Doctoral Dissertation

Doctoral Program in Bioengineering and Medical-Surgical Sciences (38th Cycle)

Integrating Robotics, Motion Analysis, and HDsEMG for Usability Testing of Medical Devices

Marco Daghero

Supervisors:
Prof. Mara Terzini
Prof. Taian Martins Vieira

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Abstract

The safe and effective use of medical devices depends not only on their technical performance, but also on their interaction with the user and the patient. Regulatory frameworks such as the European Medical Device Regulation (MDR) and the U.S. Food and Drug Administration (FDA) guidelines emphasize the importance of usability engineering to minimize use-related risks and ensure safe clinical adoption. However, usability testing is still largely based on qualitative observations and subjective questionnaires, which, although essential, provide limited objectivity and reproducibility. Quantitative approaches addressing kinematics, interaction forces, and operator workload are increasingly reported in the literature, yet they are typically applied in isolation and lack an integrated methodological framework. This doctoral thesis addresses these limitations by developing and validating a multipurpose experimental testbench that integrates robotics, motion analysis, and high-density surface electromyography (HDsEMG) to allow objective, quantitative usability testing of medical devices.

The core contribution of this work is the design of a unified workflow capable of characterizing the kinematic, kinetic, and neuromuscular aspects of medical device use under controlled and repeatable conditions. The proposed testbench combines three complementary components: (i) marker-based motion capture to record device trajectories during simulated clinical use by human operators; (ii) robotic replication of recorded trajectories using a collaborative robot equipped with a six-axis load cell, enabling standardized and repeatable force and torque measurement; and (iii) HDsEMG to quantify the amplitude and spatial distribution of muscle activation, providing objective indicators of operator workload and ergonomics. By integrating these elements into a single experimental framework, the testbench enables a comprehensive and reproducible assessment of device usability, overcoming the fragmentation of current evaluation approaches.

The thesis begins with the development and validation of the robotic testbench. A six-degree-of-freedom collaborative robot was instrumented with a high-resolution force–torque sensor and custom gripping solutions to allow secure attachment of medical devices. A multithreaded software architecture was implemented to synchronize robot motion, load cell acquisition, and eventual

external sensors. The load cell was verified through static load tests, demonstrating high accuracy and linearity of force measurements. Validation was then performed using a pilot surgical application, in which a human-performed medical maneuver was captured via motion analysis and subsequently replicated by the robot. Quantitative comparison between recorded and replicated trajectories showed high fidelity in both position and orientation, while synchronized force–torque measurements enabled detailed reconstruction of interaction loads throughout the maneuver. These results confirmed the suitability of the testbench for reliable kinematic replication and kinetic assessment.

To support the methodological foundations of the testbench, a motion analysis study was conducted to evaluate high-friction pads used in postless orthopedic traction. Pelvis displacement was quantified under progressively increasing traction loads and different bed inclinations. The study provided a fully quantitative assessment of pad performance, demonstrating near-linear load–displacement behavior and comparable effectiveness between commercial solutions. Although limited to kinematic analysis, this work contributed to the development of motion capture expertise and highlighted the value of objective measurements for medical device evaluation. A further methodological pillar of the thesis is the investigation of neuromuscular assessment using HDsEMG. A dedicated experimental study combined HDsEMG with shear wave elastography to examine the region-specific neuromechanical behavior of the medial gastrocnemius muscle during controlled isometric contractions. The results demonstrated heterogeneous excitation patterns along the muscle's proximo-distal axis and revealed region-dependent relationships between muscle activation and stiffness. This work provided the theoretical and experimental basis for integrating HDsEMG into usability testing, enabling spatially resolved evaluation of operator workload and ergonomic demands.

The full potential of the proposed testbench was demonstrated in a proof-of-concept application focused on the quantitative evaluation of videolaryngoscopes for endotracheal intubation. Human operators performed simulated intubations on a mannequin while device kinematics and forearm muscle activity were recorded. The recorded trajectories were then replicated by the robotic testbench, allowing direct measurement of forces applied to the mannequin. By integrating kinematic, kinetic and HDsEMG data, the study enabled objective comparison of different videolaryngoscope designs in terms of performance, safety-related loads, and operator ergonomics. The results highlighted how device design influences motion patterns, force transmission, and muscle activation, demonstrating the added value of a quantitative, multimodal usability assessment.

In conclusion, this thesis presents a novel, integrated methodology for medical device usability testing that combines robotics, motion analysis, and HDsEMG within a single experimental framework. The proposed testbench provides objective, repeatable descriptors of device performance, patient safety, and operator workload, complementing traditional qualitative usability evaluations and aligning with regulatory expectations for risk-informed design. Beyond the specific applications presented, the testbench offers a versatile platform for future usability studies across a wide range of medical and surgical devices, supporting evidence-based design optimization and safer clinical adoption.