

# Design and Study of a Next-Generation Computer-Assisted System for Transoral Laser Microsurgery

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## Abstract

**Objective.** To present a new computer-assisted system for improved usability, intuitiveness, efficiency, and controllability in transoral laser microsurgery (TLM).

**Study Design.** Pilot technology feasibility study.

**Setting.** A dedicated room with a simulated TLM surgical setup: surgical microscope, surgical laser system, instruments, ex vivo pig larynxes, and computer-assisted system.

**Subjects and Methods.** The computer-assisted laser microsurgery (CALM) system consists of a novel motorized laser micromanipulator and a tablet- and stylus-based control interface. The system setup includes the Leica 2 surgical microscope and the DEKA HiScan Surgical laser system. The system was validated through a first-of-its-kind observational study with 57 international surgeons with varied experience in TLM. The subjects performed real surgical tasks on ex vivo pig larynxes in a simulated TLM scenario. The qualitative aspects were established with a newly devised questionnaire assessing the usability, efficiency, and suitability of the system.

**Results.** The surgeons evaluated the CALM system with an average score of 6.29 (out of 7) in ease of use and ease of learning, while an average score of 5.96 was assigned for controllability and safety. A score of 1.51 indicated reduced workload for the subjects. Of 57 subjects, 41 stated that the CALM system allows better surgical quality than the existing TLM systems.

**Conclusions.** The CALM system augments the usability, controllability, and efficiency in TLM. It enhances the ergonomics and accuracy beyond the current state of the art, potentially improving the surgical safety and quality. The system offers the intraoperative automated scanning of

customized long incisions achieving uniform resections at the surgical site.

## Keywords

computer-assisted surgery, transoral laryngeal microsurgery, motorized laser micromanipulation, surgeon-machine interface, usability study

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Computer-assisted surgical systems play a key role in successful surgical interventions today.<sup>1</sup> The attendant advantages with computer-assisted surgical systems include increased precision for the surgeons, reduced tremor in tool handling, and simplicity of the surgical interface, among others.<sup>2</sup>

With the introduction of the transoral laser microsurgery (TLM) procedure in the field of surgical laryngology,<sup>3</sup> the key surgical functions of control (laser manipulation) and perception (visualization of the site) have relied on the effective coordination of the following: (1) a manual micromanipulator to move the free-beam surgical laser (CO<sub>2</sub> is the prevalent variety) in an area about 20 × 20 mm<sup>2</sup>, (2) visualization through a surgical microscope, and (3) laser activation through a footswitch. The challenges and limitations of this traditional setup with respect to controllability

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and ergonomics are noted in literature,<sup>4,5</sup> prompting the introduction of computer-assisted surgical approaches in TLM. Beginning with the work of Reinisch et al,<sup>6</sup> important contributions have been made in this direction.<sup>4-13</sup> A step change occurred with the introduction of high-speed scanning of the laser at the surgical site with fast, computer-controlled motorized mechanisms. Commercially available systems, such as the Lumenis AcuBlade, the KLS Martin SoftScan, and the DEKA HiScan, offer these preprogrammed fast scan patterns (eg, lines, curves) that enable higher-quality incisions with reduced carbonization.<sup>4,5</sup> Yet, these improvements in incision quality do not translate to a change in the surgical user interface itself. The problems of manual micromanipulation in a constrained space persist with the limitations of poor operating ergonomics and discomfort.<sup>7</sup>

It is well recognized in literature that human factors in the design of surgical interfaces play a major role in their success and quality.<sup>6-14</sup> Earlier research in the field explored changes to the surgical interface in TLM, ranging from replacing the manual joystick with a computer mouse<sup>8</sup> to using the da Vinci system itself.<sup>9</sup> The investigations by Giallo and his group<sup>8,10,11</sup> showed the significant advantages offered by more ergonomic interfaces where the motion of the laser deflection mirror is motorized.<sup>8,10,11</sup> Our related investigations resulted in 2 previous prototypes that successfully replaced the manual mechanisms with stylus-based systems, providing heretofore-impossible levels of accuracy, uniformity, and ease of use.<sup>7,12,13</sup>

Taking this previous research forward, the objective of this article is twofold:

- Introducing the next-generation computer-assisted laser microsurgery (CALM) concept toward improving usability, efficiency, and controllability
- Presenting a first-of-its-kind study in characterizing the system through ex vivo pig larynx trials with surgeon subjects

