

ACE BRIEF FOR NEW AND EMERGING HEALTH TECHNOLOGIES

Symani surgical system for open microsurgery

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Summary of Key Points

- Microsurgery on small anatomical structures is performed under magnification using specialised micro-instruments. Successful microsurgery depends on high precision equipment and requires fine motor skills and dexterity, which is technically and physically demanding.
- The Symani Surgical System (Medical Microinstruments) is robotic-assisted microsurgical equipment capable of precise soft tissue manipulation to perform anastomosis, suturing and ligation microsurgeries on blood vessels, nerves and lymphatic ducts.
- Symani was granted FDA De Novo clearance in April 2024 and registered with Health Sciences Authority (HSA) in April 2025.
- The key evidence base comprises eight studies – three comparative studies (Symani-assisted open microsurgery versus conventional manual hand-sewn microsurgery), and five single-arm studies. One qualitative study on surgeon experience was included as supplementary evidence.
- Overall, based on mostly small single-arm studies, Symani was found to be likely safe and effective in performing microsurgery:
 - Device failures due to technical faults (6.7%) and software issues (10%) were reported in one study.
 - Based on three comparative studies, anastomosis time was generally longer with Symani-assisted microsurgery (range 25.3 to 41.7 mins) compared with conventional hand-sewn microsurgery (range 11.8 to 14.1 mins), except one study on smaller vessels (<1mm in diameter) which showed comparable anastomosis time (11.5-17.3 mins versus 10.2-16.1 mins).
 - Rates of revision surgeries ranged from 2% to 12% for Symani-assisted microsurgery, with the same rate of 6.6% reported for both microsurgery arms in one comparative study.
 - Flap loss rates for Symani-assisted microsurgery ranged from 1.1% to 4.3% for complete loss, and 1.4% to 4.3% for partial loss, with the same rate of 3.3% reported for both microsurgery arms in one comparative study.
 - Intraoperative anastomotic patency was achieved in 95.7% to 100% of Symani-assisted surgical cases, and conversion to conventional microsurgeries ranged from 1.1% to 10%.
 - The learning curve was steep, with proficiency in using Symani reported to be reached between the 10th to 22nd cases.
- The main limitations of the evidence pool are limited comparative evidence and lack of patient-relevant outcomes such as quality of life and functional recovery. Most studies were small single-armed studies, performed in one or few specialised centres and by experienced microsurgeons, which may limit generalisability to wider settings of staff experience.

- No economic evidence was identified. The estimated cost of the Symani system is €900,000 (SGD\$1.35 million). In Singapore, rental and purchase plans for Symani are available, no local pricing information was available to ACE at time of evaluation.
- Key implementation considerations include the need for training and certification of surgeons and assistants, infrastructure planning and optimisation of intraoperative workflow, and cost considerations including capital cost, on-going maintenance and consumables use.
- Seven ongoing clinical trials were identified, with expected completion date from end 2025 to year 2030, but they are unlikely to address the evidence gaps of comparative trials.
- Several other microsurgery robotic systems are in development.
- There is a local clinical need for the robot's technical advantage in supermicrosurgery and anatomically constrained regions, precision, tremor elimination and ergonomics, and to enable more surgeons to perform microsurgery with training. Active engagement with the manufacturer to deploy Symani in a local public healthcare institution (SKG) is in progress.

I. Background

Microsurgery refers to surgical techniques performed under magnification using specialised micro-instruments on small anatomical structures such as blood vessels, nerves and lymphatic vessels that typically range from 1 to 3 mm in diameter. Advancements in the field have extended to supermicrosurgery, which can be performed on very small structures less than 0.8 mm in diameter.⁽¹⁾

Microsurgical techniques are used for reconstruction across a range of surgical fields, from reconstructive microsurgery following trauma in emergency settings, to facilitating lymphatic drainage in the treatment of lymphoedema, and plastic surgeries. Successful microsurgery depends on high precision and specialised micro-instruments such as forceps with 0.1 mm diameter tips, finer suture materials, and optical magnification devices such as operating microscopes or exoscopes. Microsurgery also requires the clinician to have fine motor skills and dexterity, which is technically and physically demanding.⁽¹⁾

Over the past two decades, the use of robotic systems in surgery has expanded, including in the field of microsurgery. Robotic-assisted microsurgical systems offer enhanced precision, motion scaling, tremor filtration and visualisation. They are also designed to improve ergonomics and to reduce surgeon fatigue during operations. However, a major drawback for the equipment is the lack of haptic feedback when using joysticks to manoeuvre. Training is therefore required for surgeons to become proficient in the use of this technology.^(1, 2)

II. Technology

The Symani Surgical System (Medical Microinstruments; hereafter referred to as Symani) is robotic-assisted microsurgical equipment, capable of soft tissue manipulation to perform anastomosis, suturing and ligation microsurgery techniques on small anatomical structures, including blood vessels, nerves and lymphatic ducts. The robotic system is intended for use during open microsurgical procedures when a motion scaling function is deemed appropriate by the surgeon.⁽³⁾

Symani is teleoperated and used in combination with conventional surgical microscopes, either optical or digital.⁽⁴⁾ The system consists of two robotic arms (NanoWrist) on which micro-instruments of a few millimetres in size can be attached. The articulated wrist features seven degrees of freedom that match the human wrist, seven to 20 times motion scaling, and tremor filtration, ultimately increasing precision and control. The surgeon operates from a remote console consisting of a chair, two joysticks and a foot switch for activating different operating modalities (Figure 1).⁽⁵⁾

