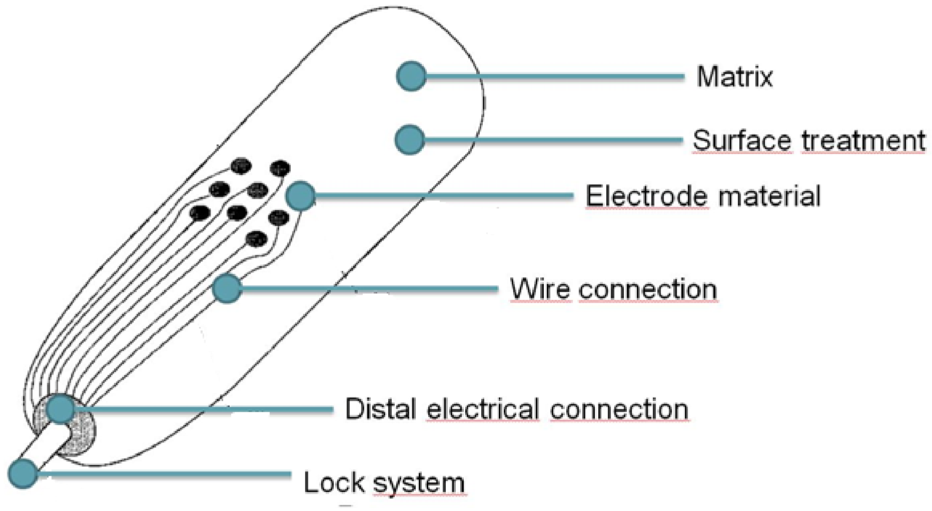

Figure 1. Schematic overview of the parts of the electrode liner.

The materials shown in Figure 1 were evaluated with different tests. A reproducible simulation was explored to check the properties of different material combinations. This simulation checked material combination samples for artefact susceptibility. The best solutions were applied to the first prototype:

- Matrix: Polyurethane
- Surface treatment: Parylen coating (cvd- chemical vapour deposition)
- Electrode material: polymer fabric hybrid
- Wire connection: conductive polymer wire with insulating parylen coating
- Distal electrical connection: spring contacts and copper segments
- Lock system: Pin Lock

3.1.2 Prototype manufacturing

The base for the prototype was a liner mould from typical commercially available liners. To generate a better anatomical fit, it was necessary to change the shape of the liner mould from round to oval. This generates a better reproducible electrode position. The mould was created out of wood and silicone (Figure 2 a).

After the evaluation of fitting with two patients, a 3D printed mould was explored. In the first step the best evaluated and produced electrodes were placed equidistant around the mould. Double-sided tape was used to fix the electrodes on the spots. Liquid polyurethane set up the ground layer and embedded the electrodes. After the curing process, the outer area from the electrodes was cut out until the conductive layer was reached. Afterwards, the designed and 3D printed connector was placed at the distal end of the liner (Figure 2 b). This connector included electrical conductive polymer wires and spring connectors. The wires were placed from the connector to the electrodes along the axis of the liner. Conductive polymer was used to connect the wires to the electrodes (Figure 2 b). Two more layers of polyurethane covered all conductive areas. This guaranteed the insulation and fixation of the wires and structures (Figure 2 c). After curing, the liner was taken off the mould and was prepared for anti-adhesive coating (Figure 2 d). This generated a comfortable skin contact and ensured that the liner could be rolled off.