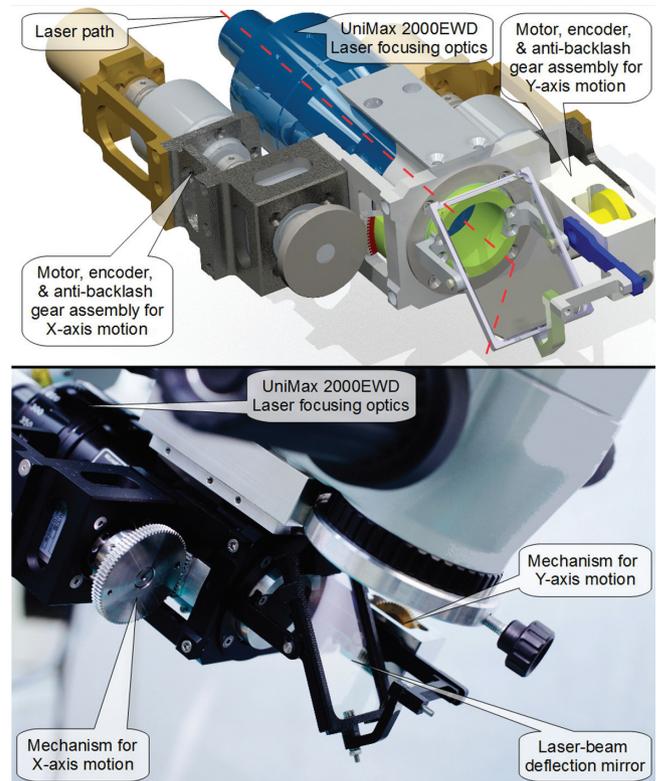
Hitherto, most studies with robot-assisted systems in TLM focused on evaluating the novel systems in nonsurgical scenarios, with comparative trials using imitation surgical tasks to suggest the improved performance.<sup>7-13</sup> To the best of our knowledge, this is the first such study where the subjects performed real surgical tasks with real tissue albeit in a simulated microsurgical scenario.

## Methods

### CALM Concept

**Figure 1** shows the CALM concept, which includes the following components.

**Novel motorized laser micromanipulator.** The novel design overcomes the limitations of earlier-generation prototypes<sup>13</sup> by including a spherical orienting mechanism that uses anti-backlash gears and high-resolution encoders. The mechanism actuates the beam splitter itself in 2 planar dimensions and is compatible with state-of-the-art commercial



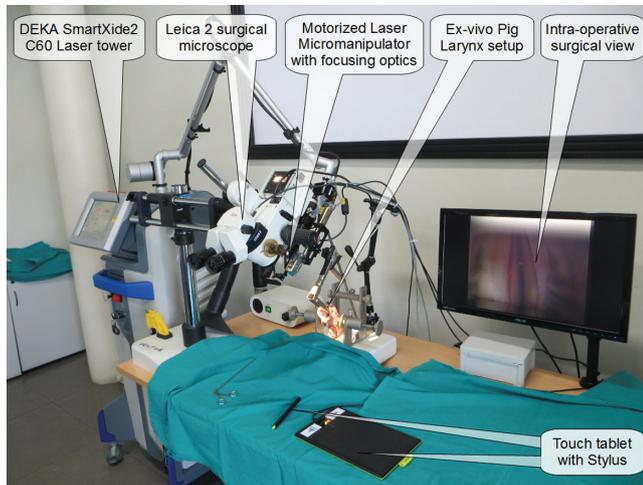
**Figure 1.** The computer-aided design model and prototype of the motorized laser micromanipulator device, which includes the UniMax 2000EWD laser-focusing optics. The mechanism allows 2-dimensional motion of the laser with an unobstructed line of sight for the surgical microscope.

microscopes and laser systems. It uses reflective laser-focusing optics, resulting in commercial-grade beam alignment and a laser spot diameter  $<0.15$  mm.<sup>9</sup> The motorized laser micromanipulator (MLM) provides high positioning accuracy ( $35 \mu\text{m}$ ), a programmable working area (up to  $40 \times 40 \text{ mm}^2$  at 400-mm distance), and user-definable scanning speeds (up to 0.1 m/s).

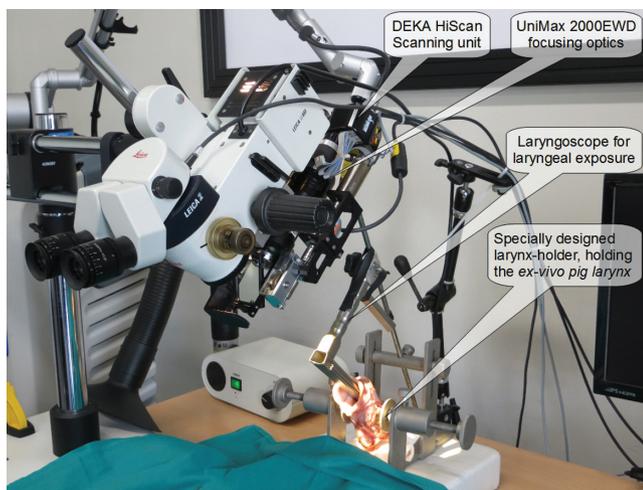
**Touch tablet with stylus.** A touch tablet with stylus controls the MLM device through a dedicated controller board and advanced control algorithm. The stylus controls the aiming of the surgical laser in real time through its motion on the tablet surface, replacing the manual joystick.

