Robotics in cardiac surgery

A summary of its uses in mitral valve surgery and coronary artery revascularisation

AH Sepehripour Specialty Registrar

G Garas Specialty Registrar

T Athanasiou Consultant
Cardiothoracic Surgeon

R Casula Consultant
Cardiothoracic Surgeon

Imperial College London

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In the late 1990s cardiac surgery experienced the introduction of robotics. The early results were encouraging. Currently, robotic telemanipulation systems are used in two major fields of cardiac surgery: mitral valve surgery and coronary artery revascularisation. In this carefully selected patient cohort, the clinical outcomes have been outstanding, with excellent mitral valve repair rates, minimal need for coronary reintervention and a vanishingly low morbidity profile. Recent advances in the field of robotics have seen development in the concept of automation: robotic systems performing surgical procedures autonomously; as well as organ-mounted robots that assist in access to the organ, heart manipulation and compensation for heart tissue motion when operating on the beating heart.

There are, however, barriers to the widespread adoption of robotic cardiac procedures including cost, institutional infrastructure, technical challenge and the lack of recognised training programmes. The lack of a demonstrated superiority of robotic procedures over minimally invasive port-access mitral valve surgery and hybrid coronary revascularisation,

in addition to market influences in the diffusion of innovation, has resulted in a significant paucity of robotic procedures being done in the UK and Europe. Consequently, the future will most likely see a surge in the application of non-robotic minimally invasive procedures and developments in novel percutaneous transcatheter techniques.

Conception

In early May 1998, Carpentier *et al*¹ performed the first open heart surgery using computer-assisted instruments in Paris. They used early prototypes of the da Vinci[®] surgical system (Intuitive Surgical, Sunnyvale, CA), predominantly for its two main features: a stable, magnified, 3D view of the operating field, and the use of computer-assisted instruments with the same dexterity and range of motion as the hand. This pioneering group operated on a 52-year-old woman presenting with an aneurysm and a large defect of the atrial septum. The operation was successful and the patient made a good recovery. The report of the operation was not widely published at the time.

The same group performed a further five computer-assisted procedures

(mitral valve repairs) in 1998 and had consistently excellent results.² These procedures were carried out through 5cm incisions (fourth intercostal space). Operative time was on average 30–60% longer than for conventional open techniques. On average, between 60% and 75% of the procedure was robotically assisted.

In May 1998, Mohr and Falk of Leipzig performed additional robotically assisted mitral valve operations as near total endoscopic procedures.³ The same Leipzig group also carried out the first robotic coronary anastomosis, albeit through an open incision.⁴ In June 1998, the first totally endoscopic robotically assisted coronary artery bypass graft (CABG) was done by the Carpentier team in Paris.⁵ Two patients successfully underwent totally endoscopic left internal thoracic artery harvest and anastomosis to the left anterior descending artery. Around the same time, in Munich, Reichenspurner *et al*⁶ embarked on the first clinical use of the voice-controlled and computer-assisted ZEUS Robotic Surgical System (Computer Motion, Goleta, CA). They successfully completed totally endoscopic voice-controlled robotically assisted CABG in two patients, with positive outcomes. Falk *et al*⁷ used a voice-controlled robotic arm in eight patients undergoing mitral valve repair. They demonstrated similarly excellent outcomes.

Following these early experiences, Nifong *et al*⁸ conducted a US Food and Drug Administration (FDA) trial to investigate the safety and efficacy of robotic mitral valve repair. A group of 38 patients undergoing mitral valve repair using the da Vinci surgical system were studied. No mortality

or significant morbidity in the study was reported. Reductions in cardiopulmonary bypass (CPB) and aortic cross-clamp times in the latter half of the study demonstrated a progressive learning curve with the technique. The same group completed a multicentre trial of the safety of mitral valve repair using the da Vinci computerised telemanipulation system.⁹ A total of 112 patients underwent surgery with no conversion to median sternotomy, no 30-day mortality and a 5-year freedom from reoperation rate of 90%. Our group at St Mary's Hospital in London reported a series with mid-term outcomes from the first 100 patients in the UK to undergo robotically assisted minimally invasive direct CABG (MIDCAB) or totally endoscopic CABG (TECAB) on the beating heart, which remains the only da Vinci robotic clinical series in the UK.¹⁰ There are currently no randomised controlled trials (RCTs) or long-term data analysing the outcomes of robotic cardiac surgery.

Robots

Minimally invasive cardiac surgery has evolved through graded levels of difficulty, with increasingly smaller access and reliance on video assistance. Carpentier *et al*⁶ defined these levels of minimally invasive cardiac surgery (Table 1).