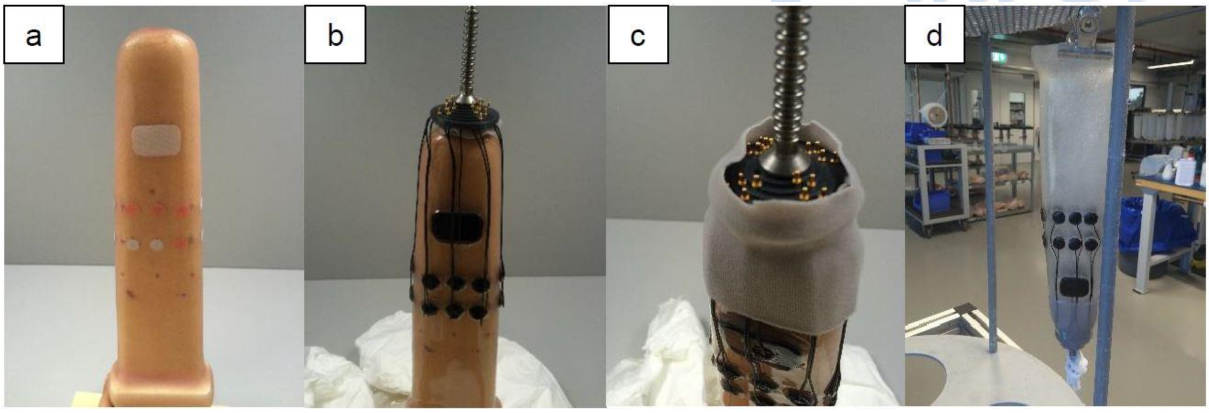

Figure 2. Improved liner mould with electrode dummy positions (a), placed connector with connected wires (b), distal connector with fabric cover to fix wires (c), preparation for coating (d).

3.2 ELECTRONICS

The starting point for the electronics of the EMG signal acquisition system was an existing desktop amplifier developed to record EMG from dry electrodes in the EU funded project AMYO (Grant No. 251555, 2011-2014). This desktop setup was made up of discrete electronic components that included:

- Instrumentation amplifiers (IA). (First stage of amplification)
- High-pass filters to remove low frequency noise generated by motion artifacts.
- 2nd Stage amplification.
- Anti-aliasing low pass filters.
- Driving circuit for the cable shield.

This discrete approach has a high number of necessary parts which makes a miniaturization difficult. If an acquisition system based on 8 bipolar channels is required, it implied the use of 8 instrumentation amplifiers, 24 operational amplifiers and at least 120 passive electronic components (e.g. resistors, capacitors), in addition to the electronic components required for power supply, analog-to-digital conversion and signal processing.

Even though the existing desktop amplifier obtained good results in terms of signal acquisition, such electronic architecture would present several drawbacks to integrate it in the prosthetic system, especially because of the amount of components required for the aimed 8 bipolar channel EMG acquisition system.

The first step for the signal acquisition system in the INPUT project was to miniaturize the available desktop amplifier. To avoid all the components described above, it was proposed the use of an analog front-end integrated circuit (IC): the ADS129X family from Texas Instruments. This IC provides a high level of integration, along with good performance for biopotential measurements. In particular, the ADS1298 is an 8 bipolar channel analog front-end that includes in a single chip:

- Electromagnetic interference filters.
- Programmable gain amplifiers.
- Multichannel simultaneous sampling using 24-bit analog-to-digital converters.
- Right-leg drive control for common mode rejection.
- Shield drive.

- Leads-off detection in case an electrode detaches from the patient's skin.

The ADS1298 is available in a 10 × 10 mm packaging, and in a smaller 8 × 8 mm packaging, which is ideal for miniaturized signal acquisition systems. Additionally, the IC can be connected to other ICs to increase the number of channels recorded. In this way, a future EMG acquisition system could have 2 analog front-ends to acquire up to 16 bipolar channel measurements.

During the first period of the INPUT project, a desktop amplifier based on this analog front-end IC was developed and tested. This prototype allowed the evaluation of the approach before further miniaturization. For visualization and further processing, the 8 bipolar signals acquired by the IC were sent to a PC using a microcontroller. Both the firmware of the microcontroller which controls the analog front-end IC and data transmission, and the software for visualization were developed.

Figure 3 shows a comparison between the previous desktop amplifier based on discrete components (8 bipolar channels), and the new desktop amplifier based on the analog front-end approach (8 bipolar channels marked in yellow). This first prototype demonstrates that the analog front-end could provide miniaturization for the future integration of the signal acquisition electronics into the prosthetic system.