**State-of-the-art commercial equipment.** The Leica 2 surgical microscope (Leica, Wetzlar, Germany) is used for binocular surgical site visualization. The UniMax 2000EWD (Reliant Technologies, Inc, Foster City, California) reflective optics system is used for laser-focusing. The SmartXide2 C60 laser system (DEKA, Calenzano, Italy), including the HiScan Surgical scanning unit, serves as the surgical ablation  $\text{CO}_2$  laser. The footswitch activates the ablation laser.

**Figure 2** shows the integrated system. The CALM system offers an innovative feature: programmable scans for the laser beam, termed *preview mode*. In this mode, the



**Figure 2.** Computer-assisted laser microsurgery concept: The touch tablet controls the aiming of the laser, commanding the motorized laser micromanipulator device in real time. The system is connected to the Leica 2 surgical microscope and the DEKA SmartXide2 C60 laser tower.



**Figure 3.** Close-up view of the ex vivo pig larynx setup. The image shows the motorized laser micromanipulator device connected to the focusing optics and DEKA HiScan unit. The specially designed larynx holder is also seen with the STORZ laryngoscope.

surgeon can intraoperatively program long incision paths of desired shapes using the stylus itself. The MLM executes these paths automatically at user-definable speeds. This gives the surgeon a preview of the intended cut through the motion of the visible laser. The laser can then be activated as desired through the footswitch.

### Experiment Design

For evaluating the CALM system for applicability in real TLM scenarios, a representative microsurgical setup was prepared. In a first-of-its-kind study, ex vivo pig larynxes, due to their resemblance to human larynxes,<sup>15</sup> were utilized as simulated targets, positioned in a specially designed holder. **Figure 3** presents the arrangement of the experiment and

details. The ex vivo larynxes were acquired from the supermarket, and only designated personnel handled them. The setup and takedown of the experiment were done with appropriate protection equipment. The larynxes were disposed in designated containers at the end of each session.

### Subjects and Groups

Fifty-seven international surgeons from laryngology and head and neck specialties were chosen as subjects (mean age, 41.33 years; 45 men, 12 women). Their mean experience in TLM procedures was 8.74 years (range, 0-29 years; **Table 1**). Seventeen subjects declared that cordectomies were the most typical surgery that they practiced, while others declared a variety of procedures. Based on the demographic data collected and the subjects' given experience in TLM, groups were classified as follows: experts, TLM experience  $\geq 10$  years (22 men, 3 women); nonexperts, TLM experience  $< 10$  years (23 men, 9 women).

The nature of the study, not involving human or animal clinical trials, did not require prior Ethics Committee approval. The Ethics Committee of Liguria Region granted the exemption, including the use of ex vivo pig larynxes for trials with human subjects.

### Experimental Tasks

**Figure 4** shows a sample image of the experimental task being performed. The subjects were asked to perform cordectomies. The nonexperts were asked to perform a partial cordectomy, incising 1 layer off the vocal fold mucosa. The expert subjects were asked to perform a type I or type II cordectomy. The surgeons used regular TLM microsurgical forceps for tissue manipulation. Before beginning the surgical trial, the subjects took 3 to 5 minutes to acclimatize with the CALM system and the control of the laser with the stylus. The subjects were asked to use the preview mode for incisions. The experiment design and trials are seen in the video accompanying the article.

### Subjective Measures

For the evaluations, a new questionnaire was devised according to the System Usability Scale and the NASA-TLX (Task Load Index).<sup>16,17</sup> The questionnaire accounted not only for the ergonomics and intuitiveness aspects of the system but also the suitability and perceived usefulness of the features of the system in relation to TLM (laser control, resection quality, etc). The questionnaire was organized into 4 subgroups: usability, controllability, workload, and suitability to TLM (**Table 2**). The subjects were asked to mark their degree of agreement with the statements on a 7-point Likert scale.<sup>17</sup> The questions were presented to the subjects in randomized order to avoid any answering bias. At the end of the trials, an additional question asked the subjects to opine whether the surgical quality with the CALM system would be better, similar, or worse than any state-of-the-art systems in their experience.

