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Novel modular 2-DOF microsurgical forceps for Transoral Laser Microsurgeries: Ergonomic design and preliminary evaluation

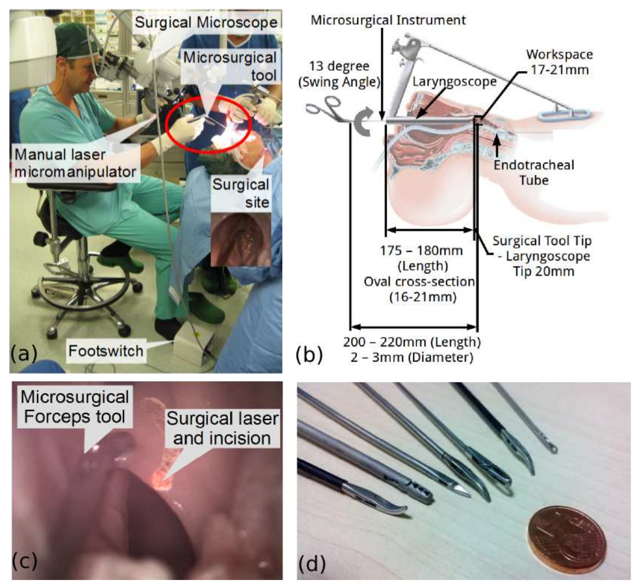
Manish Chauhan, Giacinto Barresi, Nikhil Deshpande, Darwin G. Caldwell, and Leonardo S. Mattos,
Department of Advanced Robotics, Istituto Italiano di Tecnologia (IIT), Via Morego 30, Genova, 16163, Italy
Email: {manish.chauhan, giacinto.barresi, nikhil.deshpande, darwin.caldwell, leonardo.mattos}@iit.it

***Abstract*—Transoral Laser Microsurgeries (TLM) demand a great level of control and precision in intraoperative tissue manipulation. The optimal eradication of the diseased tissue is possible only with coordinated control of the laser aiming for incision and the microsurgical tools for orienting and stretching the tissue. However, the traditional microsurgical tools are long, single purpose, one degree-of-freedom (DOF), rigid tools with smal range of motion and a normal grasping handle inducing non-ergonomic usage. This paper presents a novel, modular microsurgical tool to overcome the challenges of the traditional tools and improve the surgeon-tool usage experience. The novel design adds a rotational DOF to expand the reach and functionality of the tool. The device is provided with an ergonomic grasping handle that avoids extreme wrist excursions and is capable of adapting to the variety of tools used in TLM within the same design. The performance of the new microsurgical tool was evaluated through a subjective assessment with both medical students and expert surgeons.The evaluation demonstrated a general acceptance of the new forceps tool, with the expert surgeons providing positive appraisals for the improved functionality and user experience with the tool. The improved functionality, usability, and ergonomics point to the potential suitability of the device for TLM. The parameters assessed in the preliminary evaluation not only provide a sense of the advantages of the novel design, but also guide future evolution of the tool design.**

***Index Terms*—microsurgical forceps, ergonomic design, surgeon assessment, transoral laser microsurgeries**

I. INTRODUCTION

Transoral Laser Microsurgeries (TLM) involve the use of a surgical laser for the treatment of abnormalities in the upper aero-digestive tract (UADT) without any external incisions. Laser Phonomicrosurgery (LP), a state-of-the-art procedure within the TLM domain, is employed for the treatment of anomalies on the vocal cords, e.g., tumours, cysts, etc. [1], [2]. The traditional system currently used in the operating room employs a CO_2 surgical laser, coupled with a surgical microscope. The surgical site is exposed using a laryngoscope which allows a direct line-of-sight for the microscope. Figure 1a shows the traditional TLM setup. As is seen, a manual micromanipulator joystick is used to aim the laser beam at the surgical area from outside the mouth, from a distance of about 400 mm, while the surgical area is about 40 x 40 mm^2. Any intra-operative surgical tools, such as suction, irrigation, cauterization, as well as microsurgical forceps, are inserted through the laryngoscope and manually operated for intra-operative tissue manipulation and assistance. It is clear that TLM is a complex otolaryngological procedure requiring the surgeons to overcome: (i) poor operating ergonomics, (ii) difficult hand-eye-foot coordination, and (iii) coordinated control of the tools for manipulation and incision.