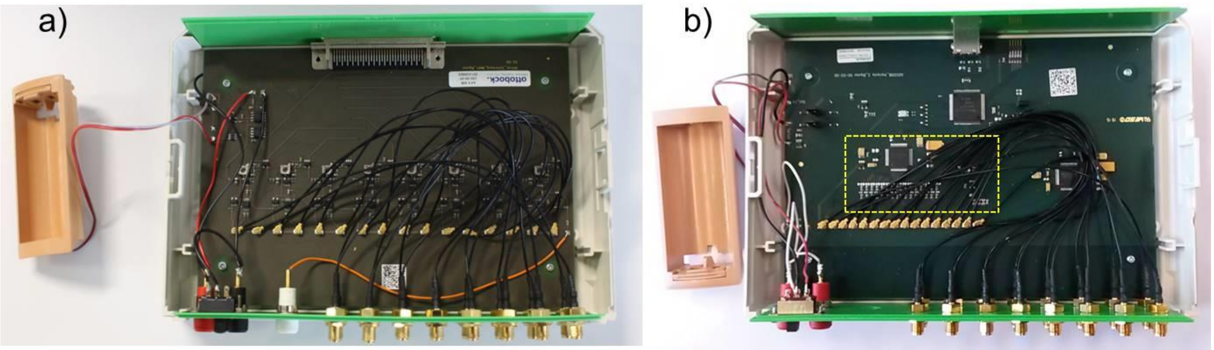

Figure 3. Comparison between the desktop EMG acquisition system. a) Previous desktop amplifier based on discrete components (AMYO project). b) Desktop amplifier based on analog front-end. The image shows a desktop setup for 16 bipolar channels; only the marked zone is required for 8 bipolar channels.

4 Results

4.1 Amplifier evaluation with able-bodied subjects

Six able-bodied subjects (ages ranging between 20 - 35 years) participated in an EMG acquisition study to test the designed signal acquisition system prototype based on the analog front-end approach (hereinafter referred to as ADS), and compare its behaviour with the previous desktop amplifier based on electronic discrete components (hereinafter referred to as INA), For this study, bipolar EMG signals were acquired using 8 dry metal electrodes distributed on a silicon-fabric armlet, in order to record force contractions at the lateral, ventral, medial and dorsal areas of the subjects' left forearm. After signal acquisition, the recordings were further processed in Matlab to calculate the signal-to-noise ratio (SNR), and were exported to Excel for further analysis. The results obtained are shown in Figures 4.

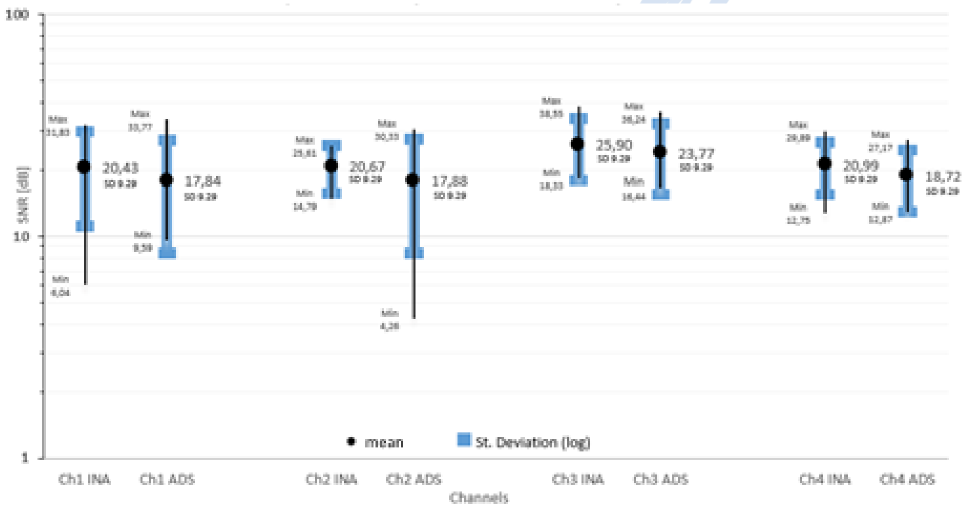

Figure 4. Comparison between previous desktop amplifier based on discrete components (INA) and the developed signal acquisition system based on an analog front-end (ADS). Four bipolar EMG channels were recorded.

Figure 4 shows the SNR results obtained in the 4 bipolar channels using both acquisition systems. Even if the ADS prototype based on the analog front-end approach had a slightly lower SNR ratio compared to the INA desktop based on discrete components, the ADS had much fewer electronic components, which will enable further miniaturization to integrate the electronics into the prosthetic system.

Further work is suggested to improve the robustness of the ADS prototype. Different strategies could be implemented, including the use of the right-leg drive (RLD) operation and lead-off control of the ADS1298. Additionally, a new design of the ADS prototype should be developed to test smaller IC packaging, improving further miniaturization.

5 SUBCONTRACTING

Ottobock didn't subcontract in this work package. All work was done by ourselves.