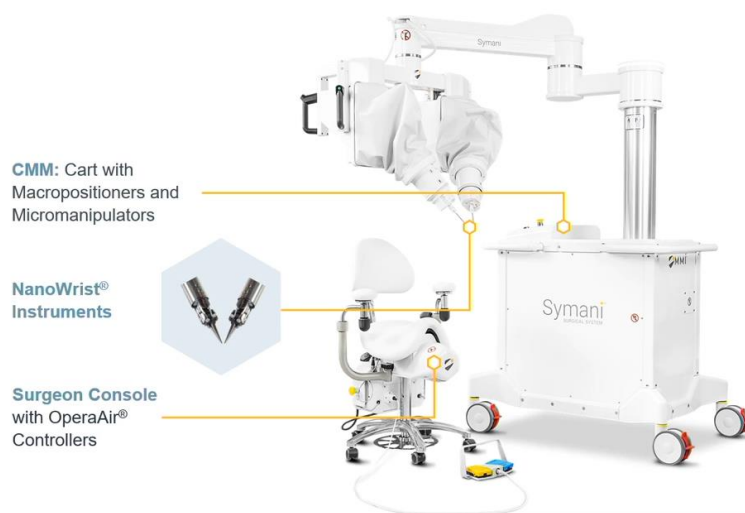


Figure 1 Overview of Symani Surgical System (Medical Microinstruments, Inc., Wilmington, Delaware, US)

Image from: <https://www.mmimicro.com/our-technology/symani-surgical-system/>

III. Regulatory and Subsidy Status

Symani is the only United States (US) Food and Drug Administration (FDA)-approved open microsurgery robot. It was granted De Novo clearance in April 2024⁽⁴⁾ and 510(k) clearances in 2025.⁽⁶⁻⁸⁾ In the US, Symani is indicated for dissection of soft tissues, and for anastomosis, suturing, and ligation microsurgery techniques on small blood vessels and lymphatic ducts between 0.1 and 2.5 mm in open free-flap surgery of the breast, mouth, scalp, and extremities, and in open lymphatic surgery of the extremities.⁽⁴⁾ It can only be used in adult patients.

Symani obtained Singapore Health Sciences Authority (HSA) registration in April 2025. Unlike the US registration, in Singapore, Symani can be for surgery in adult and paediatric patients. This broader indication for use in Singapore (and Europe) allows microsurgical soft tissue manipulation on small anatomical structures, including blood vessels, lymphatic ducts, and

nerves in open surgery procedures. However, the system is not intended for use on the heart, central circulatory system, or central nervous system.⁽³⁾

Symani is not used in public healthcare institutions in Singapore.

IV. Stage of Development in Singapore

- | | |
|---|--|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Investigational / Experimental (subject of clinical trials or deviate from standard practice and not routinely used) | <input type="checkbox"/> Established <i>but</i> modification in indication or technique |
| <input type="checkbox"/> Nearly established | <input type="checkbox"/> Established <i>but</i> should consider for reassessment (due to perceived no/low value) |

Sengkang General Hospital is currently in active collaboration with Medical Microinstruments Inc. for the deployment and clinical development of the Symani microsurgical platform. This partnership encompasses surgical training, credentialing, intraoperative workflow optimisation, and prospective data collection (Personal Communication, Senior Consultant, Plastic Surgeon, Singapore General Hospital, March 2026).

V. Treatment Pathway

In Singapore, patients requiring open microsurgical procedures, such as anastomosis, currently undergo conventional operations without robot assistance. Symani-assisted open microsurgery may be an alternative option to conventional manual hand-sewn techniques. Based on best available information at the time of evaluation, there are no clinical practice guidelines that outline clinical considerations or help guide when to choose robot-assisted microsurgeries over conventional techniques. Choice may be based on factors such as availability of robots, clinician preference, institutional practices and cost. Should a Symani-assisted microsurgery fail, surgeons will need to convert to conventional manual surgery.^(9, 10) Refer to treatment pathway in Appendix A.

Local clinicians confirmed that the treatment pathway reflects the proposed place of Symani in open microsurgical procedures. They highlighted the potential role of Symani particularly in supermicrosurgeries which are difficult to perform without robotic assistance. Additionally, a clinician opined that a robot-assisted system will likely replace all instances of conventional hand-sewn anastomosis over time. However, surgeons still need to be proficient in conventional operations, as robots can break down or malfunction during surgery (Personal communication, Head and Senior Consultant, Plastic Surgeon, Changi General Hospital, November 2025).

VI. Summary of Evidence

The assessment was conducted based on the Population, Intervention, Comparator and Outcome (PICO) criteria listed in Table 1. Literature searches were conducted in relevant

international health technology assessment (HTA) databases, Cochrane Library, PubMed and Embase.

Table 1: PICO criteria

Population	Patients undergoing open microsurgical procedures of the blood vessels, nerves and lymphatic ducts
Intervention	Symani Surgical System assisted open microsurgery
Comparator	Conventional open microsurgery without robot assistance
Outcome	<p>Safety: adverse events (e.g. thrombosis, infection)</p> <p>Clinical effectiveness: percentage of procedural success (e.g. viable flap, flap loss, re-exploration of anastomosis), operation or anastomosis time, length of hospital stay, postoperative physical functioning, pain, health-related quality of life, patient satisfaction</p> <p>Cost effectiveness: cost, incremental cost-effectiveness ratio</p> <p>Others: surgeon's experience (e.g. comfort, control, eliminated tremors, enhanced precision) and learning curve</p>

The key evidence base consists of eight studies, which included i) three comparative studies, comparing Symani-assisted open microsurgery with conventional manual hand-sewn surgeries,⁽¹¹⁻¹³⁾ and ii) five single-arm studies, ranging from 22 to 100 microsurgery or supermicrosurgery cases.^(9, 10, 14-16) One qualitative study included as supplementary evidence, reported on user experience from 13 European microsurgical centres, including more than 900 clinical cases of robotic-assisted microsurgeries using Symani and MUSA-2 microsurgical robot (Microsure B.V., Eindhoven, Netherlands).⁽¹⁷⁾

