ASSESSING SURGICAL INSTRUMENT USABILITY WITH A TESTBENCH BASED ON MOTION CAPTURE AND ROBOTIC ARM: A PILOT STUDY

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Abstract— **The potential of robots in assessing the usability of medical devices is yet to be explored, despite the increasing regulatory requirements for manufacturers. This study introduces a testbench combining motion analysis and robotics to assess the end-point force experienced by surgeons in their clinical practice. The hand-surgical-instrument trajectory, measured with a motion capture system while a single subject emulated a routine surgery, was reproduced with a robotic arm. The end-point force was then measured with a load cell. Results demonstrate optimal agreement between captured and reproduced trajectories, enabling precise force analysis. Its potential versatility and accuracy make it well-suited for device evaluation in regulatory compliance.**

Keywords— **robotic arm; motion analysis; usability; medical devices, surgical maneuver.**

I. INTRODUCTION

Biorobotics has been progressively entering the medical practice in the last decades (Crosswell et al., 2018). Nowadays, clinicians and surgeons commonly use robots for delivering the most effective treatment, from minimally invasive procedures to rehabilitation devices (Morgan et al., 2022). However, the potential of robots in assessing the performance and the usability of medical and surgical instruments remains an underexplored area (Kyrarini et al., 2021). This issue has gained fundamental importance since the entry into force in the EU of the new Medical Devices Regulation (MDR) and supporting manufacturers in the regulatory process has become crucial for biomedical research. In this framework, exploiting motion capture to record surgeon's maneuvers and replicate them through a sensorized robotic arm could be a viable tool to assess the interplaying loads during surgical instruments handling. The aim of this study is to develop a multipurpose testbench to detect, mimic and analyse a surgical mock maneuver and evaluate its feasibility recurring to a pilot application.

II. MATERIALS AND METHODS

A movement of a sling introducer, mimicking a trans-obturator tape (TOT) surgery for treating urinary incontinence, was performed on a commercial suture pad (Skillssist DIY) and captured through a 12-camera marker-based motion capture system (Figure 1A).

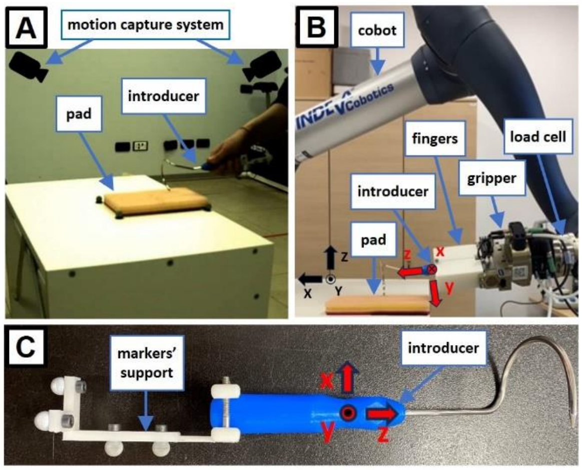

Fig. 1: (A) motion capture of a TOT sling introducer; (B) trajectory reproduction and measure of forces with a robotic arm; (C) 3D-printed support for attaching markers to the introducer.

The movement was measured using 4 reflective markers attached to the introducer's handle through a custom 3D-printed support manufactured in-house (Figure 1C). The coordinates of each marker were sampled at 100 Hz and then low-pass filtered with a 4th order, zero-lag Butterworth filter (cut-off frequency at 2 Hz), to reduce noise and artefacts. The 4 markers were then used to define a local reference system oriented consistently with the introducer and record the displacement of its center of mass. The pose coordinates, in terms of position and orientation, were then imposed to the end-effector of a robotic arm (6-DOF Doosan H2515 cobot, Figure 1B), downsampled to 5 Hz. The introducer was mounted on the robot's end-effector through a pneumatic gripper (Schunk srl) with custom 3D-printed fingers (Figure 1B). The forces applied on the introducer during the movement reproduction were measured by the 6-axis force-torque sensor in Figure 1B (Schunk srl FT-AXIA 80, resolution = 0.01 N / 5 N·mm).