To establish the significance of the results, the frequency distribution of the assigned scores was used as a metric. For

**Table 1.** Demographics of Subjects, Sorted by Years of Experience in TLM.

Experience TLM, y	0	0	0	0	0	0	0	0	0	0	0	0
Expert/nonexpert	N	N	N	N	N	N	N	N	N	N	N	N
Sex	M	F	F	F	M	F	M	F	M	F	M	M
Age, y	40	32	26	26	34	31	26	29	47	26	42	28
Experience TLM, y	0	0	1	1	1	1	1	1	1	2	2	3
Expert/nonexpert	N	N	N	N	N	N	N	N	N	N	N	N
Sex	M	M	M	M	M	M	M	F	M	M	M	M
Age, y	27	27	29	30	29	28	30	30	30	27	59	29
Experience TLM, y	3	4	4	5	7	8	8	9	10	10	10	10
Expert/nonexpert	N	N	N	N	N	N	N	N	E	E	E	E
Sex	M	F	M	F	M	M	M	M	M	M	F	M
Age, y	26	29	60	31	51	37	38	36	44	39	42	50
Experience TLM, y	10	10	10	10	10	12	15	15	16	16	18	18
Expert/nonexpert	E	E	E	E	E	E	E	E	E	E	E	E
Sex	M	M	M	M	M	M	F	M	M	M	F	M
Age, y	42	47	53	62	57	38	47	60	61	41	48	54
Experience TLM, y	20	20	20	20	20	21	23	24	29			
Expert/nonexpert	E	E	E	E	E	E	E	E	E			
Sex	M	M	M	M	M	M	M	M	M			
Age, y	54	57	58	50	62	56	50	51	63			

Abbreviations: E, expert (TLM experience  $\geq 10$  years); F, female; M, male; N, nonexpert (TLM experience  $< 10$  years); TLM, transoral laser microsurgery.

instance, a high score for statement S1 (ie, 7) and a low score for statement S8 (ie, 1) would each imply a positive evaluation for the CALM system (**Table 2**). Therefore, to obtain a statistical *P* value, the Pearson chi-square test for

goodness of fit<sup>18,19</sup> was used, which accommodates a comparison of 2 sets within the same sample condition.<sup>20</sup> Here, the sets are the frequencies of favorable scores (ie, a score of 7 or 1 per statement) against the nonfavorable scores (ie, a score other than 7 or 1).

## Results

### Overall Scores

**Figure 5** shows the mean scores for the subjective measures of all the subjects. **Table 3** shows the results of the statistical tests. The “Frequency of Score” column captures the number of subjects who assigned the favorable and nonfavorable scores for the corresponding statements. For the chi-square test, the expected frequency is 8.14 for the favorable score (57 subjects over the 7-point scale) and 48.86 for the nonfavorable score. The “ $\chi^2(1)$  Value” and “Significance at  $P < .05$ ” columns show the chi-square statistics.



**Figure 4.** Experimental setup with surgeons using the computer-assisted laser microsurgery system for trials with the ex vivo pig larynxes, which was designed to resemble a transoral laser microsurgical station. A footswitch activates the surgical laser.

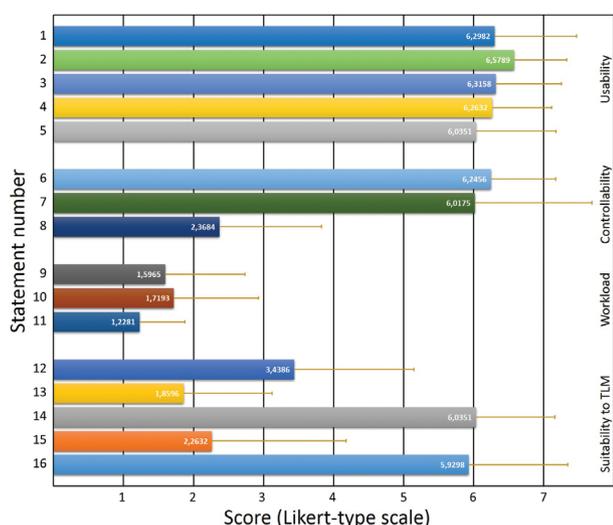
*Usability:* The average score in the usability subgroup is 6.29 (SD = 0.97). As seen in the table, all 5 statements show that the favorable scoring by the subjects was at a statistically significant level.

*Controllability:* With respect to its controllability, the system scored an average 5.96 (SD = 1.35). Even so, all 3 statements scored favorably at a statistically significant level.

*Workload:* Here, the system scored an average of 1.51 (SD = 0.99) demonstrating a favorable evaluation of the system. Expectedly, low scores on all 3 statements are statistically significant.