The evidence base, inclusion and exclusion criteria are listed in Table B1 (Appendix B), while the study design and characteristics of the included studies are presented in Table B2 (Appendix B). Note that two studies included patients undergoing supermicrosurgeries, with Dastagir et al. (2024) assessing the effects of Symani in vessels <1mm in diameter.^(11, 14) Of the three comparative studies, only Dastagir et al. (2024) matched patients using clinical and patient characteristics.⁽¹¹⁾ Tolksdorf et al. (2024) compared robotic-assisted surgeries with conventional surgeries that were performed at the same time in another room, or when patients refused robotic surgery.⁽¹²⁾ The third study Barbon et al. (2022) did not report details on how the two study arms were chosen.⁽¹³⁾

Safety

Adverse events were reported for Symani-assisted microsurgeries only. One study reported device failures due to technical faults (6.7%) and software issues (10%). They also reported one case (3.3%) of lacerated arterial anastomosis, which occurred when a surgeon's rapid movement caused the master console and robot to desynchronise.⁽¹²⁾

Other adverse events from microsurgery include thrombosis (3.1% to 8%),^(9, 10, 13) haematoma (1% to 2%),^(10, 16) wound complications (2-5%),^(10, 16) and infection (6.4%)⁽¹⁶⁾. Death of two patients (2%) was reported in one study, but was not related to the use of Symani.⁽¹⁶⁾

Table 2: Summary of adverse events in Symani-assisted microsurgeries

Studies (N ^a)	Device failures	Thrombosis	Haematoma	Wound complications	Others
Dastagir et al. (2024) ⁽¹¹⁾	0/31 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)

(n=31 anastomoses)					
Gorji et al. (2024) ⁽⁹⁾ (n=23)	NR	1/23 (4.3%)	NR	NR	-
Struebing et al. (2024) ⁽¹⁰⁾ (n=100)	NR	8/100 (8%)	2/100 (2%)	<ul style="list-style-type: none"> Wound breakdown: 2/100 (2%) Delayed wound healing: 5/100 (5%) 	-
Tolksdorf et al. (2024) ⁽¹²⁾ (n=30)	<ul style="list-style-type: none"> Technical faults: 2/30 (6.7%) Software issues: 3/30 (10%) 	NR	NR	NR	Lacerated arterial anastomosis: 1/30 (3.3%)
von Reibnitz et al. (2024) ⁽¹⁶⁾ (n=100)	NR	NR	1/100 (1%)	Wound dehiscence: 3/100 (3%)	<ul style="list-style-type: none"> Infections: 6/100 (6.4%) Death, not related to use of Symani: 2/100 (2%)
Barbon et al. (2022) ⁽¹³⁾ (n=32 anastomoses)	NR	1/32 (3.1%)	NR	NR	<ul style="list-style-type: none"> Seroma formation: 4/32 (12.5%)
Abbreviations: NR, not reported					
Notes:					
^a n= number of surgical cases, unless otherwise stated					

Effectiveness

Anastomosis time and learning curve

Of the three comparative studies, two found that anastomosis time was significantly longer using Symani as compared to a conventional hand-sewn technique (Table 3). In Tolksdorf et al. (2024), mean arterial and venous anastomosis time using Symani were 32.5 and 41.7 minutes, respectively, compared to 11.8 and 13.4 minutes for conventional hand-sewn surgery.⁽¹²⁾ Six microsurgeons were involved in this study.⁽¹²⁾ In Barbon et al. (2022), all lympho-venous, arterial, and lympho-lymphatic microsurgeries were performed by one surgeon.⁽¹³⁾ The authors reported a mean anastomosis time of 25.3 minutes with Symani compared to 14.1 minutes in hand-sewn surgeries.⁽¹³⁾

In contrast, in the comparative study by Dastagir et al. (2024) with microsurgeries performed on smaller vessels (<1mm in diameter), the authors found that arterial and venous

anastomosis timing was comparable between Symani and hand-sewn surgery by an experienced microsurgeon, ranging from 10.2 to 17.3 minutes.⁽¹¹⁾

Table 3: Mean anastomosis time with Symani-assisted microsurgeries compared with hand-sewn microsurgeries

Study	Anastomosis type (n)	Mean anastomosis time (SD)		
		Symani (n)	Hand-sewn (n)	P value
Dastagir et al. (2024) ⁽¹¹⁾	Arterial (n=33)	17.3 ± 1.9 min (n=15)	16.1 ± 1.4 min (n=18)	P = 0.0883
	Venous (n=29)	11.5 ± 1.3 min (n=16)	10.2 ± 1.8 min (n=13)	P = 0.0972
Tolksdorf et al. (2024) ⁽¹²⁾	Arterial (n=64)	32.5 ± 10.6 min (n=30)	11.8 ± 3.6 min (n=34)	P < 0.001
	Venous (n=63)	41.7 ± 15.2 min (n=29)	13.4 ± 3.8 min (n=34)	P < 0.001
Barbon et al. (2022) ⁽¹³⁾	Lympho-venous, arterial, lympho-lymphatic (n=43)	25.3 ± 12.3 min (n=32)	14.1 ± 4.3 min (n=11)	P < 0.01

Other single-arm studies performing robot-assisted arterial and venous anastomosis reported timings more in line with Tolksdorf et al. (2024), ranging from 20 mins to 60 mins for Symani-assisted surgeries, and acknowledged the steep learning curve.^(9, 10, 15) Many studies reported that surgical times decreased as the number of robotic-assisted surgeries increased, surgeons gained experience and staff become more familiar with the setup of the Symani machine (refer Appendix C).^(9, 11, 13-15) Proficiency was reportedly reached by the 10th to 22nd cases,^(11, 13, 14) with the most substantial technical progress within the first eight cases.⁽¹⁴⁾