III. Results and Discussion

The comparison between the displacement (Figure 2A) and orientation (Figure 2C) of the introducer captured by the motion tracking system and the one reproduced with the robotic arm suggests optimal agreement between the pairs of curves.

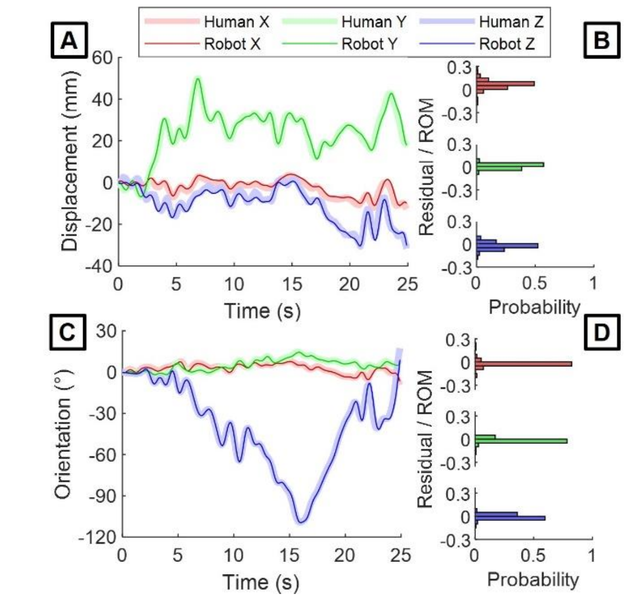

Fig. 2: Introducer displacement trajectory (A) and residuals' distribution (B) with respect to the initial stance in the global reference frame. Introducer orientation trajectory (C) and residuals' distribution (D) represented as fixed-axes ZYX Euler angles in the local reference frame.

Indeed, the residual between the captured and reproduced pose is lower than 15 % of the range of motion (ROM) for the displacement (Figure 2B) and 10 % of the ROM for the orientation (Figure 2D), in 95% of the samples recorded. Figure 3 reports the force and torque measured by the load cell, along the 3 local directions of the introducer frame. Analysis of the temporal trends enables to identify peak force (in the X direction) and torque (in the Y direction), along with their respective timings. Additionally, the torque along the Z axis is substantially lower in comparison to the other two components. Furthermore, synchronization between kinematic and kinetic information allows to easily identify force and torque applied on the introducer during key phases of a surgical maneuver.

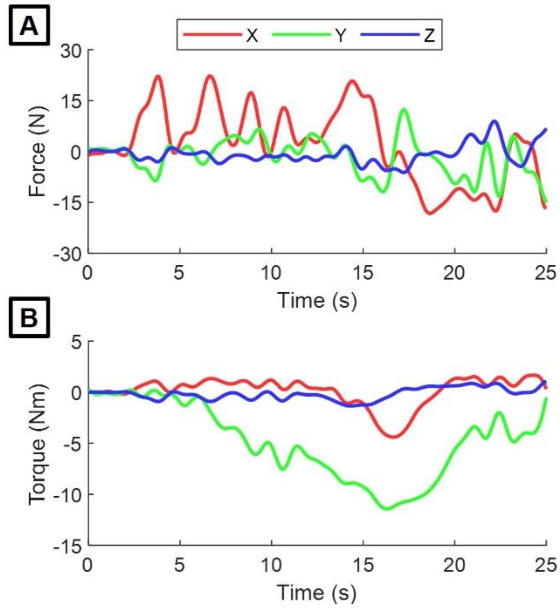

Fig. 3: Force (A) and Torque (B) applied on the introducer, along the 3 local directions of its reference frame.

IV. Conclusions

This pilot study presents a novel testbench useful for assessing medical device usability. It allows to accurately mimic a surgical maneuver, enabling synchronized 6-axis force measure. This approach is promising for enhancing device usability evaluation and compliance with regulatory standards, by assessing the interplaying loads during surgical instruments handling in a controlled environment.

Acknowledgements

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