A NEW ACTIVE SHOULDER PROSTHESIS: 
FROM THE DESIGN TO THE FIRST CLINICAL APPLICATION

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ABSTRACT
INAIL and DIEM prototyped a new externally-powered prosthetic shoulder developed for interscapulothoracic and first-proximal trans-humeral amputees. The articulation consist of two connected powered joints that allow the elevation of the upper arm in any vertical plane passing through the shoulder centre of rotation. The development of the mechanism is the result of a rigorous approach, which made it possible to systematically combine both the technical and the clinical aspects involved in the design of a prosthetic device.

The prototype underwent laboratory tests needed to evaluate the mechanism’s performance (e.g. the maximum payload) and the electrical requirements (e.g. the current draining). Based also on the results retrieved from these tests, an on-board embedded controller was implemented. The electronic unit can control a prosthesis with up to five powered joints and can manage different control strategies, according to the amputees’ preferences.

The prototype with the embedded control system has been recently integrated within the prosthesis, provided with hand, wrist and elbow, of a proximal trans-humeral amputee who firstly tested the new device.

This paper provides an overview of the development of the actual prosthesis, reports the main patient’s feedback and outlines the future developments.

1. INTRODUCTION
Nowadays no powered prosthetic shoulders are available on the market: current prosthetic solutions comprise at most passive articulations with locking mechanisms or frictional spherical joints. The orientation of these devices can be adjusted with the help of the sound limb, if present, or using fixed points in the surrounding environment, in the case of bilateral amputees. These solutions, due to the restricted mobility offered and the difficult passive adjustment required, preclude the possibility to perform important activities of the daily living, e.g. those requiring above-the-shoulder reaching.

Prototypes of actuated shoulder mechanisms have been proposed in the literature [1–4], but they do not appear to be easily applicable in the standard clinical practice.

In order to overcome these functional and technical limitations, the INAIL Prostheses Centre and the University of Bologna, developed a 2-degree-of-freedom active shoulder suitable for interscapulothoracic and first proximal trans-humeral amputees [5]. The new prototype is fully compatible with current commercial components for myoelectric prostheses. This paper provides an overview of the development of the prototype and reports the main feedback from a patient following a preliminary clinical assessment.

2. MATERIALS AND METHODS
2.1 Development of the shoulder prototype
The development of the prototype was based on a methodology which takes into consideration the patients’ requirements and the need to integrate the final mechanism into the prosthetic arm already used by the patient (if any). In particular, the functional performance of the device was always balanced with the actual wearability of the resulting artificial arm (otherwise the risk was to design a high-performance device finally refused by amputees e.g.
because of a high weight, an intricate control or bad appearance). The methodology comprises different steps, briefly overviewed below.

1) Kinematic Simulations – In order to determine the topology and geometry of the shoulder mechanism, a limited set of motor tasks were simulated by alternative kinematic models. Models differed in the combination and number of degrees-of-freedom (DoFs). The activities (e.g. feeding, personal hygiene, dressing and generic manipulation) were selected to be the most significant for the functional autonomy in the everyday living of an upper-limb amputee. The criteria used to select the final model were, among the others, the ability to execute the activities and the lowest kinematic requirements. From the results a shoulder model formed by two powered revolute joints with incident and orthogonal axes and a passive joint was selected. The two actuated DoFs allow a spherical motion of the arm, while the passive DoF allows the passive humeral intra-extra rotation [Fig 1(a)].

2) Feasibility – The selected shoulder model was implemented in a detailed mechanism with a CAD software. As from point 1), two connected powered joints, J1 and J2, and a passive one, JH, form the articulation [Fig. 1(a)]: the active joints respectively actuate the rotation $\theta_1$ about a vertical axis (fixed to the prosthesis socket) and the rotation $\theta_2$ about a horizontal axis, whose orientation is determined by $\theta_1$. In other words, the actuation of the first joint selects the vertical plane along which the second joint elevates the upper-arm. Joint J1 is a simple actuated revolute joint, whereas J2 is basically composed by an inverted slider-crank mechanism. This latter makes it possible to obtain a high torque without the use of a speed reducer with a great transmission ratio (and thus without low efficiency and high bulk). The passive revolute joint is a friction disc currently used at the INAIL Prostheses Centre and it is simply integrated at the extremity of the second joint.

3) Design and prototyping – Kinetostatic simulations of important activities of the daily living were carried out by a 3D-model of a full prosthetic arm including the shoulder mechanism. The retrieved data were used to dimension the actuators and the power transmission chains. After this stage, the mechanism was finally prototyped [Fig. 1(b)]. J1 is driven by a commercial DC motor with nominal voltage $U_N = 6$ V, maximum output power $P_{max} = 4.55$ W, stall torque $M_H = 21.2$ N·mm. The total reduction ratio of the kinematic chain is $i_1 = 1:1050$, provided mostly by a commercial Harmonic Drive (GE) reducer. Similarly J2 is driven by a commercial DC motor ($U_N = 12$ V, $P_{max} = 17.00$ W, $M_H = 80$ N·mm), whereas the total reduction ratio is not constant, depending on the parallel mechanisms configuration: the maximum value achieved is $i_2 = 1:1187$.

