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ORIGINAL ARTICLE – RECONSTRUCTIVE ONCOLOGY

New Robotic System with Wristed Microinstruments Allows Precise Reconstructive Microsurgery: Preclinical Study

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ABSTRACT

Background. Microsurgery allows complex reconstruction of tissue defects after oncological resections or severe trauma. Performing these procedures may be limited by human tremor, precision, and manual dexterity. A new robot designed specifically for microsurgery with wristed microinstruments and motion scaling may reduce human tremor and thus enhance precision. This randomized controlled preclinical trial investigated whether this new robotic system can successfully perform microsurgical needle driving, suturing, and anastomosis.

Methods. Expert microsurgeons and novices completed six needle passage exercises and performed six anastomoses by hand and six with the new robot. Experienced microsurgeons blindly assessed the quality of the procedures. Precision in microneedle driving and stitch placement was assessed by calculating suturing distances and angulation. Performance of microsurgical anastomoses was assessed by time, learning curves, and the Anastomosis Lapse Index score for objective performance assessment.

Results. Refined precision in suturing was achieved with the robot when compared with the manual technique regarding suture distances ($p = 0.02$) and angulation ($p < 0.01$). The time required to perform microsurgical anastomoses was longer with the robot, however, both expert and novice microsurgeons reduced times with practice. The objective evaluation of the anastomoses performed by novices showed better results with the robot.

Conclusions. This study demonstrated the feasibility of performing precise microsutures and anastomoses using a new robotic system. Compared to standard manual techniques, robotic procedures were longer in time, but showed greater precision.

Microsurgery is a surgical technique that uses optical magnification and dedicated instrumentation to operate on delicate sub-millimeter anatomy. It is currently applied in the reconstruction of defects after oncological resections as well as after traumatic injuries and treatment of congenital pathologies. It allows high-precision dissection and suture and, therefore, is used by several surgical specialties such as plastic and reconstructive surgery, maxillofacial, otolarynology (ENT), orthopedics, and neurosurgery, among others.

Various types of cancer are treated aggressively with early excision, microsurgical reconstruction with free flaps, and chemo/radiotherapy. Breast cancer reconstruction after mastectomy can be performed by using microsurgical autologous tissue flaps.[1,2] In head and neck cancers, microsurgery allows complex reconstructions of the mandible and the tongue.[3,4] Similarly, many microsurgical flaps provide optimal treatment for patients with cancers of the extremities.[5,6] Furthermore, (super)microsurgery is also applied to reverse the development of cancer treatment-related lymphedema.[7–9]

During the last two decades, surgery has seen the introduction of many robotic systems and associated instrumentation with different characteristics and fields of application, improving the surgeon's precision.

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Microsurgery represents one of the most technically demanding surgical disciplines, however, it has passively seen the development of robotic surgery. Technical advances in microscopes, microinstruments and sutures have enabled microsurgeons to perform complex free tissue transfers by anastomosing small arteries, veins, nerves, and lymphatics. However, the use of microsurgery in the clinical setting still requires long and complex trainings to overcome a steep learning curve.[10]

Robotics primarily has been applied to the field of endoscopic and laparoscopic surgery with the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA), which was specifically designed for improving laparoscopic minimally invasive surgery,[11] and to a lesser extent orthopedic, spinal and brain surgery with product offerings from Mako[12], Mazor,[13] and Rosa.[14] The advances achieved in such a short time, together with the benefits for surgeons and patients, have recently led to an increase in the use and development of robotic devices and platforms for general surgery.[15] Reconstructive surgery has remained largely untouched by robotics to date, with the exception of a group of pioneering surgeons in an innovative attempt to obtain benefits of the Da Vinci robot beyond FDA approved indications.[16–18] In this sense, Selber et al. have demonstrated several different applications in reconstructive surgery, including transoral robotic reconstruction of oropharyngeal defects, harvesting of latissimus dorsi muscle, rectus abdominis muscle and DIEP flap, as well as microvascular and nerve anastomoses[18–22]. These studies demonstrated the benefit of wristed instrumentation together with major drawbacks related to large instrument size and tips, a limited visual magnification, and poor resolution associated with a limited scaling factor.