Top Left - (1a) Traditional TLM setup. **Top Right** - (1b) Cross-sectional view of TLM surgical area. **Bottom Left** – (1c) Microsurgical forceps keeping the vocal cord tissue in traction during laser cutting. **Bottom Right** – (1d) Types of microsurgical tools in LP.

Figure 1. Traditional Surgical tools used for LP

State-of-the-art microsurgical forceps used in LP are single purpose, one degree-of-freedom (DOF) long and rigid tools, with a normal scissor-like grasping handle at the proximal end, an average shaft length of about 200-220 mm, and a distal end cross-section of about 2 - 3 mm. The tools are usually pre-curved for access to the two sides of the vocal folds. The surgical site in LP, i.e., the vocal cords, varies in size from 17–21 mm (males) to 11–15 mm (females)[3]. The structure and size of the vocal cords demand a great level of accuracy and dexterity from the surgeon for proper tissue positioning and exposure at sub-mm scale. For the best cutting conditions with the laser, the tissue needs to be maintained perpendicular to the laser path and in traction (stretched). Achieving these goals is difficult and error-prone:

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(i) the surgeons are operating long tools with small distal openings in extremely restricted workspaces; (ii) the hand and wrist positions during the procedure are non-ergonomic inducing tremors and wrist excursions over the long surgical hours; (iii) the surgeons are vulnerable to stress and fatigue in the hands which can directly impact the ability for complete pathology removal and safety of the operations; and (iv) the coordinated control of the tool and the laser requires considerable skill during a time-consuming procedure which can be developed only after long hours of extensive training. Figure 1b shows a cross-sectional view of the TLM surgical area.

The research in this paper addresses the limitations in the traditional, manual, microsurgical forceps through a complete redesign of the tool operation and surgeon interface. The main components of the novel design are: (i) a rotational DOF in addition to the open/close DOF; (ii) a grip-locking mechanism to maintain forceps jaws in closed position; and (iii) an ergonomic handle including a push-button for open/close and a rotating knob. The features and benefits of the novel forceps include: (i) allowing the surgeon to grip-n-turn the tissue facilitating better exposure of the site and enhanced tissue manipulation ability; (ii) facilitating access to different parts of the vocal cords removing the need to use different tools for different parts; (iii) ability to lock the forceps with gripped tissue allowing simpler control of tissue positioning and traction; and (iv) easy-to-use and comfortable handling of the tool. The novel tool design and its features are evaluated using methodologies of ergonomics and user experience assessment with particular attention to the human factors, e.g., ease-of-control, workload, etc. [4]. Different subjective parameters were considered during the preliminary assessment of the user experience with the novel microsurgical forceps design. These parameters not only provide a sense of the advantages of the redesign, but also guide further evolution of the tool designs.