Other effectiveness outcomes

Across the evidence base, procedural success was measured as anastomotic patency, need for revision surgeries, conversion to conventional microsurgeries, and flap loss rates for free flap surgeries (refer to Table 4). Of the three comparative studies, only Tolksdorf et al. (2024) reported the comparative rates in both arms. Revision surgeries (6.6%) and flap loss rates (3.3%) were the same for both the Symani-assisted and hand-sewn surgery arms.⁽¹²⁾

Overall, revision surgeries rates ranged from 2% to 12%,^(9, 10, 12, 15, 16) due to adverse events including thrombosis, haematoma and wound complications. In one study, seven cases (7.5%) required re-suturing of anastomosis to be performed during the operation⁽¹⁵⁾ Conversion from Symani-assisted to conventional microsurgeries ranged from 1.1% to 10%,^(9, 10, 12, 15) due to intraoperative complications, including restricted access with robots, technical faults and software issues.

Four studies reported low flap loss rates, ranging from 1.1% to 4.3% for complete loss,^(9, 10, 12, 15) and 1.4% to 4.3% for partial loss.^(9, 10) Reasons for flap loss were due to adverse events of microsurgery, such as thrombosis.

Intraoperative anastomotic patency was generally acceptable, reported as 95.7% to 100% using the Symani robot.^(9, 11, 13, 14) In von Reibnitz et al. (2024), 86% of patients (6/7) with lymphedema or central lymphatic disorder experienced volume reduction in upper extremities, with a mean volume difference of -281 ml (-7.6% compared to initial limb volume) at a mean follow-up of 10.1 months. Volume reduction in lower extremities was reported in 72% of patients (23/32), with a mean volume difference of -288 ml (-1.4%) at a mean follow-up of 10.1 months.⁽¹⁶⁾

Table 4: Summary of effectiveness outcomes

Studies (N ^a)	Revisions	Conversion to conventional surgery	Flap loss	Anastomotic patency
Comparative studies				
Dastagir et al. (2024) ⁽¹¹⁾ (I: n=31 anastomoses; C:n=31 anastomoses)	NR	NR	NA	I: 31/31 (100%) C: NR
Tolksdorf et al. (2024) ⁽¹²⁾ (I: n=30; C:n=30)	I: 2/30 (6.6%) C: 2/30 (6.6%)	3/30 (10%)	I: 1/30 (3.3%) C: 1/30 (3.3%)	NR
Barbon et al. (2022) ⁽¹³⁾ (I: n=32 anastomoses; C:n=11 anastomoses)	NR	NR	NR	I: Numbers not reported (97.5%) C: NR
Single-arm studies				
Chen et al. (2025) ⁽¹⁴⁾ (n=22)	NR	NR	NA	22/22 (100%)
Spille et al. (2025) ⁽¹⁵⁾ (n=93)	<ul style="list-style-type: none"> Revision surgery: 3/93 (3.2%) Re-suturing of anastomosis: 7/93 (7.5%) 	1/93 (1.1%)	1.1% (1/93)	NR
Gorji et al. (2024) ⁽⁹⁾ (n=23)	2/23 (8.7%)	1/23 (4.3%)	<ul style="list-style-type: none"> Flap loss: 1/23 (4.3%) Partial flap necrosis (<5% total flap surface area): 1/23 (4.3%) 	22/23 (95.7%)
Struebing et al. (2024) ⁽¹⁰⁾ (n=100)	12/100 (12%)	3% (3/100)	<ul style="list-style-type: none"> Complete flap loss: 2/73 in free flap group (2.7%) Partial flap loss: 1/73 in free flap group (1.4%) 	NR
von Reibnitz et al. (2024) ⁽¹⁶⁾ (n=100)	2/100 (2%)	NR	NA	Infections: 6/100 (6.4% of all surgical sites)
Abbreviation: C, comparator (conventional hand-sewn microsurgery); I, intervention (Symani-assisted microsurgery); NA, not applicable; NR, not reported Notes: ^a n= number of surgical cases, unless otherwise stated				

Surgeon's experience

Authors of most studies acknowledged that Symani microsurgical robot enhanced precision, eliminated tremors with increased degrees of freedom,^(9, 10, 12-14, 16) and also reduced surgeons' fatigue^(11, 14) with better ergonomics.^(9, 11, 16) However, some technical difficulties were reported, which included insufficient grip strength,^(10, 17) robotic parts becoming sticky from blood staining and adhering to sutures⁽¹³⁾ or excess soft tissues⁽⁹⁾. These became less of an issue with experience.

Gorji et al. (2024) assessed surgical performance using the modified Structured Assessment of Microsurgical Skills (SAMS) score and assessed surgeons' satisfaction using a questionnaire.⁽⁹⁾ The SAMS category score of "steadiness" was rated at the maximum score of five due to tremor elimination by the robot. Other SAMS scores were significantly higher for the last group of surgeries compared with the first, indicating an improvement in surgical experience (refer to Appendix D). Subjective satisfaction was equal or better with the robot-assisted surgery in most categories such as "intraoperative tremor", "freedom of movement", and "operative comfort", as compared to conventional microsurgery techniques (refer to Appendix E).⁽⁹⁾

Supplementary evidence included a consensus study by the European Federation of Societies for Microsurgery (EFSM), where a modified nominal group technique was applied to summarise the experiences of Symani and MUSA-2 users. Responses from 13 European microsurgical centres, with a combined experience of more than 900 clinical cases using either robot were presented. The top current indication for open robotic microsurgery was "lymphatic supermicrosurgery" which received 49% of votes and had 100% consensus. "Higher precision" was perceived as the top current benefit (43% of all votes, 100% consensus), followed by "tremor reduction" (34%) and "less fatigue" (15%).⁽¹⁷⁾

Cost or cost-effectiveness

No cost or cost-effectiveness studies for Symani were identified.

