A NUMERICAL AND EXPERIMENTAL APPROACH FOR EVALUATING THE RELIABILITY OF CERVICAL SURGICAL INSTRUMENTATION

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Introduction

Multi-use Surgical Instruments (SI) are composed of several instruments made of stainless steel, which can be reused and stored in the hospital for several surgery acts after sterilization to avoid cross-infection among the patients. The sterilization process is generally performed internally at the hospital hosting the kit and it is an energy-intense process (20kWh of electricity and 500l of water for medium- to large-sized hospitals) [1]. These procedures lead also to complications in terms of (i) significant time loss in performing the safety and hygienic protocols; (ii) elaborated logistic management in the hospital [2]; (iii) fracture in the operating room due to difficulties in assessing the performances of the instruments after several usages (30 cases of intra-operative SI breakages of a total of 8132 surgeries [3, 4]). The introduction of the single-use SI can overcome the limitations reported above and also improve the economic and environmental impact that still occurs with standard instrumentation [1], [3]–[6].

This work aims to provide a workflow for the mechanical redesign of a multi-use SI into single-use SI (Figure 1), starting from the analysis of the current situation. The case study is an instrumentation kit for cervical cage implantation (Sharkage system, 2B1 s.r.l, Milan, Italy, Figure 1a).

Materials and Methods

The redesign of the instruments was based on two steps *(i) Estimation of the mechanical strength through a validated approach.* The ad-hoc simulation was performed on the most critical component of the kit using Abaqus 2022 (Dassault Systèmes, SIMULIA Corp., RI) assigning stainless steel material (E=210GPa; υ=0.3) to the SI and imposing a displacement (7 mm) to an ad-hoc undeformable setup (Figure 1.b1, a friction equal to 0.3 was defined). Three different experimental tests were performed to validate the model in terms of stiffness (K, slope of force-displacement curve) and local strains (ε_{Princ}) measured using the strain-gauge rosette. *(ii) Development of an in-vivo measurement system* to identify the boundary conditions to which the instrumentation is subjected during surgery. An axial-torsional measuring system to be used during the surgical act was designed and tested (Figure 1.b2).

Results

(i) Estimation of the mechanical strength through a validated approach. The numerical model demonstrated good agreement with the experimental test (with a percentage difference of less than 10% in terms of K and ε_{Princ}). In the SI different zones resulted to be effected by

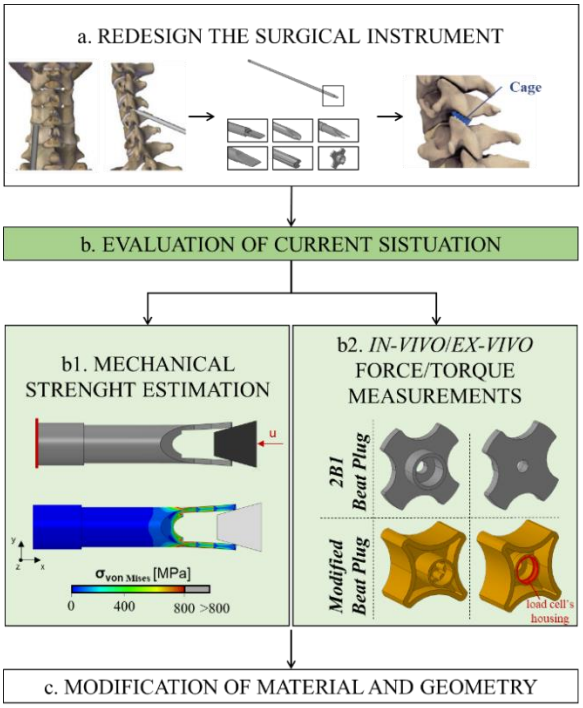

Figure 1: The workflow for the mechanical evaluation of the current SI.

von Mises stresses greater than the yielding stress (800 MPa) when the force is equal to 38 N (Figure 1.b1).

Development of an in-vivo measurement system. To record the force and torque during the surgery, the design of the beat plug was modified to house the bi-axial load cell (Figure 1.b2). Therefore, this information will be the basics in redesigning and assigning the new material to the single-use SI. A future step will be to perform the measurement activity during a real surgery or on cadaveric specimens.

Discussion

This work presents a path to redesign a SI starting from the knowledge of its mechanical behaviour. The final goal is reducing the life cycle assessment's economic and environmental impact of the instrument kit [2, 4].

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