**Table 2.** Questionnaire Items.

Item	Statement
<b>Usability</b>	
S1	It was easy to control/use the system.
S2	I found this system was easy to learn, so I could start using it quickly.
S3	I would like to use the system again for this kind of task.
S4	My performance in this task with this system was satisfying.
S5	I would recommend this system to a colleague.
<b>Controllability</b>	
S6	The system control was precise.
S7	The system was safe to use.
S8	It was easy to make errors with this system.
<b>Workload</b>	
S9	The control of the system induced fatigue in my hand.
S10	Maintaining attention to what I was doing was difficult.
S11	I was stressed, irritated, and annoyed using this system during the task.
<b>Suitability to transoral laser microsurgery</b>	
S12	The system allows laser operations not previously possible.
S13	The system is not appropriate for fine resections.
S14	The system is an improvement over current laser microsurgery devices.
S15	The system does not allow all laser operations I am used to performing.
S16	The system is appropriate for large resections.



**Figure 5.** Overall mean scores for the questionnaire evaluations. The scores are organized according to the 4 subgroups: usability, controllability, workload, and suitability to transoral laser microsurgery (TLM). Error bars represent SD.

*Suitability to TLM:* The average score for the suitability evaluation is 5.46 (SD = 1.48). Although most subscales are evaluated favorably, the subscale on the possible surgical operations with CALM shows uncertainty at 3.44 (SD = 1.70,  $P = .117$ ).

**Feedback from Expert Surgeons**

For a comparative analysis, a quasi-experimental design<sup>21</sup> was adopted where the independent variable of expertise was

manipulated to have 2 conditions: experts versus nonexperts. Since the data distribution after this manipulation did not satisfy the assumptions of analysis of variance, the nonparametric Wilcoxon rank sum test<sup>22</sup> was used to compare the medians of scores. **Figure 6** compares the scores assigned by the experts against the nonexperts. **Table 4** shows the  $P$  values establishing the statistical significance of the differences in the results under the 2 conditions.

*Usability:* Here, the experts and nonexperts assign scores that are statistically indistinct: ease of use ( $P = .4453$ ), easy to learn ( $P = .5056$ ), and satisfactory in performance ( $P = .7346$ ).

*Controllability:* The simulated testing scenario implies a significant divergence of opinion ( $P = .0386$ ) indicating that the experts do not agree with the nonexperts. Even so, the safety and error subscales both show agreement.

*Workload:* The experts agree that the system is comfortable and not stress inducing (workload subgroup; **Figure 6**). The ease-of-attention subscale is scored favorably ( $P = .9797$ ).

*Suitability to TLM:* As seen, the experts' scores agree with the overall scores for CALM's improvement and suitability to large resections. Yet, the experts diverge from the nonexperts for the system permitting fine resections ( $P = .0107$ ).

**Surgical Quality Preference**

**Table 5** shows the scores comparing the perceived surgical quality with CALM against the state-of-the-art systems

**Table 3.** Results of Subjective Measures: Chi-square Test for Goodness of Fit.

Statement	Score (Out of 7)	Frequency of Score	$\chi^2(1)$	P Value <sup>a</sup>
<b>Usability</b>				
S1. Easy to use	Mean = 6.298 SD = 1.169	Favorable, 7 33 Nonfavorable, <7 24	88.857	<.001
S2. Easy to learn	Mean = 6.578 SD = 0.748	Favorable, 7 39 Nonfavorable, <7 18	136.51	<.001
S3. Use the system again	Mean = 6.315 SD = 0.939	Favorable, 7 32 Nonfavorable, <7 25	81.60	<.001
S4. Satisfying performance	Mean = 6.263 SD = 0.849	Favorable, 7 25 Nonfavorable, <7 32	40.47	<.001
S5. Recommend to other surgeons	Mean = 6.035 SD = 0.139	Favorable, 7 21 Nonfavorable, <7 36	23.70	<.001
<b>Controllability</b>				
S6. Precise to control	Mean = 6.246 SD = 0.923	Favorable, 7 29 Nonfavorable, <7 28	62.37	<.001
S7. Safe to use	Mean = 6.018 SD = 1.670	Favorable, 7 29 Nonfavorable, <7 28	62.37	<.001
S8. Easy to make errors	Mean = 2.368 SD = 1.459	Favorable, 1 20 Nonfavorable, >1 37	20.16	<.001
<b>Workload</b>				
S9. System-induced fatigue	Mean = 1.596 SD = 1.137	Favorable, 1 37 Nonfavorable, >1 20	119.38	<.001
S10. Difficult to maintain attention	Mean = 1.719 SD = 1.210	Favorable, 1 33 Nonfavorable, >1 24	88.58	<.001
S11. Stressful to use the system	Mean = 1.228 SD = 0.649	Favorable, 1 48 Nonfavorable, >1 9	227.72	<.001
<b>Suitability to transoral laser microsurgery</b>				
S12. Allows new laser operations	Mean = 3.438 SD = 1.706	Favorable, 7 4 Nonfavorable, <7 53	2.46	<b>.117</b>
S13. System not fit for fine resections	Mean = 1.859 SD = 1.263	Favorable, 1 29 Nonfavorable, >1 28	62.37	<.001
S14. Improvement on current systems	Mean = 6.035 SD = 1.123	Favorable, 7 26 Nonfavorable, <7 31	45.72	<.001
S15. Does not allow operations	Mean = 2.263 SD = 1.915	Favorable, 1 31 Nonfavorable, >1 26	74.90	<.001
S16. System fit for large resections	Mean = 5.929 SD = 1.412	Favorable, 7 25 Nonfavorable, <7 32	40.47	<.001