Key uncertainties

Most studies on Symani were single-armed, small case series, ranging from 22 to 100 cases. Surgeries were performed in a single or a few specialised centres and by experienced microsurgeons, meaning the findings may not be generalisable to other settings with a wider range of staff experience. Limited comparative data were available, mainly for anastomotic time. The included studies focused on procedural outcomes and not patient-relevant outcomes such as pain, patient satisfaction, postoperative physical functioning and health-related quality of life.

Another limitation is that cost or cost-effectiveness studies were not available. This information is needed to assess the true value of integrating Symani into local routine microsurgery.

Ongoing trials

Seven ongoing clinical trials were identified, with expected completion dates from the end of 2025 out to 2030. Some studies are expected to be conducted for new Symani indications, such as in transfixing keratoplasty, or for neurosurgical procedures in patients with

Moyamoya disease, but are unlikely to provide comparative data for currently approved indications.

Additionally, clinician shared that two multi-institutional clinical trials are currently conducted locally, focusing on the use of Symani for neurolymphatic surgery in Alzheimer’s disease and lymphovenous bypasses for treatment of normal pressure hydrocephalus shunt nonresponders (Personal communication, Senior Consultant, Plastic Surgeon, Singapore General Hospital, March 2026).

Table 5: Ongoing clinical trial

Study (Trial ID)	Population & estimated enrolment	Brief description	Estimated study completion date
PRIMO Post-Market Clinical Follow Up Study (NCT04843436)	Patients undergoing microsurgical reconstructions, n=429	Post-market, non-randomised, multicentre study to monitor the safety and performance of Symani in microsurgical reconstructive procedures in a real life setting.	December 2025
GRACE: Graft Robot-Assisted Corneal Enhancement (NCT06844123)	Patients undergoing penetrating keratoplasty, n=10	Microsurgical robot in <u>transfixing keratoplasty</u> in humans.	April 2027
REMIND: Robotic-Enabled Microsurgical Intervention for Neurodegenerative Disease (NCT07178210)	Patients with Alzheimer's disease and lymphatic obstruction, n=15	To evaluate the safety and feasibility of using the Symani System and microsurgical techniques in the deep cervical lymph nodes (dCLNs) in the setting of <u>mild to moderate Alzheimer's disease and lymphatic obstruction</u> .	June 2027
The Symani Restore Study (NCT07140731)	Adult patients with Moyamoya disease, n=15	Early feasibility study of Symani for neurosurgical procedure in adult patients with <u>Moyamoya disease</u> .	September 2027
REGEN: A Prospective, Randomized, Open Label Study to Expand the Use of Symani® Surgical System for Peripheral Nerve Repair (NCT07084207)	Patients with traumatic sensory nerve lesions of a finger nerve distal to the carpal tunnel who are treated with nerve suturing; n=100	To evaluate the Symani System's safety and effectiveness for <u>microsurgical nerve coaptation</u> , following nerve injuries to the hand.	March 2028
CONNECT: A multi-cohort, prospective investigation of the Symani® Surgical System (NCT06866197)	Patients undergoing microsurgical anastomosis, n=180	To evaluate the Symani System's safety and effectiveness for microsurgical anastomosis during <u>free tissue transfer surgery and lymphatic surgery</u> .	May 2028
PRIME: A Global, Prospective, Real-World, Investigation of the Symani® Surgical System for Microsurgical Anastomosis (NCT06628219)	Patients undergoing microsurgical anastomosis, n=1000	To evaluate the Symani System's safety and effectiveness for microsurgical anastomosis during <u>free tissue transfer surgery and lymphatic surgery</u> .	February 2030
Cervical Lymphatico-Venous Bypass for Treatment of Alzheimer's Disease - Proof of Concept Study (CLyVeB-AD-1 Study)	Patients with Alzheimer's disease, n=10	To assess safety and preliminary efficacy of deep cervical lymph node to venous bypass procedure with Symani in patients with <u>Alzheimer's disease</u> .	March 2030

Augmentation of Glymphatic Pathways via Lymphovenous Bypasses of the Head and Neck Region	Idiopathic normal pressure hydrocephalus shunt non-responders	NA	NA
Abbreviations: NA, not available			

Summary

Overall, evidence from mostly single-arm studies showed that Symani is likely safe and effective in performing microsurgery, with some reports of device failures due to device faults (6.7%) and software issues (10%). Evidence from three comparative studies showed that while anastomosis time under Symani-assisted microsurgery is likely to be longer compared to conventional hand-sewn surgery, except for one study on smaller vessels (<1mm in diameter). Performance in the setup and use of the system improved with user experience. For Symani-assisted microsurgeries, revision surgeries were reported in 2% to 12% and flap loss in 1.1% to 4.3%, with no evidence of differences between the groups reported in limited comparative data. Conversion to conventional microsurgery occurred in 1.1% to 10% of the cases, and intraoperative anastomotic patency was achieved in 95.7% to 100% of the cases. Subjective surgeon experience reports acknowledged that Symani enhanced precision, eliminated tremors, provided better ergonomics and reduced surgeons' fatigue.

However, current evidence was limited to mainly small single-arm studies without longer-term patient-relevant outcomes reported. Future studies should also evaluate the cost or cost-effectiveness of using Symani, compared with conventional non-robotic-assisted microsurgeries.

VII. Estimated Costs

According to overseas news media reports from 2020, the entire Symani system costs €900,000 (SGD\$1.35 million).⁽¹⁸⁾ However, this is unlikely to have included the cost of consumables such as drapes, and ongoing maintenance costs. Local clinicians confirmed that, in Singapore, rental and purchase plans for Symani are available (Personal communication, Head and Senior Consultant, Plastic Surgeon, Changi General Hospital, November 2025). However, no local pricing information was available to ACE at time of evaluation.