Recently, the MUSA system (Microsure, Eindhoven, The Netherlands) has been designed specifically for microsurgical applications by Microsure to aid in stabilizing movements of the microsurgeon by filtering tremors and scaling down motions of instruments. MUSA uses standard non-wristed microsurgical instruments mounted on robotic arms with six proximal degrees of freedom, driven by master instruments mounted on the bedside.[23] The system controls the standard microinstruments by the use of joysticks while working in an ergonomically comfortable position. The system has been tested in preclinical and clinical studies representing a further step forward in performing microsurgical anastomoses and reducing lymphedema severity after breast cancer surgeries through the performance of lymphatic anastomoses.[24] Except for the MUSA robot, the rest of the current robotic surgical platforms are not specifically designed to perform microsurgery. However, there is a need to overcome the limitations related to instruments used with most robotic systems. In this sense, a new robotic platform (Symani® Surgical System, MMI, Pisa, Italy) has been specially designed for microsurgery with the world's smallest and wristed surgical microinstruments, which are intended to improve the surgeon's natural dexterity and range of motion beyond the capability of the human hand. Therefore, the purpose of this study was to evaluate the Symani robotic system's performance and precision compared to the traditional manual technique. This study also describes new synthetic models for robotic microsurgery training.

METHODS

In order to assess the potential benefits of motion precision and dexterity of the robotic system, different bench tests have been performed involving several users, as discussed in the following sections. All tests have been conducted in a dedicated and equipped clinical room at the Medical Micro Instrument (MMI) headquarters based in Pisa, Italy.

The Robotic System

The Symani Surgical System is a robotic platform specifically designed by Medical MicroInstruments (MMI S.p.A.) for open microsurgical procedures. It was CE certified in 2019 assuring conformity with European health, safety, and environmental protection standards. The system consists of a master console interacting with a slave on which articulated microinstruments are installed and easily positioned across an anatomical region (Fig 1a). The master console consists of an ergonomic chair equipped with surgeon-controlled manipulators along with a footswitch. The disposable articulated micro-instruments (NanoWrist® instruments, US10864051B2[25]) are installed on the two robotic arms (Fig 1b and 1c). The surgeon can directly move the manipulators in the same way as manual instrumentation, while the robot scales down and communicates these movements to the arms and microinstruments. The system features 7-20X motion scaling with tremor filtration. The robot was used together with the operating microscope Pentero 800 (Carl Zeiss Meditec AG, Jena, Germany). The same microscope was used during manual procedures but with conventional instruments (S&T AG, Neuhausen, Switzerland).

Users

Forty users were enrolled for testing the system, including 20 experts and 20 novices. Experts were surgeons with five or more years of experience in microsurgery practice and with no experience in robotic surgery. Novice users were volunteer medical trainees with no previous experience in microsurgery and with short experience in basic general surgical suturing.

