From Benchtop to Operating Room: The Evolution of the Galen Platform

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(DOI10.31256/HSMR2019.8)

INTRODUCTION

The Galen is a cooperatively-controlled robotic platform designed for precise microsurgery [1]. With the aid of hand tremor cancellation and adaptable geometric constraints the system has the potential of enabling the wider use of minimally invasive surgery (MIS) with inherent benefits for the patient and surgeon. Intuitive operation, small footprint and ability to work with standard surgical instruments lead to minimal disturbance to the established workflows [1]. These benefits make the Galen a versatile robotic platform for multiple disciplines, including otolaryngology, neurosurgery and similar fields where high-precision and accuracy are crucial.

Conceptualized at Johns Hopkins University (JHU) and licensed for commercial development by Galen Robotics, Inc. in 2016, the system has undergone a series of design improvements on the path to commercialization. This paper explores this transition of the Galen Platform from the lab bench to the OR as well as the technical, market and user-driven factors that guided the design process.

Disclaimer: *The Galen platform is under development by Galen Robotics, Inc. and is not for commercial sale.*

DESIGN PROCESS

1- Robotic ENT Microsurgery System (REMS)

a) Needs identification

The REMS was designed to address the challenges in minimally invasive otolaryngology procedures. Delicate and millimeter-scale anatomy is often accessed through natural orifices or by drilling through bone concealing highly-sensitive anatomy. Manipulation of these delicate structures requires extreme caution as hand tremor and accidental contact with other anatomies can create adverse complications. These risks, amplified by difficult ergonomics and prolonged procedures, may overweigh the potential benefits of certain interventions.

b) Implementation

Developed at the JHU LCSR, the REMS is the initial surgical robot prototype for ENT in the Galen family. While the core technology of cooperatively controlled "steady-hand" robots is well established, the REMS is the first application of this technology in otolaryngology, to our knowledge [1]. The REMS incorporates five degrees-of-freedom (DOF) for manipulation of standard surgical instruments: two one-DOF rotational stages are connected to a delta parallel system for three-DOF Cartesian positioning. The overall size of the REMS was determined by its work volume which is roughly the size of a human skull. In order to demonstrate different surgical setups, the REMS was integrated onto the Preoperative Positioning System (PPS) that allowed the work volume of the REMS to be aligned with the surgical site using a motorized frame [2].

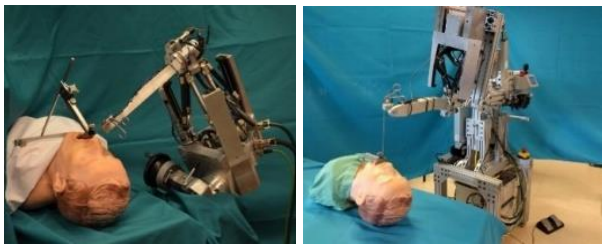

Fig. 1, 2 Standalone REMS (left) and REMS + PPS (right)

c) Evaluation

The REMS has been tested through several cadaver and phantom-based studies that simulated microlaryngeal surgery, sinus surgery and vessel anastomosis. A few prior publications have addressed the resolution, accuracy, stiffness and disruption to existing surgical workflows [1-3]. The robot achieved 0.140 mm translational and 0.0011 rad mean error after calibration [1]. It has also been shown that the REMS improved the peer-reviewed performance of novice surgeons during an anastomosis task by more than threefold [1]. The results of these studies, along with the personal reviews by around 100 surgeons have led to the following conclusions:

- The assumed needs have been verified: Certain otolaryngology interventions are error-prone, require difficult ergonomics and are too time consuming.
- The REMS serves as a valid test-bed to demonstrate the benefits of robotic assistance in otolaryngology surgeries, including decreased error rates, improved ergonomics and time savings.

2- Galen Mk. 1

a) Needs identification

Following commercialization, a new market research effort, backed by surgeon reviews outside otolaryngology revealed that the underlying technology of the REMS could also be useful in other disciplines, including spine and neurosurgery. These procedures often deal with larger anatomies and may require heavier instruments than those used in ENT. These findings, along with the identified improvements to user interface, mobility and cosmetics drove the design of the next prototype: *Galen Mk. 1*.

b) Implementation

In order to meet the larger spatial and force requirements of spine and neurosurgery, the design of Galen Mk.1 included sturdier structural elements, higher performance actuators, as well as a 250% larger work volume over the REMS. Furthermore, the following design changes were

implemented to improve the user experience and workflow:

- Non-motorized, weight-balanced PPS for more intuitive coarse positioning
- All electronics self-contained within the robot body
- Adjustable touch screen for user interface
- Skins for easy cleaning

Fig. 3, 4 Galen Mk. 1 concept and implementation

c) Evaluation

The Galen Mk. 1 was demonstrated to more than 80 international surgeons at the 2017 American Academy of Otolaryngology (AAO) Annual Meeting in Chicago, IL. The reception was positive particularly in reference to the robot's feel and performance. The main criticisms were the large footprint and the compliance of the PPS.

The robot has been shown to reduce unwanted tool-to-tissue forces that cause complications in microsurgery. In a study that measured lateral forces applied to the incus during placement and crimping of a stapes prosthesis, a decrease from 469.3 to 272.2 mN during crimping was reported when using the robot versus freehand [4].

3- Galen Mk. 2

a) Needs identification

Having the market needs and the potential benefits of the system reverified by a larger and more diverse sample of users, the next step towards a commercial medical device involved the determination of the requirements and a Failure Mode and Effects Analysis (FMEA) in compliance with the FDA regulations. In addition to design improvements to comply with these regulations, the next prototype also needed an overhaul of the PPS to alleviate the user criticism relating to the large footprint, insufficient stiffness and the time-consuming coarse position adjustment process.

Fig. 5, 6 Galen Mk. 2 concept and implementation

b) Implementation

The third-generation prototype of the robotic platform, the Galen Mk. 2 has completely eliminated the PPS for coarse positioning. Instead, the active delta stage was enlarged accordingly to make up for it. The resulting system is simpler, stiffer and has a smaller footprint.

In order to mitigate the identified hazards and satisfy regulatory requirements the new design includes safety circuits, joint brakes and redundant encoders on all axes. Finally, a new force sensor accommodates larger loads, allowing for a broader set of applications.

c) Evaluation

Several studies are in progress using the Mk. 2 to evaluate its utility in otolaryngology as well as in neurosurgery and orthopedics. Verification tests and early cadaveric studies have shown improved utility over its predecessors due to increased work volume, repeatability and stiffness.

Fig. 7 Cadaveric transoral thyroidectomy study with Mk. 2

DISCUSSION

Through the translational research efforts and the consequent commercial development, the Galen's potential in overcoming the challenges of minimally invasive otolaryngology surgeries has been demonstrated. To hit the next milestone of human trials, the development will be focused on regulatory compliance and integration into established hospital workflows. The team has identified design improvements in sterility, usability and maintainability, accordingly.

Close coordination between engineers and surgeons has been instrumental in navigating Galen's path from the lab bench to the OR. The authors believe that the many discoveries and setbacks along the way will be well justified in helping real patients.

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