VIII. Implementation Considerations

Before Symani-assisted microsurgeries can be conducted, several implementation considerations would need to be addressed and factored into the decision for use.

First, training is crucial for the surgical team. For surgeons, training involves adapting to the absence of tactile feedback and mastering navigation within a virtual workspace. The operation team would also need to be trained in the intraoperative workflow, including installation of the system, sterility preparations and assistance during the surgery. Locally, training and certification by the robotic credentialing committee is required (Personal communication, Head and Senior Consultant, Plastic Surgeon, Changi General Hospital, November 2025).

Second, infrastructure and intraoperative workflow changes are needed to accommodate the Symani machine and workspace setup. Preinstallation planning will be required beforehand, to ensure that the platform fits in the operating room, and that existing infrastructure is able to take the weight of the machine (Personal communication, Head and Senior Consultants, Plastic Surgeon; Changi General Hospital, November 2025; Singapore General Hospital, March 2026). Overseas experience indicates that planned positioning of the Symani operating unit with the use of microscope or exoscope screens is crucial, to allow unimpeded movements within the room and to avoid the machine causing electromagnetic interference with other operating room equipment.^(19, 20) Assistance is also needed for pre-operative vessel preparation and positioning of the Symani arms to avoid surgical collisions and interference, and to assist the surgeon with tasks such as rinsing or cutting the sutures.^(11, 19)

Third, the capital cost of acquiring or renting the robot, ongoing consumables and maintenance costs can also be a significant hurdle. Institutions would also need to factor in training costs, operating room modifications and other associated costs. Surgical duration may be longer with the use of robots, which further increases operating room cost and requires prolonged anaesthesia for patients. While adoption of Symani may reduce cost of failed free flap procedures, prolonged hospital admissions, and societal cost of lymphedema mismanagement, local clinicians opined that the cost-effectiveness of Symani will need to be established alongside ways to optimise consumable costs (Personal communication, Head and Senior Consultant, Plastic Surgeon; Changi General Hospital, November 2025; Singapore General Hospital, March 2026).

IX. Concurrent Developments

Besides Symani, the MUSA-2 (Microsure B.V., Eindhoven, Netherlands) is another designated microsurgical robot currently used in Europe.^(1, 17) MUSA-2 has not received FDA approval, but has been CE marked since 2019. The next-generation MUSA-3 is now in development, and will supersede the older model, with planned FDA and CE-mark clearance.⁽²¹⁾

Compared with Symani, the MUSA utilises existing microsurgical instruments which can be connected to the robotic system via adapters. This allows for a more seamless integration with conventional microsurgery setup and may reduce waste and cost.⁽²¹⁾

Local clinicians opined that other microsurgical robots in development or use overseas include Japan's Sony robot (Personal communication, Head and Senior Consultant, Plastic Surgeon, Changi General Hospital, September 2024). A Japanese microsurgical robot with similar indications as Symani (F.MED) is likely to be in the process of obtaining Japan's regulatory approval.⁽²²⁾

X. Additional Information

According to a local clinician, Symani allows surgeons to perform anastomosis on very small vessels with great accuracy and without the need for intense sub-specialty training. Additionally, in Singapore, the number of surgeons currently able to perform supermicrosurgery is limited, and those who can often suffer from repetitive strain injury. The Symani platform allows a surgeon to perform supermicrosurgery, particularly for lymphatic

supermicrosurgery (with vessels ranging 0.3-0.8mm), with optimised ergonomics, reduced fatigue and strain. (Personal communication, Head and Senior Consultants, Plastic Surgeon; Changi General Hospital, November 2025; Singapore General Hospital, March 2026). Of note, early experience from SKH has demonstrated improved surgical precision through motion scaling and tremor filtration, reduced training requirements when compared to conventional supermicrosurgery, and better ergonomics while maintaining comparable clinical outcomes (Personal communication, Senior Consultant, Plastic Surgeon, Singapore General Hospital, March 2025).

Local clinicians opined that Symani platform expands the range of supermicrosurgery enabling sub-0.4mm vessel anastomoses not routinely performed by hand, whilst facilitating microsurgery in anatomically constrained or difficult-to-access regions. Given Symani's early development stage, they opined that it could be reasonable to consider clinical use only in selected tertiary centres with governance framework with prospective registries, defined credentialing pathways, and outcome monitoring to generate local outcome and cost-effectiveness data. (Personal communication, Senior Consultants and Consultants, Plastic Surgeon, Hand Surgeons and Neurosurgeons; Changi General Hospital, November 2025; Singapore General Hospital, March 2026; National University Hospital and National Neuroscience Institute; and March 2026).

According to the EFSM consensus study, European surgeons voted "remote microsurgery" as the top future indication (28%) for robotic-assisted microsurgery, followed by "enabling microsurgery for less experienced surgeon" (26%). They also voted "additional tools" as the most important next technological improvement (35%), followed by "smaller robots/ better handling" (28%), "integrated optics" (19%), and "more flexible instruments" (18%). The most valuable long-term goal for robotic microsurgery was "automation" (32%) followed by "reduction of invasiveness and morbidity" (29%) and "cost reduction" (24%).⁽¹⁷⁾