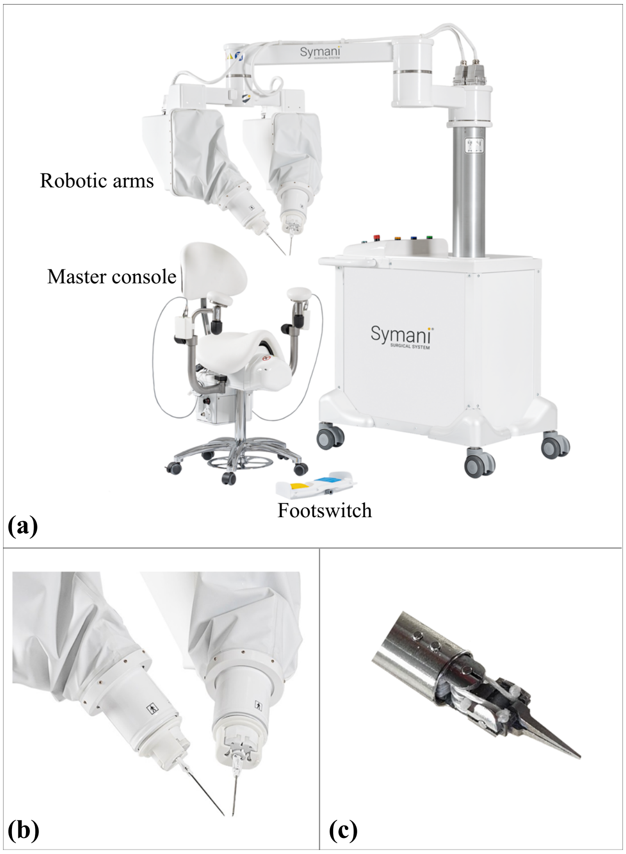


FIG. 1. Symani robotic surgical system. **a** Components of the microsurgery robot. **b** Robotic arms. **c** Articulated wrist robotic microinstrument.

Training Sessions

Before performing anastomoses, each subject participated in a brief training session on the Symani Surgical System including three dedicated exercises (Fig 2a). The first training task was a pick-and-place exercise, aimed to increase confidence with scaling and overall robotic motion transmission. The second task was a precision pick-and-place exercise aimed to increase confidence with the system's high precision scaled motion and in particular with the articulation of the instrument wrist. The third exercise was a path aimed to teach and force the user to use bimanual control. To complete the training session, each exercise was repeated three times by each user.

Bench Tests

Bench tests included needle passage in synthetic tissue and anastomoses in 1 mm-diameter vessels (by WetLab Corporation, Japan). These tests used standard microsurgery training models—execution of stitch placement and knot tying on validated synthetic models (latex patches and silicone tubes)[26]—to assess the precision of completing microsurgical tasks with the Symani robotic system compared to the standard manual technique. All surgeons used the same type of wristed microinstruments for the training sessions and bench tests.