II. Previous Work

The recognition that surgical instruments need a re-examination of their functionality and usability has driven recent investigations into the use of advanced technologies for hand-held surgical tools. In the domain of manually operated surgical tools, there are mostly commercial devices such as the art2DRIVE[5], art2CURVE[6], and the SILS Hand Instruments[7]. These commercial tools provide ergonomic grasping handles and allow two-dimensional tool-tip articulation (bending and rotation). They generally have a tool-shaft diameter of about 5 mm and use a remote-center-of-motion (usually the laparoscopic incision port on the patient body) as a pivot point against which the tools can be articulated at the surgical site in nearly hemispherical space. In state-of-the-art TLM, the microsurgical tools tend to have a maximum shaft diameter of 3 mm, and the surgeons use the tools in free space without a remote pivot point. These commercial tools are therefore deemed inappropriate for the TLM surgical procedure. Yet, as noted earlier, advanced functionalities in the traditional one-dimensional tools of TLM are highly desirable. The SerpENT articulating instruments [8] are the only commercially available tools that come close to the TLM application area. The tools allow up to $240°$ bending in one dimension allowing an increased reach for the forceps jaws, while also giving 7 different bending-lock positions. The limitations of these instruments: (i) the continued use of the non-ergonomic grasping handles, and (ii) the sub-optimal tool-shaft lengths (~ 140 mm vs. the desired ~ 200 mm), constrain their adoption in TLM.

This research approaches the redesign of the traditional microsurgical tools in TLM from a user-centered perspective. The focus is on a uniform tool interface for the surgeon and adding functionality, i.e., rotational DOF and grip-locking, and features to improve the usability and ergonomics. As highlighted in the introduction, the novel forceps takes into account subjective factors related to surgeon skills, limitations, and needs. This user-centered perspective, based on ergonomics methodologies, e.g., subjective questionnaires after user testing [9], shall assist in the design of the novel microsurgical forceps tool. It will allow the redesigned tool to either maintain or increase the level of its usability and user experience, while progressively adding new functionalities.

III. Design of the novel microsurgical forceps

A. *Design constraints and motivations*

The TLM application domain served as specifications and constraints for the re-design of the microsurgical forceps. Along with the size and lengths of the tools, the following constraints are also included:

1) The tools are hand-held and manually operated. Therefore, the tool grasping handles cannot be big and heavy. They need to be ergonomically designed to allow easy usage and adoption by the surgeons.
2) The tools are used in the line-of-sight of the surgical microscope view. The handles therefore need to be sized optimally to avoid any surgical view occlusion.

The key motivations for the re-design, as highlighted earlier, were to add functionality to improve tissue manipulation capabilities as well as improve the ergonomics of the tool handling.

1) As seen in Fig. 1d, there are various commonly used tool-tips in TLM. Yet, the operating principles of the tools are similar, with an outer hollow shaft and a translating open/close DOF [10]. The novel design adopts a modular architecture so as to have a common surgeon handle interface, while allowing interchangeability of different tool-tips in the same device design.
2) Considering the dimensional constraints, the novel designs utilize the traditional microsurgical forceps as their basis and mechanisms are introduced at the proximal ends. The focus therefore is on enhancing the functionality of the tool (e.g., rotational DOF and locking) while improving the ergonomics of the device.
3) To maintain a low profile in costs, sizes, and weights of the new design, the components are fabricated using ABS-plastic through additive manufacturing, making low-cost rapid prototyping a key feature of the design.

The novel design consists of three individual modules: (i) the modular microsurgical tool shaft; (ii) the microsurgical tool-shaft holder; and (iii) the grasping handle (Refer Fig. 2). The details of the design are described in the following subsections.