<sup>a</sup>Significance at  $P < .05$ . Bold indicates that the favorable score is not statistically significant.

based on the usage experience of the surgeons. A majority of the surgeons (41 of 57, 71.9%,  $P < .001$ ) agree that the CALM system would provide “better” surgical quality.

## Discussion

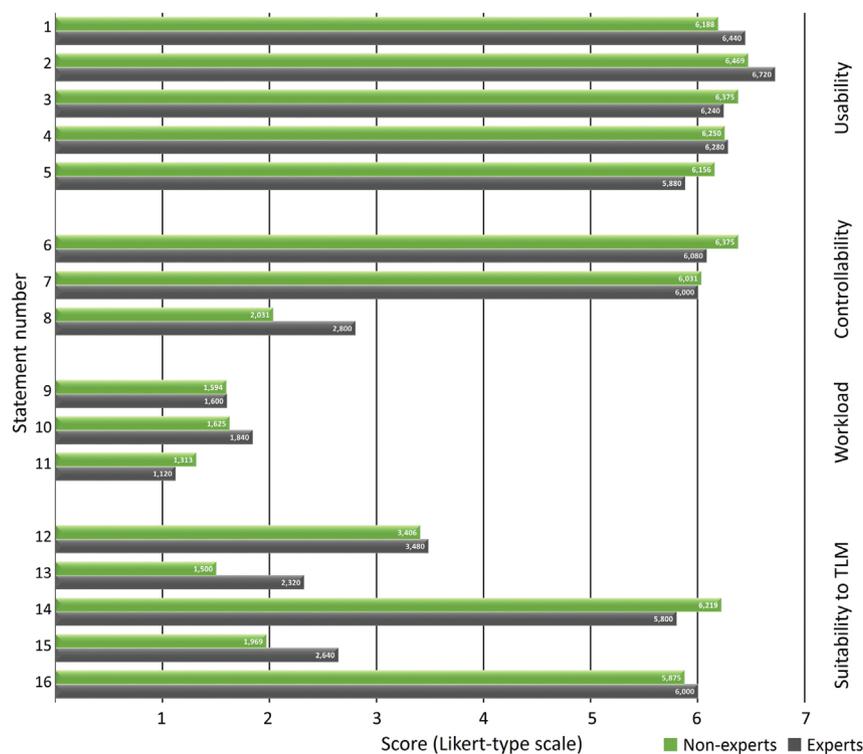
This article presents the novel CALM system, created to provide improved accuracy, controllability, safety, and better ergonomics for TLM procedures. To achieve these objectives, the next-generation MLM device was integrated into the CALM concept. The evaluation of the subjective questionnaire points to the advantages of the CALM concept.

### Overall Scores

The high usability scores underline the comfort and adaptability of the CALM system in a surgical scenario.

Integrated with the MLM, the pen-like stylus replaces the manual joystick and allows intuitive control, dramatically simplifying the surgeon-machine interface against the non-ergonomic and nonoptimally located manual joystick. The stylus can be located in a comfortable position and orientation and includes the gesture-scaling feature, which maps large drawing-like hand gestures to ultrafine laser motions.

The scores of accuracy and safety being  $>6$  demonstrate the perceived benefits with the CALM system. The not-so-emphatic score on the error subscale is understood as an artifact of the simulated ex vivo and bleeding-free scenario of the trials. It is conceivable that surgeons perceived the setup as resembling a game, leading them to underestimate the need for carefulness during usage.<sup>23</sup> Yet, this aspect is countered not only by the system’s technical design itself



**Figure 6.** Comparative scores for questionnaire. The values show a close correlation between the scores for the expert surgeons and the rest of the subjects for all 4 subgroups. TLM, transoral laser microsurgery.

but also by the surgeons' positive evaluations on the other subscales.