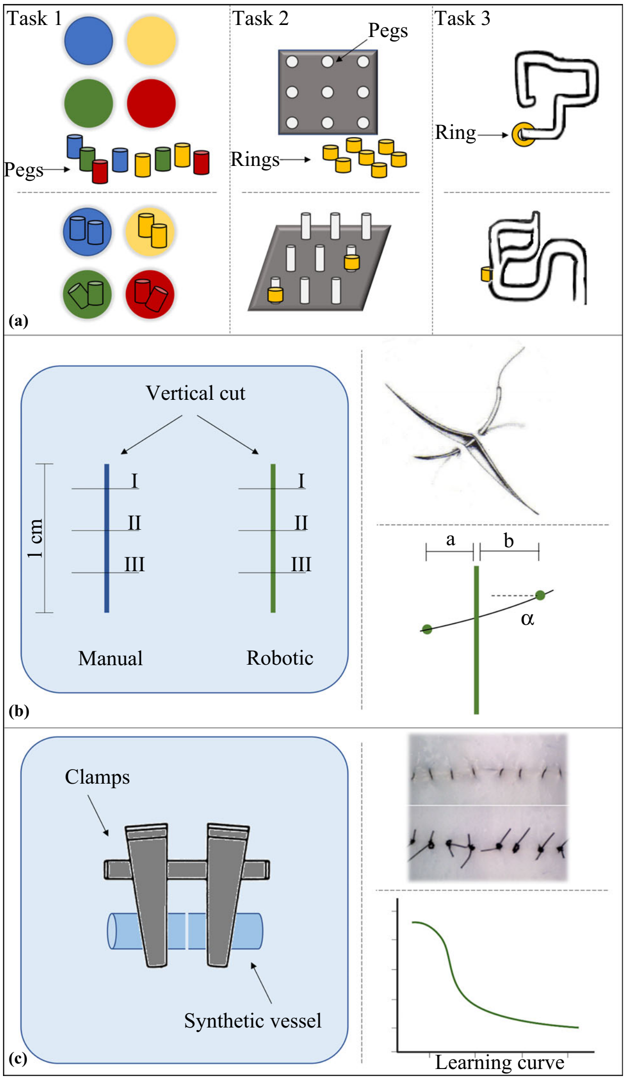


FIG. 2. Training exercises, needle passage, and anastomois tests. **a** Training exercises: For Task 1, the surgeon has to pick small colored pegs and place them in the corresponding colored basket; For Task 2, the surgeon must pick the yellow rings and place each of them vertically on the corresponding pins; For Task 3, the surgeon must grab the yellow ring and move it along the three-dimensional trajectory having to pass the ring from the left to the right hand several times. **b** Needle passage test: On the left, the cuts for three needle passages made manually and another three with the robot are represented; On the right, "a" and "b" represents the entry and exit points, and "α" the angle of needle pass. **c** Anastomosis test: On the left, representative image of the synthetic vessel to be anastomosed and the placement of the microvascular clamps; on the right above the images to evaluate with the ALI score; on the right below, a representative image of a learning curve.

Needle Passage Test Needle passage is defined as the placement of a needle across two separate tissue walls.

This test, already used in standard microsurgery training,[27] aims to evaluate the precision in stitch placement. The setup used consists of a frame holding a latex patch, with two vertical cuts of 1 cm in length: one dedicated for the manual needle passages and the other dedicated for the robotic needle passages (Fig 2b). Each of the 40 users performed six needle passages by using 10/0 nylon sutures (S&T AG, Neuhausen, Switzerland), three using the manual technique and three using the Symani robot. A Dino-Lite digital microscope (model AM73915MZT, AnMo Electronics Corporation, Taiwan) was used to acquire images of each needle passage. DinoCapture 2.0 software was used to calculate the entry and exit points of needle passage as well as angle of needle pass (parameters a, b and α represented in Fig 2b). In the optimal needle passage, the needle should enter and exit orthogonally to the cut line ($\alpha = 0°$) and the distances from the entry/exit points from the cut line should be the same (a = b). Distances were calculated by using the parameter Δ = a-b (positive value).

Anastomosis Test Anastomosis on synthetic vessels is a standard training model to acquire circular suturing skills, which are essential for reconstructive microsurgery. We used this test to evaluate the feasibility of suturing with the robot. The setup (Fig 2c) used for the test consists of a standard surgical clamp (ABB-22, S&T AG, Switzerland) and a silicone microvessel (WetLab Corporation, Japan). For microsurgical anastomosis 10/0 nylon sutures (S&T AG, Switzerland) were used. A total of 72 anastomoses were performed and evaluated. Three expert microsurgeons and three novices performed six anastomoses of eight interrupted sutures with the standard manual technique and with the Symani robot. Each suture had to be performed with a first double loop, followed by second and third single loops. Robotic and manual procedures were compared by analyzing the following parameters: Anastomosis net time (net time to perform the single anastomoses), suture net time (net time to perform each single suture) and overall suture quality (assessed through the Anastomosis Lapse Index [ALI][28] by a blinded experienced microsurgeon and educator). Learning curves for both robotic and manual anastomoses also were evaluated.

Statistical Analysis

Statistical analyses were performed using GraphPad Prism software version 8.0 (GraphPad Software, San Diego, CA, USA). All data reported are consistently expressed as arithmetic mean ± standard error. All p values lower than 0.05 were considered significant. Statistical significance was analyzed for needle passage and anastomosis tests by using a two-way ANOVA test (repeated measures, multiple comparison test by Sidak, 95% confidence interval). The learning curves were calculated by plotting data trend lines.