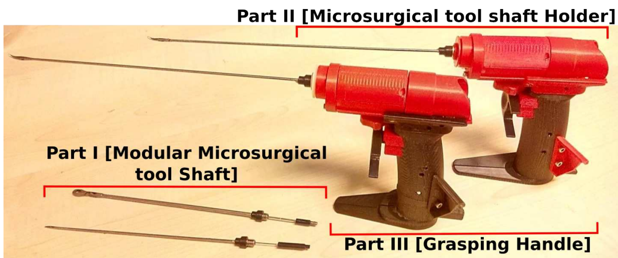
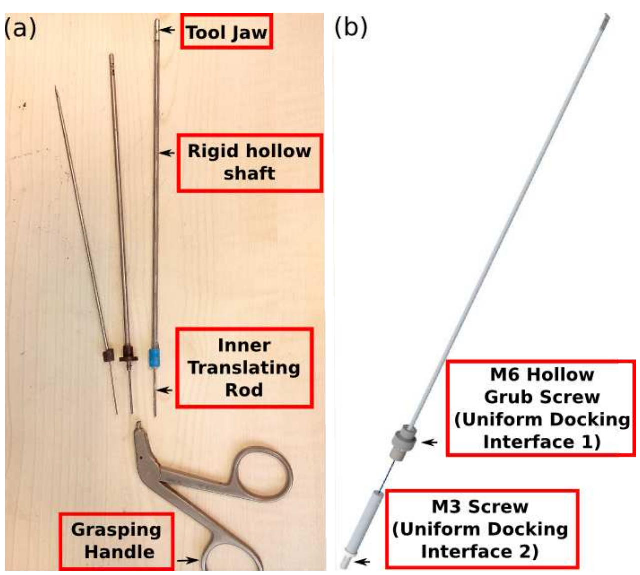


Figure 2. Novel modular 2-DOF microsurgical forceps

B. The modular Microsurgical tool shaft

The microsurgical tool shaft is a modified version of traditional microsurgical forceps used in LP. The traditional forceps were dis-assembled, as seen in Fig. 3a , and the modular tool shaft was formed consisting of an outer shaft (ϕ 2.5 mm) which holds an inner translating rod (ϕ 1 mm). The translation of the rod provides the open-close DOF. In the traditional tool, a translation of about 3 mm moves the forceps jaws from a completely open position to a completely closed position. At the proximal end of the modular tool shaft, two adaptations (Uniform Docking interface 1 and 2) are introduced, as seen in Fig. 3b. These allow the tool shaft to easily dock into the other components of the tool. These adaptations can be introduced into different tool shafts with different tool-tips allowing interchangeability.



Left - (3a) Dis-assembled traditional forceps **Right** - (3b) Modifications introduced in tool shaft

Figure 3. Modular Tool Shaft

C. The Microsurgical tool-shaft holder

This component forms the backbone of the design and incorporates the mechanisms for the open/close and rotational DOFs.

1) The rotational DOF is achieved with the help of an anti-backlash miter gear assembly (Nordex LHS E2-30). The inner translating rod of the modular tool shaft passes through the gear assembly, while the outer shaft docks into the *axial* miter gear through the M6 screw joint. A rotation knob is coupled to the *normal* miter gear through a set of spur gears allowing simple, manual, and simultaneous rotation and open/close of the modular tool. The design of the rotation knob and its location was finalized through a consultative process with different users for improving the ergonomics of the device. The rotation knob is easily controlled by either the thumb or the index finger, providing 360° rotation in both clockwise and anti-clockwise direction.
2) A friction-less slider assembly docks into the inner translating rod at the proximal end, providing the open/close of the gripper jaws. The slider assembly includes an internal bearing to allow free motion of the rod with the rotational DOF. A bracket on the other end of the slider assembly is used for coupling it to a set of linkages (housed in the grasping handle) providing linear motion of the assembly.

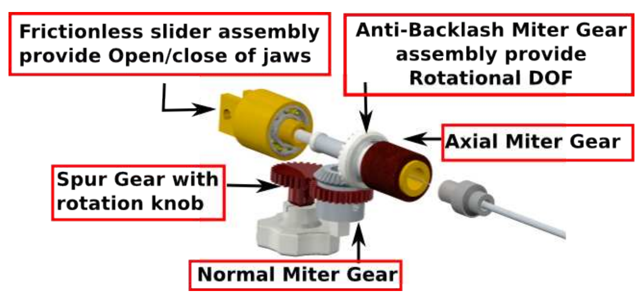


Figure 4. Perspective views of the design showing the uniform docking system.