4) Bench tests – A series of tests were performed on a test bench specifically developed at the INAIL Prostheses Centre to experimentally characterize prosthetic devices. In particular the joints’ maximum performance (in terms of velocity and payload) and their mechanical efficiency (varying with velocity and payload; average values $\eta_1 = 0.25$ and $\eta_2 = 0.45$ for J1 and J2, respectively) were estimated [6]. Moreover, several information related to the control were retrieved, and in particular about the current draining.

5) Controller design – An on-board control unit was designed and manufactured based mainly on the maximum current and voltage required by the motors, and on the need to maintain the compatibility with commercially available prosthetic components. The control unit consists of a Microchip PIC18F4431 microcontroller and 5 motor drivers. Receiving as inputs at most 4 EMG signals, the control unit can engage the 5 motors of the prosthetic arm, i.e. of shoulder, elbow, wrist and hand. By referring to the common control scheme where the joints are sequentially activated one at a time, 3 control strategies for joint switching were implemented in the controller: EMG co-contraction, $3^{rd}$ electrode selection and double command.
2.2 Clinical tests

A complete prosthesis, equipped with the new shoulder prototype and the control unit, was fitted on a patient for a one-day-test [Fig. 1(c)]. The patient was a male, 32 years-old, first proximal trans-humeral amputee with a very short stump at the right side and with a partial complex amputation of the left hand. The patient commonly uses a myoelectric prosthesis with hand, prono-supination and elbow joint in his daily life; two EMG electrodes are placed inside the socket. The subject controls the joints one at a time, cyclically switching between motors by means of a traction-switch engaged with an ante-retropulsion of the shoulder girdles. The control strategy was not modified with the introduction of the shoulder mechanism.

The patient used the new prosthesis for about 3 hours, executing common activities of the daily living which involved the use of the shoulder (in particular, but not limited to, the grasping of objects placed at heights above the shoulder-level, Fig 1(c)). To collect the feelings of the patient about the current prototype and for guiding in future developments, at the end of the test the patient completed a simple VAS questionnaire.

3. RESULTS

The questionnaire main outcomes are summarized in Table 1. The prosthesis weight (2.8 kg) is tolerable in the resting position (8/10) and well balanced (9/10) with respect to the sound limb. On the contrary, the load at the stump during flexion of the arm determines an excessive strain (3/10; above all when elevating the arm with the forearm completely extended); the velocity of the shoulder joints (about 40°/s) is good (8/10), whereas the payload (limited to 0.5 kg in order not to cause pain to the stump) should be risen to 1 kg (6/10); the noise is unacceptable (1/10); the control strategy is effective but not efficient, because too slow due to the high number of motors to be controlled (4/10); finally, its appearance is acceptable (7/10).
Table 1: the most significant patient’s opinions about the prosthesis equipped with the new shoulder mechanism.

<table>
<thead>
<tr>
<th>Question</th>
<th>Patient’s opinion</th>
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<tbody>
<tr>
<td>The weight of the prosthesis is tolerable</td>
<td>8</td>
</tr>
<tr>
<td>The prosthesis is symmetric with respect to the sound limb</td>
<td>9</td>
</tr>
<tr>
<td>The load at the stump is tolerable when using the prosthesis</td>
<td>3</td>
</tr>
<tr>
<td>The velocities of the shoulder joints are adequate</td>
<td>8</td>
</tr>
<tr>
<td>The payload at the hand is sufficient</td>
<td>6</td>
</tr>
<tr>
<td>The noise level of the shoulder joints is tolerable</td>
<td>1</td>
</tr>
<tr>
<td>The control strategy is simple</td>
<td>6</td>
</tr>
<tr>
<td>The appearance of the prosthesis is human-like</td>
<td>7</td>
</tr>
<tr>
<td>The donning and doffing is simple</td>
<td>9</td>
</tr>
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4. DISCUSSION AND CONCLUSION

From a technical viewpoint, the prototype showed to be consistent with expectations, both considering range of motion and electromechanical performances.

The new complete prosthesis, thanks to its high mobility, can greatly improve the functional autonomy of patients with a high level of amputation. However, the clinical tests revealed margins for improvements. Firstly, the sequential control strategy via traction-switch does not exploit the high mobility of the prosthesis. Alternative strategies for a more direct switching of the commands are needed. In particular, a voice control system integrated with the EMG-based control that allows the patient to directly select the joint to be activated seems promising [7]. Secondly, the noise of the mechanism will need to be reduced by reconsidering the quality of the manufacturing and/or design of some components (e.g. gears). Finally, in order to guarantee the proper wearability of the prosthesis, the socket should be re-conceived (with a wider contact area) to reduce the load on the patient’s stump and thorax during the functioning of the arm.

REFERENCES