RESULTS

Needle Passage Test

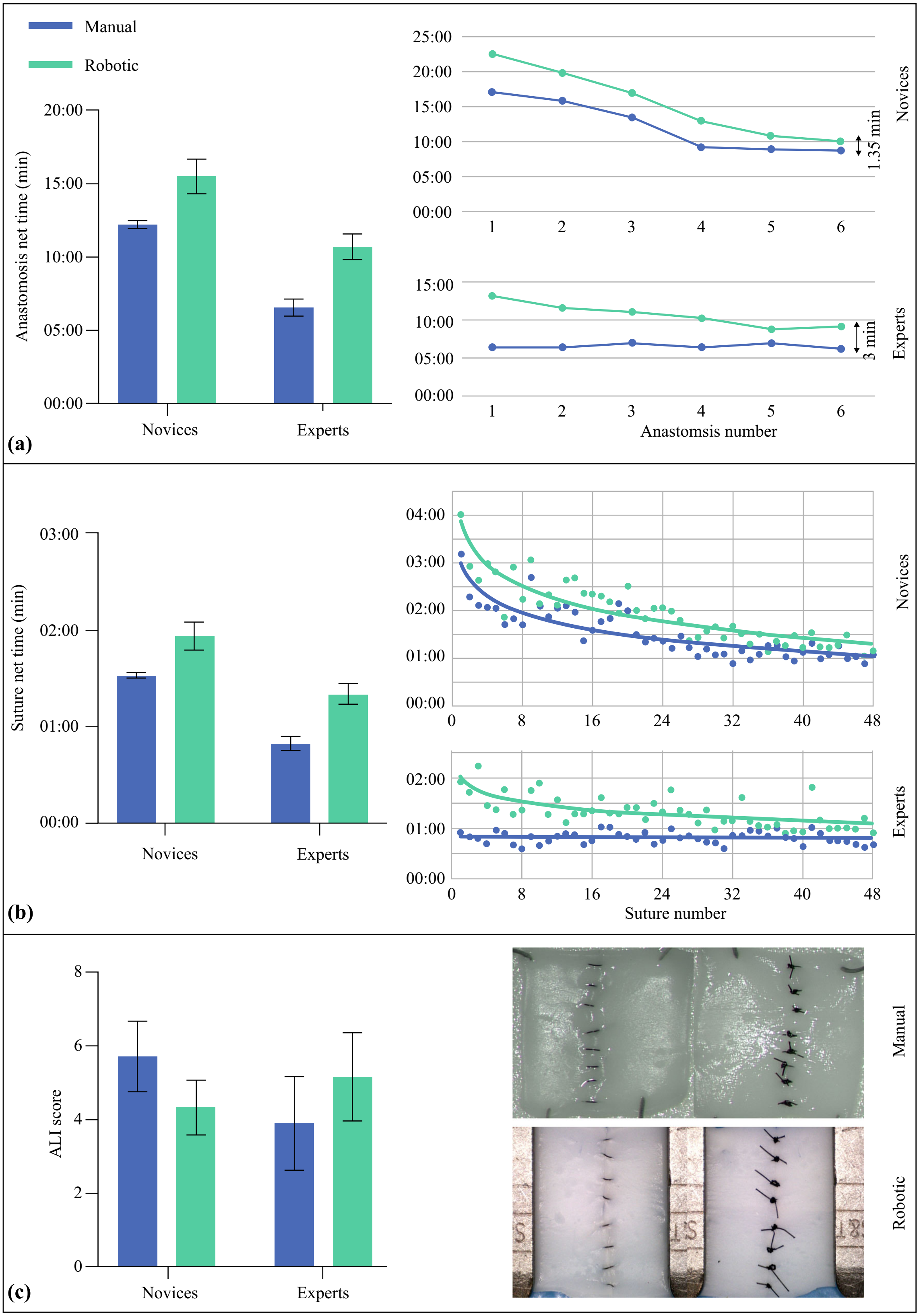
After a brief adaptation training of the surgeons to the robotic system, the needle passage test was performed. This test assessed distance between entry and exit needle passage as well as the angle of needle passage. Fig 3a shows two representative images of this test where values of distances (a, b) and angles (α) are indicated. Mean values for novices and expert microsurgeons are represented in Fig 3b, showing differences in distances at the point of entry and exit of the needle with respect to the edge of the tissue (Δ = a−b), as well as the values of the incident angles (α).