D. The grasping handle

The grasping handle forms the user handling component of the device, and serves as the common surgeon interface. The assembly of the modular microsurgical tool shaft and the microsurgical tool-shaft holder docks into the grasping handle by sliding through the provided guide-ways. The design of the handle was based on ergonomic principles to avoid wrist excursions during tissue manipulation and was inspired from the design of computer graphics and gaming joysticks[11].

An ergonomically designed push-button guided by a compression spring serves to open/close the gripper jaws. A set of linkages couple the push-button to the slider assembly of the holder providing linear translation of the slider assembly through simple kinematic inversion.

1) Simple pressing of the push-button closes the forceps jaws. The internal compression spring housed inside

the grasping handle provides the auto-return for the button.

2) The grip-locking functionality is also designed into the grasping handle and the push-button. Two levers are included on the push-button design. Once the push-button is pressed into gripper close position, shifting the levers down locks the grip, while shifting the levers up again releases the lock. (Refer Fig. 5).

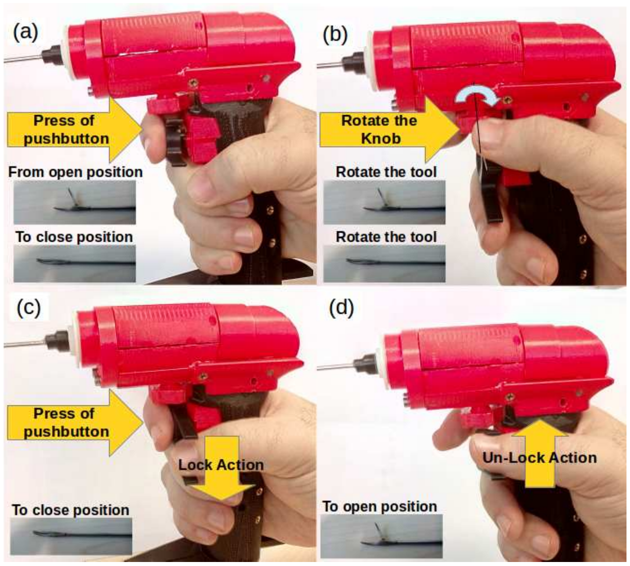


Figure 5. Modular forceps operating technique

The novel microsurgical forceps, assembled and ready-to-use, are depicted in Fig. 2.

IV. Evaluation and User Trials

The novel microsurgical forceps replace the traditional forceps in their functionality as well as their surgeon handling interface. Since they are a manual operation tool, their acceptability and relevance to the surgical task in TLM is guided by the subjective experience of a user/surgeon handling the tool. To account for these factors, a series of user trials were conducted to obtain a preliminary evaluation of the new forceps. The trials were designed to compare the user experience in two conditions: (i) C1: the traditional forceps; and (ii) C2: the new forceps. The trial setup, shown in Fig. 6, involved performing near-real surgical manoeuvre's such as: insertion/retraction through the laryngoscope, tissue grasping, manipulation, stretching, pulling, etc., using free-hand motion. The subjects were also encouraged to use the new tool without any specific instruction of handedness, e.g., using the tool in either hand according to their usage preference. For the task, ex-vivo pig larynxes were used since they most closely simulate the human larynx. The trials were performed at San Martino Hospital in Genoa, Italy, and the complete control of the environmental and social context inside the trial room helped avoid any disturbance.

In order to quantify the user experience, the evaluations of the users were collected as part of a questionnaire with scores in 7-point Likert-type scales [12]. The questionnaire