The preview mode feature automatically scans the laser along hand-drawn incision paths. This feature combines the high-speed scanning of the DEKA HiScan Surgical system with long automated incisions. Traditionally, to make long incisions, the surgeon controls the joystick and makes multiple passes manually. To achieve desired precision and accuracy is very difficult, if not impossible, even for highly skilled surgeons. On the contrary, under computer control, the automated incisions offer improved accuracy and uniformity of resections, which is not available in any traditional system. This plays a major role in alleviating the control and fatigue problems with the manual micromanipulator. It frees up the surgeon's laser hand, reducing the hand fatigue and potentially allowing the use of 2 hands for tissue manipulation—a distinct advantage when accessing difficult margins in the surgical site. The positive evaluations here demonstrate the potential safety, usefulness, and benefit of the CALM system for future clinical use.

In terms of TLM suitability, the scores indicate that the subjects do not immediately perceive the benefits of CALM (as seen in S12), highlighting the scope for improvement in the design as well as study setup.

### Expert Feedback

The experts' scores demonstrate that the CALM system provides potential improvements in usability, learnability, performance, comfort, and safety. The absence of a statistically

significant difference between experts and nonexperts affirmed the absence of any lack-of-experience bias. Yet, with regard to suitability to TLM and perceived surgical quality, the evaluation of the experts was conservative. On deeper consultation, the expert surgeons noted an important limitation with the system. Most expert surgeons are used to state-of-the-art commercial systems that offer the high-speed scanning patterns as stated earlier. When using these devices, the surgeons frequently use buttons located near the micromanipulator joystick to orient the patterns as they perform incisions. Although CALM includes the state-of-the-art DEKA HiScan Surgical system and integrates its scanning laser delivery features, the functionality to orient the patterns was not integrated into the surgeon interface at the time of the trials. This hindered the surgeons' ability to perform incisions to their satisfaction, leading them to opine that, in its current state, the system is limited in its capabilities. This functionality is a required addition to the CALM system and is part of future work.

### Surgical Quality

As seen in **Table 5**, although CALM is rated "better" overall by an overwhelming number of subjects (41 of 57), the expert surgeons are more cautious in their assessment of the surgical quality. The almost 50-50 split between "better" and "similar" for the experts is significant and needs further examination, especially since none of the subjects considered the CALM system to be worse than the traditional systems. A statistically significant difference was found

**Table 4.** Comparison of Scores between Experts and Nonexperts: Wilcoxon Rank Sum Test for Comparison of Medians.

Statement	Category	Score (Out of 7)			Rank Sum Value	P Value <sup>a</sup>
		Mean	SD	Median		
<b>Usability</b>						
S1. Easy to use	Expert	6.44	0.961	7.0	766.5	.4453
	Nonexpert	6.188	1.330	7.0		
S2. Easy to learn	Expert	6.72	0.458	7.0	761.0	.5056
	Nonexpert	6.469	0.915	7.0		
S3. Use the system again	Expert	6.24	1.091	7.0	713.5	.8510
	Nonexpert	6.375	0.833	7.0		
S4. Satisfying performance	Expert	6.28	0.891	6.0	745.0	.7346
	Nonexpert	6.25	0.842	6.0		
S5. Recommend to other surgeons	Expert	5.88	1.364	6.0	684.0	.4812
	Nonexpert	6.156	0.954	6.0		
<b>Controllability</b>						
S6. Precise to control	Expert	6.08	1.038	6.0	660.5	.2623
	Nonexpert	6.375	0.833	7.0		
S7. Safe to use	Expert	6.00	1.683	7.0	722.0	.9803
	Nonexpert	6.031	1.713	6.5		
S8. Easy to make errors	Expert	2.80	1.555	2.0	848.5	<b>.0386</b>
	Nonexpert	2.031	1.332	2.0		
<b>Workload</b>						
S9. System-induced fatigue	Expert	1.60	1.258	1.0	704.5	.7462
	Nonexpert	1.594	1.073	1.0		
S10. Difficult to maintain attention	Expert	1.84	1.463	1.0	728.0	.9797
	Nonexpert	1.625	1.008	1.0		
S11. Stressful to use the system	Expert	1.12	0.332	1.0	695.0	.4822
	Nonexpert	1.313	0.821	1.0		
<b>Suitability to transoral laser microsurgery</b>						
S12. Allows new laser operations	Expert	3.48	1.828	4.0	738.0	.8340
	Nonexpert	3.406	1.663	3.0		
S13. System not fit for fine resections	Expert	2.32	1.574	2.0	870.5	<b>.0107</b>
	Nonexpert	1.50	0.842	1.0		
S14. Improvement on current systems	Expert	5.80	1.291	6.0	654.5	.2348
	Nonexpert	6.219	0.975	6.5		
S15. Does not allow operations	Expert	2.64	2.158	2.0	786.5	.2801
	Nonexpert	1.969	1.713	1.0		
S16. System fit for large resections	Expert	6.00	1.258	6.0	733.0	.9010
	Nonexpert	5.875	1.561	6.0		

<sup>a</sup>Significance at  $P < .05$ . Bold indicates that the divergence of scores between experts and nonexperts is statistically significant.