For all users the mean values of the difference between entry and exit needle passage were 0.22 ± 0.02mm for the manual technique and 0.17 ± 0.02mm for the robotic one (Fig 3b). The two-way ANOVA showed that robotic needle passage improved precision (p = 0.02), with no significant interaction between experience level. Interestingly, a novice achieved the best result with a difference of entry and exit needle passage of only 0.01mm using the Symani robot.

Regarding angles of incidence in needle passage (Fig 3b right), the mean values for all users were 10.16 ± 0.97° for the manual technique and 6.37 ± 0.64° with the use of the robot. The angles of needle passage ranged from 1.01° (the best value achieved by an expert microsurgeon using the Symani robot) to 23.63° (performed by a novice using the manual technique). Overall, on both manual and robotic, novice users had lower performance than experts ($p < 0.01$). Interestingly, novices using the robot improved performance compared to the manual technique ($p < 0.01$). Expert microsurgeons also obtained better values with the robot, but the differences were not significant (p = 0.5).

Anastomosis Test

The time needed to complete each of the twelve anastomoses (six with the robot, six with manual technique) per surgeon was tracked (Fig 4a). The mean anastomosis time for novices was 15 ± 1.18min with the robot and 12 ± 0.25min manually, which compares to 11 ± 0.87min with the robot and 6.5 ± 0.58min manually for expert microsurgeons. For both expert and novice microsurgeons, the time to perform an anastomosis with the robot decreased with practice. Novices improved times in both the robotic and manual procedures. However, the experts did not show


Manual
Robotic
Anastomosis net time (min)
20:00
15:00
10:00
05:00
00:00
Novices
Experts
25:00
1.35 min
3 min
1
2
3
4
5
6
Anastomsis number
(a)
Suture net time (min)
03:00
02:00
01:00
04:00
0
8
16
24
32
40
48
Suture number
(b)
ALI score
8
6
4
2
0
(c)

◀**FIG. 4.** Anastomosis test. **a** Anastomosis net times for novices and expert microsurgeons: comparision of means on the left, and net anastomosis time curves on the right. **b** Suture net times for novices and expert microsurgeons: Mean values on the left, curves showing manual and robotic suturing times on the right. **c** Results of anastomosis lapse index (ALI) assessment for the anastomoses performed by novices and experts using manual and robotic techniques; on the right, representative images of internal and external view of the manual (top) and robotic (bottom) anastomosis.

The robot is a flexible platform that uses the principles of teleoperation to provide surgeons with high precision and dexterity in manipulation of very small anatomy such as microvessels, peripheral nerves, and lymphatics. The console can be positioned at the patient bedside and is used together with a surgical microscope or a heads-up 3D microscopic visualization system. This setup enhances the surgeon's postural ergonomics while working in submillimetric anatomical structures. Compared to the other commercially available microsurgery-specific robot,[24] this system uses specifically designed articulated microinstruments which are mounted on two robotic arms moved by the master with fine precision over any anatomical region.