Table I
Evaluation statements

S1. The tool control (and activation) was precise.
S2. I found the tool control was easy to learn, so I could start using it quickly.
S3. The posture required during the task induced fatigue.
S4. The tool control (and activation) was safe.
S5. The tool control (and activation) induced fatigue in my hand.
S6. It is easy to make errors with this tool.
S7. My performance with this tool in this task was satisfying.
S8. The tool control (and activation) was easy.
S9. I would recommend this tool to a colleague.
S10. It is satisfying to use the tool and I would like to use it again for this kind of task.
S11. I was stressed, irritated, and annoyed during this task.
TP. Preference of C1 or C2

was made of 11 statements describing different aspects of usability and user experience (with particular attention to ease-of-control, comfort, and safety). It has been structured in order to check the most common issues in surgeon tool interaction for ergonomic design of the tool. The users had to indicate their degree of agreement with each statement along a line divided in 7 intervals (the score "1" means "I strongly disagree" with the statement, while the score 7 implies "I strongly agree" with it). The questionnaire is shown in Table I. Additionally, the subjects also had to compare their overall experience with both conditions by expressing a degree of tool preference (TP) for C1 or C2 along another 7-points Likert-type scale ("1" is a strong preference for C1, while "7" is a strong preference for C2). Two sets of trials were conducted, one with medical students, and the other with expert surgeons, in order to have a representative sample of the potential user population.

A. Trials with medical students

The first set of trials involved medical students (both undergraduate and graduate). The students did not have any experience either with TLM or with the usage of the traditional microsurgical forceps. This allowed the evaluation of the newly designed tool without any inherent bias in the subjects and provided information about the preferences of subjects with medical background: such data would be highly relevant for the design of surgical training procedures. 8 medical students (5 female, 3 male; average age 27.75 years) performed the trials. For the trial task, the subjects were allowed to familiarize themselves with the tool, then use it in the trial for the near-real surgical manoeuvre's for at least 2 minutes. After each tool condition (C1 or C2), the subjects filled out the questionnaire from Table I rating their experience with it.

Out of the 8 subjects, 4 were asked to trial C1-before-C2, while the other 4 trialed C2-before-C1. This method allowed to balance any potential effects of experience with one condition before the other.

B. Trials with expert surgeons

The trials with experts were performed with 4 expert medical doctors (1 female, 3 male; average age 33.5) with 1 to 20 years of experience in head-and-neck surgery. In this case, the subjects were made to trial only C2, i.e., the novel forceps tool. They filled out the questionnaire just the one time and expressed their preference for the new tool against the traditional one, with which they already had years of experience. These trials served to provide information about the preferences of expert subjects helping to understand the difficulties in technological shift. Expert surgeons are able to estimate risks and opportunities offered by new devices in real contexts. They provided informal feedback on the added functionalities of the new design.

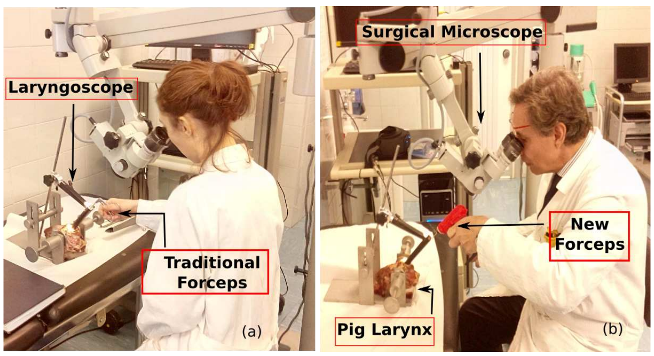


Figure 6. User trials
Left – (6a) Trial with the traditional microsurgical forceps. **Right** – (6b) Trial with the proposed microsurgical forceps

V. Results

The scores for the questionnaire evaluations are listed in the Table II.