**Table 5.** Comparison of Scores between Experts and Nonexperts: Chi-square Test for Contingency Table for Surgical Quality.

Item	Category	Rating			Total	$\chi^2$	P Value <sup>a</sup>
		Better	Similar	Worse			
Surgical quality of CALM system <sup>b</sup>	Expert	13	12	0	25	8.607	.0033
	Nonexpert	28	04	0	32		
	Total	41	16	0	57		

Abbreviation: CALM, computer-assisted laser microsurgery.

<sup>a</sup>Significance at  $P < .05$ .

<sup>b</sup>In comparison with traditional systems.

between the expert and nonexpert groups. The nonexpert group tended to judge the CALM system “better” than the traditional one (87.5%), much more so than the expert group (52%,  $P = .0033$ ). This can be attributed to the experts treating the system, in its current state, as a game-like scenario.<sup>23</sup> Instead, the perceived usefulness of the CALM system may rank higher for the less-experienced surgeons, thereby highlighting its potential impact on training times.

### Limitations of the Study

The article presents a novel system with a first-of-its-kind trial setup with ex vivo tissue. The study provides a survey of experience of the subjects in a simulated preclinical scenario. The assertions of improvements in accuracy, usability, ergonomics, and safety are not based on experiences in live surgery. Ex vivo pig larynxes, though useful as simulated targets, differ significantly from actual surgery and therefore cannot provide the real understanding of CALM’s surgical application. It is evident from the evaluations of system suitability that a human clinical setting is needed for surgeons to acclimatize to the bimanual usage of the stylus with the intraoperative instruments. Therefore, more controlled trials in the live surgical scenario are needed to ratify the benefits of the CALM system proposed here.

Additionally, the present study is only a subjective analysis of the system. Further objective evaluation is warranted to establish quantitative and unbiased comparison of CALM against current surgical systems and interfaces.

### Conclusions

The CALM concept allows surgeons to perform operations using a stylus instead of the traditional manual micromanipulator joystick, making laser aiming more intuitive and consistent. The system is comfortable and offers better use of the surgeons’ manual dexterity. It augments the surgeons’ fine manual skills through gesture scaling and magnification, thereby improving safety of the surgical procedures. The system offers automatic execution of intraoperative programmable scans (preview mode) combined with the high-speed scanning feature. Beyond this, it can potentially greatly reduce the amount of training required to achieve proficiency in TLM.

The subjective evaluation with 57 international surgeons demonstrated the preference for the CALM system in TLM, especially with respect to ease of use, ease of learning, safety, reduced mental effort, and its suitability for the execution of uniform, fine, and long resections. The article presents a first-of-its-kind study with surgeon subjects performing real surgical tasks with real tissue (ex vivo pig larynxes) in a simulated microsurgical setup. The study establishes an effective methodology for future evaluations of computer-assisted surgical systems in TLM or other procedures. The results provide a pathway for the CALM system’s progress to the TLM operating room.

In the extension of this research, it is important to account for the limitations of the system and the feedback

from the surgeons to improve the usefulness of CALM in TLM. Consequently, the CALM system is now in the process of being upgraded in design to incorporate the capability of scanning pattern orientation within the tablet interface itself. The new prototype will be evaluated jointly by the surgeons and engineers with cadaver trials. This shall provide further groundwork for the eventual clinical trials with the system.

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### Author Contributions

**Nikhil Deshpande**, conception and design of study, data acquisition and analysis, drafting, revising, final approval, and accountability for the work; **Giorgio Peretti**, data acquisition, revising, final approval, and accountability for the work; **Francesco Mora**, design of study, data acquisition, revising, final approval, and accountability for the work; **Luca Guastini**, design of study, experimental setup, data acquisition, revising, final approval, and accountability for the work; **Jinoh Lee**, data acquisition, data analysis, revising, final approval, and accountability for the work; **Giacinto Barresi**, data acquisition and analysis, drafting, revising, final approval, and accountability for the work; **Darwin G. Caldwell**, design of study, revising, final approval, and accountability for the work; **Leonardo S. Mattos**, design of study, data acquisition, revising, final approval, and accountability for the work.

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