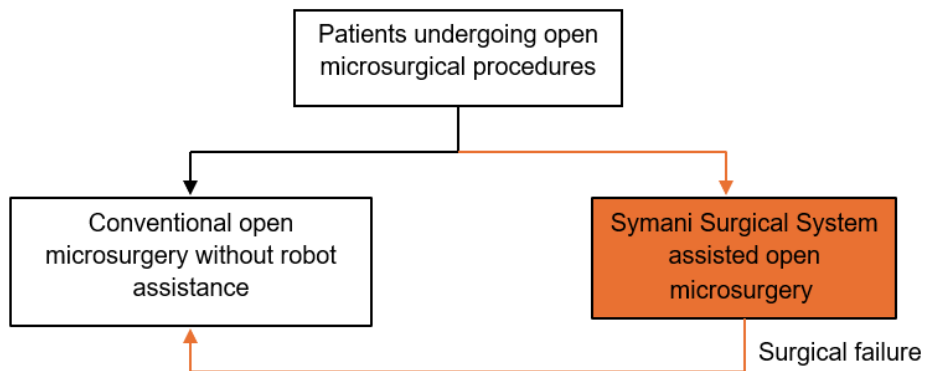
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Appendix

Appendix A: Proposed place of Symani Surgical System in the treatment pathway of open microsurgical procedures



Appendix B: Studies identified and study design

Table B1: List of included studies

Type of studies	Key evidence	Supplementary evidence
Comparative study	3	—
Single-arm study	5	—
Qualitative study	—	1
Note: 1. Inclusion criteria a. Studies that fulfil the PICO criteria listed in Table 1. 2. Exclusion criteria a. Studies only available in the abstract form, animal studies, pre-clinical studies. b. Case study or case series with less than 20 patients were excluded.		

Table B2: Study characteristics of key evidence base

Studies	Study design (N*), country	Surgical indication	Surgeon number and experience
Comparative studies (Symani compared with manual hand-sewn surgery)			
Dastagir et al. (2024) ⁽¹¹⁾	Comparative study I: 10 Symani-assisted cases (n=31 anastomoses) C: 11 manual hand-sewn cases (n=31 anastomoses) Germany	(Super-)microsurgery of blood vessels (<1mm) after hand trauma	One experienced microsurgeon
Tolksdorf et al. (2024) ⁽¹²⁾	Comparative study I: 30 Symani cases (n=59 anastomoses) C: 30 hand-sewn cases (n=68 anastomoses) Germany	Free flap surgery in cranio- and maxillofacial surgery	Six (3 males and 3 females)
Barbon et al. (2022) ⁽¹³⁾	Comparative study I: 22 Symani cases (n=32 anastomoses) C: Hand-sewn (n=11 anastomoses) Switzerland	Lymphatic reconstructive surgery, free flap reconstruction, or nerve coaptation	One experienced surgeon
Single-arm studies			
Chen et al. (2025) ⁽¹⁴⁾	Case series (n=22), NR	Lymph node-to-vein anastomosis supermicrosurgery	One (also the senior author of study)
Spille et al. (2025) ⁽¹⁵⁾	Prospective case series (n=93), Germany	Free flap reconstruction in head and neck region	Few experienced surgeons, numbers not reported
Gorji et al. (2024) ⁽⁹⁾	Case series (n=23), Germany	Free flaps for breast, extremity, and head reconstruction	Most cases were performed by the senior author. Total four surgeons.
Struebing et al. (2024) ⁽¹⁰⁾	Case series (n=100), Germany	Free flaps (73%), nerve surgery (20%), and lymphovenous anastomoses (6%)	Multiple surgeons, numbers not specified
von Reibnitz et al. (2024) ⁽¹⁶⁾	Case series (n=100), Switzerland	Lymphatic reconstruction with lymphatic tissue transfer and/or lymphovenous anastomoses /lympholymphatic anastomoses	Two surgeons
Abbreviations: C, comparator; I, intervention; NR, not reported Notes: N= number of surgical cases, unless otherwise stated			

Appendix C: Learning curves with Symani-assisted microsurgery

Figure C1: Learning curve from Dastagir 2024⁽¹¹⁾

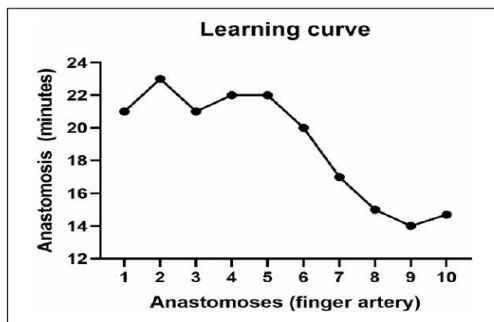


Figure showing that the first Symani-assisted surgery took 21 minutes, but this was reduced by 30% to 14.7 minutes in the 10th surgery. The average anastomosis time of the first five surgeries was 22 minutes, compared to 16 minutes for the last five ($p = 0.04$).

Figure C2: Learning curve from Barbon 2022⁽¹³⁾

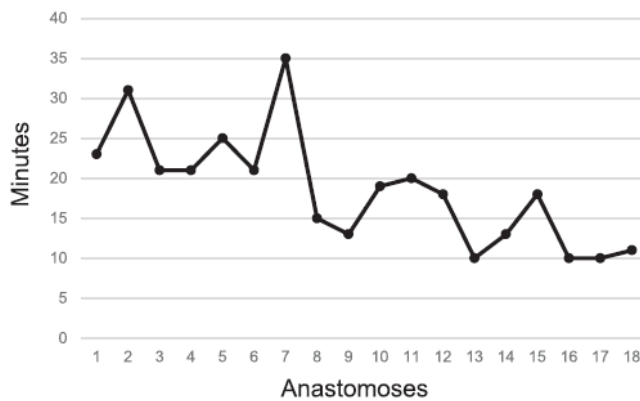


Figure showing the anastomosis time for 18 consecutive Symani-assisted surgeries, with significant decrease in last cases. Authors reported that last cases were reaching comparable times to hand-sewn anastomoses.