Microsurgery is one of the most technically demanding surgical subspecialties. Human capabilities are limited in precision and accuracy owing to physical tremor,[29] human fatigue, and the difficulty in handling tools in extremely confined spaces. In difficult depth surgical approaches and lower sidewall angles, robot-assisted surgery has demonstrated shorter surgery times and higher comfort for the surgeon.[30] Additionally, robotic platforms have proven to aid in overcoming existing limits of manual technique by filtering out tremor and by incorporating motion scaling.[31] In this sense, the innovative design of the Symani robot allows movements of greater angulation than the human hand. The size of the small wristed microsurgical instruments allow for an unobstructed view of the target anatomy, since the nanowrist needle holder and dilator measure 3mm in diameter. These instruments allow proper handling of very small caliber sutures such as the 10/0 used in this study, but they can also actuate smaller sutures such as 12/0, thus facilitating supermicrosurgery. In addition, the system features 7-20X motion scaling with tremor filtration. Combined with specific microinstruments, this motion scaling enhances surgeons' dexterity while performing precise micromovements.

This study demonstrated the performance of the Symani robot to be equivalent or superior to the manual technique. In the needle passage test, Symani obtained greater precision in stitch placement compared to the manual execution ($p = 0.02$), with smaller distance differences between the entry and exit points with respect to the cut. Regarding accuracy on the angulation of the needle entrance in the tissue, the performance was superior in the novices who used the robot compared to the manual technique ($p < 0.01$). Notably, even expert microsurgeons obtained better values with the robot, although these were not statistically significant.

Similarly to the results obtained by van Mulken et al.,[23] the robotic-assisted microsurgery anastomoses on synthetic vessels demanded more surgical time compared with conventional microsurgery technique. The learning curves of novices were steep for both manual and robotic procedures. The technical aspects of robotic microsurgery can be gained by learners with no prior microsurgery or robotic experience[32], novices can even learn robotic microsurgery more quickly than open microsurgery, thus, robotics may have implications for training and democratization of microsurgery. On the other hand, expert microsurgeons' learning curves were approximately constant across manual anastomoses while robotic suturing times significantly decreased with practice. Both expert and novice microsurgeons reduced the net time to perform the anastomoses as well as the time to execute each individual suture with robotic practice. This suggests that after overcoming the learning curve, the times may be even more similar between the robotic and the conventional manual techniques. That said, completion time is not a key parameter for anastomotic success.[33] Long-term patency, which was not measurable in this bench test study, is used to assess anastomic success. Patency is directly related to optimal stitch suturing monitored in the needle passage test and by the objective assessment method used[34].

The quality of the anastomotic sutures was objectively assessed using the ALI score.[28] The superiority of robotic performances compared to the manual technique was observed on novice users although it was not significant. On the other hand, expert microsurgeons obtained better results with manual sutures, which is not surprising given their years of experience with manual technique and the few hours of training received with the robotic device.

The need for objective performance evaluation and for standardizing training methods for surgeons has become paramount, given the increasing application of microsurgery and in particular robotic-assisted microsurgery.[10,35] This study used synthetic validation methods, replacing the use of animals in research in accordance with the principles of the three Rs, with current legislation in Europe (Directive 2010/63/EU), and following recommendations of Institutional Animal Care and Use Committees worldwide.[36] The bench tests presented herein have shown to be effective in improving both novices and microsurgeons' ability in using Symani. As a result, these bench tests should be considered key components of the training program for this robot. Indeed, such structured training allows surgeons to gain experience in microsurgery using synthetic models before moving onto animal models, thus reducing the use of animals in research and training, as required by international agencies for the development of healthcare equipment. Despite several benefits, the use of synthetic models, which negate assessment of vessel patency, bleeding, and thrombosis, is a limitation of this study. Therefore, the next step to validate the Symani robot is the development of animal studies under Good Laboratory Practice (GLP) regulation, a quality system to ensure uniformity, consistency, reliability and reproducibility of biomedical research.

CONCLUSION

Microsurgery suturing and anastomosis performance on silicone microvessels is feasible using the Symani robotic surgical system. The new robot significantly improved the precision of suturing despite requiring a longer time to perform the anastomoses compared to the conventional technique. High precision and quality of microsuturing are clinically relevant parameters. Therefore, it represents encouraging preclinical results. Further validation in preclinical and clinical studies is warranted.

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DISCLOSURES The authors declare no conflicts of interest.

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