Table II
Scores for Questionnaire

	Medical students				Experts	
	C1		C2		C2	
	m	sd	m	sd	m	sd
S1	5.38	1.58	4.75	0.83	4	1.87
S2	6.50	0.71	5.13	1.36	6.25	0.83
S3	2.38	1.49	4.13	1.62	3.5	1.66
S4	4.75	1.3	4.88	1.69	5.25	1.48
S5	3.0	1.66	4.25	1.48	3	1.22
S6	3.75	1.64	4.0	1.87	3.25	1.09
S7	4.63	1.49	4.5	1.87	5.25	0.83
S8	5.5	1.32	4.63	1.58	6.25	1.3
S9	4.75	1.3	4.75	1.2	5	1.58
S10	4.88	1.27	5	1.32	6	1.73
S11	2.13	1.76	3.00	1.94	1.75	0.83
TP	m=2.5; sd = 2.35				3	2.45

A. Results for medical students

The results for the medical students showed an average acceptance for the new forceps tools. The new design proved advantageous in terms of ease-of-control, safety, and precision, but seemed to suffer on aspects related to ease of learning and fatigue (statements - S2, S3, S5, S8, S11). This characteristic can be understood with respect to the change in the tool handling interface. The traditional forceps have the conventional two-finger, scissor-like grasping handle, with which all subjects would have a lifetime of training. The new design instead offers a wrist-based handle. The feedback indicates that naive subjects would require a longer learning curve to adapt to the new design. Yet, no clear preference for the traditional tool was evident in the last question (TP). This indicated that the new design had the potential to be used in a real surgical scenario.

B. Results for expert surgeons

The scores from expert surgeons suggested a different and positive trends for the new design. Significant advantages were expressed in terms of ease of learning, safety of operation, performance satisfaction, and ease-of-control. The surgeons found enough evidence in the new design to be willing to use it themselves in a surgical scenario, as well as recommend this system to colleagues. Importantly, the expert surgeons do not indicate handling-related stress and posture fatigue with the new tool. This feedback is contrary to the one expressed by the naive subjects. The positive evaluations of the experts in almost all aspects of the questionnaire highlights the effect of experience and expertise in understanding the opportunities offered by this new design in terms of function.

C. Discussion

The goal of this new microsurgical forceps is to make it applicable, usable, and advantageous in a TLM surgical scenario. In this context, the following informal, qualitative feedback received from the experts was invaluable in guiding the further evolution of the tool:

1) The rotational DOF is useful for accessing different parts of the vocal cords without needing to use different pre-curved tools.
2) The grip-locking mechanism is useful to manipulate tissue in different positions and maintain it in position for longer duration.
3) The size of the proximal mechanisms needs to be reduced more to further avoid surgical view occlusion.

The scores from the questionnaire were not processed through statistical inference methods at this stage due to the limited number of measurements and subjects. These preliminary evaluations have highlighted the critical issues relating to fatigue and posture of the user during tool handling which need to be weighed equitably against the introduction of new functionalities such as control of tissue rotation. The encouraging evaluations of the experts helped considerably to evolve the concept of the common tool interface for the surgeon and validated the design choices.

VI. Conclusions and Future Work

A novel, modular, hand-held, microsurgical device is presented here, with the added functionality of tool-shaft rotation and uniform interfaces for adaptability to differentmicrosurgical tool shafts. The tool is designed keeping in mind the ergonomic principles of human device usage. It is provided with an actuation push-button for gripper open/close which is also capable of locking the forceps while keeping the

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tissue gripped. The preliminary assessment demonstrates a general acceptance of the new forceps tool by both medical students and experts. It is noted however, that the medical students experienced difficulties in using the new forceps in terms of fatigue and learning. On the other hand, the experts appreciated the new designs without experiencing the same issues as perceived by the students. Thus, the potential of the new device design is clearly evaluated more positively according to the degree of expertise of the subjects. The encouraging evaluations by the expert surgeons pointed to the possible application of the new designs in the real TLM surgical scenario.

In future work, the feedback from the preliminary evaluations shall be used to further optimize the design of the tool. These preliminary user trials offered rich information in order to guide future experimental evaluations. The experimental tasks shall be improved for a full statistical analysis with all criteria (e.g. more subjects) of the next versions. The next steps shall investigate hand-held, robot-assisted solutions for microsurgical forceps tools allowing further enhancements in functionality and ergonomic usage designs.

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