Figure C3: Learning curve from Gorji 2024⁽⁹⁾

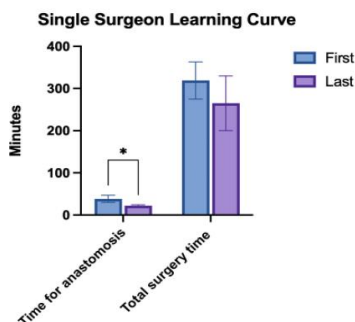


Figure showing average anastomosis time of 38.3 ± 8.6 mins for the first group of 4 cases and 22 ± 2.2 mins in the last group of 4 cases ($p < 0.05$). Despite the significant differences in anastomosis time between the groups and steep learning curve, the authors reported nearly similar times towards the end of the series.

Appendix D: Modified Structured Assessment of Microsurgical Skills (mSAMS) scores⁽⁹⁾

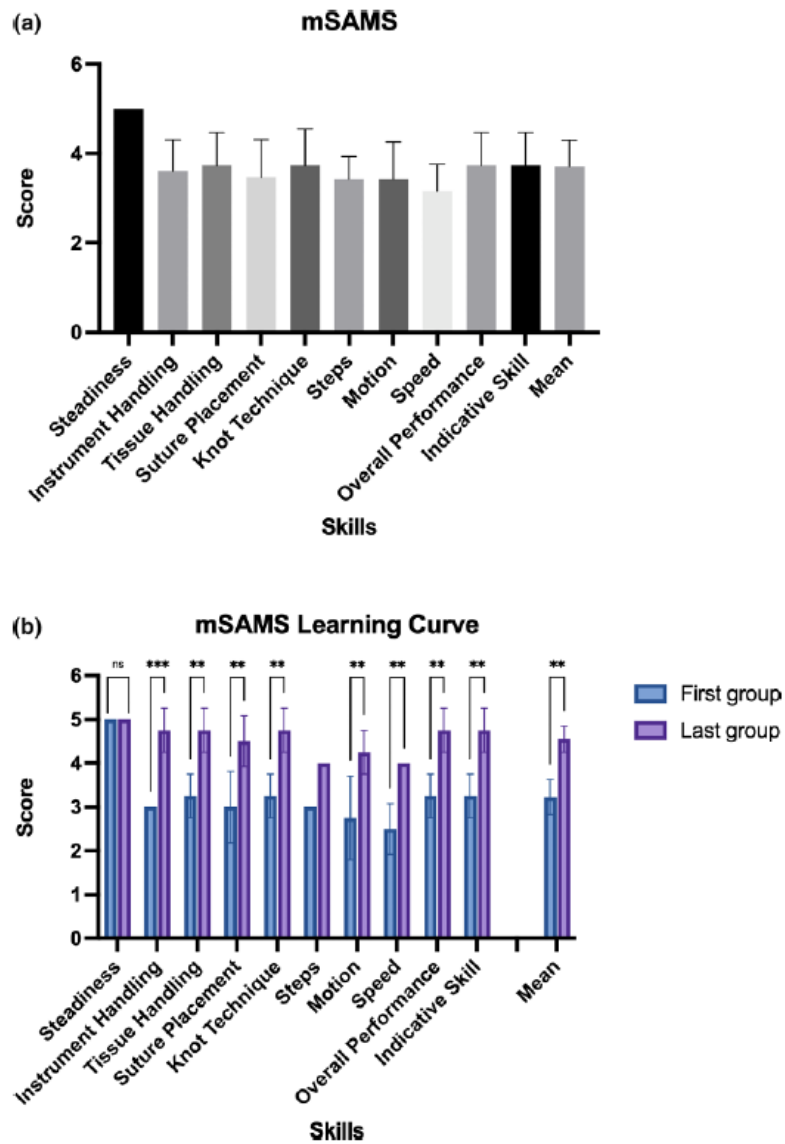
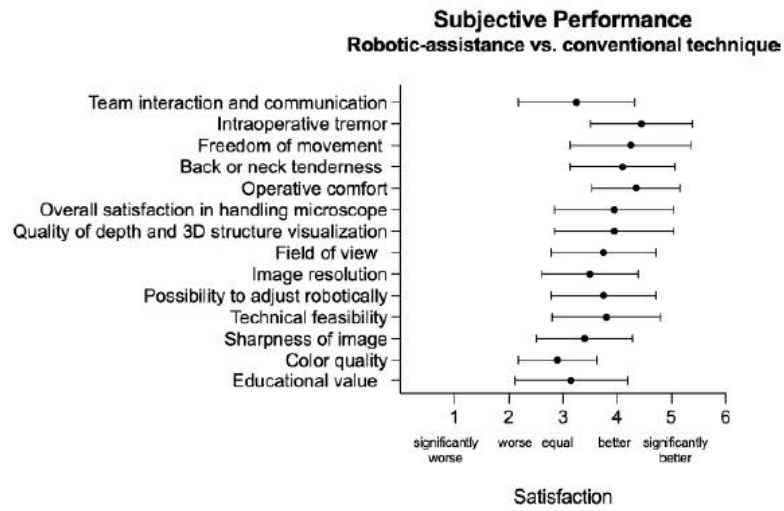


Figure showing (a) modified Structured Assessment of Microsurgical Skills (mSAMS) scores across different domains, ranging from a mean of 3.2 (speed) to 5 (steadiness). A higher score indicates better performance, with a maximum score of 5. Robot-assisted anastomoses were video recorded and blindly evaluated by an experienced microsurgeon according to the mSAMS. (b) Bar chart comparing the performance of the first and last group of robot-assisted anastomoses. Note: ns = not significant; ** $p < 0.01$; *** $p < 0.001$

Appendix E: Subjective performance of robotic-assisted versus conventional microsurgery techniques⁽⁹⁾



Dots represent individual values with mean and standard deviation shown for each category.