Table 1 Evolution levels of minimally invasive cardiac surgery

Level	Type
1	Mini incision (10–12cm) Direct vision
2	Micro incision (4–6cm) Video assisted
3	Micro incision (4–6cm) or port incision Video directed
4	Port incision – robotic instruments Video directed

Figure 1 a) The four motion axes possible with standard endoscopic instruments **b)** Robotic instruments allow for two additional degrees of freedom of motion in the form of a wrist at the tip of the instrument

In minimally invasive cardiac surgery, the ultimate aim is to perform surgery without compromising the integrity of the chest. Endoscopic access to the heart reduces trauma to the patient. It substantially complicates the surgical approach, however, requiring more sophisticated instruments with higher precision, dexterity and intuitive remote handling. Standard endoscopic instruments possess only four degrees of freedom of motion (four motion axes) whereas six degrees of freedom are required to allow an instrument free orientation in a 3D space (Fig 1). Using a fixed entry point (port), the operator is forced to 'reverse motion' because of the fulcrum effect. Motion transmission is also directly dependent on the ratio of internal and external instrument shaft length, which may lead to inaccurate scaling.¹¹ Higher handling forces are required to balance shear forces on the instrument shaft, leading to accelerated muscular fatigue in the operator and, fundamentally, a

Table 2 Cleveland Clinic strong and relative contraindications for robotic mitral valve surgery

Strong	Relative
Previous right thoracotomy	Previous sternotomy
Significant aortic root/ascending aortic dilation	Mild aortic stenosis or regurgitation
Moderate or severe aortic valve regurgitation	Reduced left ventricular function (ejection fraction < 50%)
Fixed pulmonary hypertension (> 60 mmHg)	Variable pulmonary hypertension (> 50 mmHg)
Right ventricular dysfunction	Limited peripheral arterial disease
Severe generalised peripheral arterial disease	Chest deformity (pectus/scoliosis)
Calcification of the aortic root/ascending aorta	Asymptomatic, mild coronary disease
Mitral annular calcification	Moderate pulmonary dysfunction
Myocardial infarction or ischaemia < 30 days	Asymptomatic cerebrovascular disease
Coronary artery disease requiring coronary artery bypass graft	
Severe pulmonary dysfunction	
Symptomatic cerebrovascular disease or stroke < 30 days	
Severe liver dysfunction	
Significant bleeding disorder	

non-linear force relationship.¹² During endoscopic surgery, there is almost inevitably a misalignment of the camera viewing angle and the instrument orientation. This creates a visuomotor incompatibility and significantly impairs the operator's cognitive and motor skills.^{13,14}

In their seminal work, *Computer-Integrated Surgery*, Taylor *et al*¹⁵ from Johns Hopkins and Massachusetts Institute of Technology (MIT) described the rationale of a partnership of complementary capabilities between surgeon and machine, highlighting the weaknesses and strengths of both. The initial generation of medical robots were in three major forms. The simplest forms were robots that were programmed to perform a precise task. Predominantly used in orthopaedic or neurosurgery,¹⁶ these image-guided machines would be programmed using preoperative

(or intraoperative) patient datasets and would execute a precise task. A more refined form of robot was the assisting device, used almost solely for position control of endoscopes during video assisted surgery. Simple speech commands allowed precise positioning of the scope, avoiding tremor and fatigue-induced image shift. The final form of the initial generation of medical robots worked on the concept of telemanipulation in a master-and-slave formation. These machines were in constant control by the operator, who was positioned at a remote input device (master), and the commands were executed by the manipulator (slave).

Current clinical practice

Mitral valve surgery

Gillinov *et al*,¹⁷ from the Cleveland Clinic, reported short-term outcomes in the first 1,000 patients undergoing robotic primary mitral valve

surgery. All but two patients (one mitral stenosis and one fibroelastoma) had severe mitral regurgitation. The aetiology of mitral regurgitation was predominantly degenerative (96%), with a small proportion of rheumatic, ischaemic and endocarditis. Isolated posterior leaflet prolapse was seen in 80%, isolated anterior leaflet prolapse in 2.5% and bileaflet prolapse in 17%. The operative strategy included femoral cannulation for CPB, aortic cross-clamping using the Chitwood clamp in 74% and endoaortic balloon occlusion in 26%. Access to the mitral valve was through a right mini-thoracotomy, through which the robotic arms were deployed. The da Vinci S™ and Si™ models were used. Concomitant procedures included ablation for atrial fibrillation in 7.2%, atrial septal defect (ASD) closure in 9% and tricuspid valve repair in 0.2%. Mitral valve repair rate was 99.5%.

After the first 200 cases, both CPB and aortic cross-clamp times stabilised at around 120 minutes and 80 minutes, respectively. The conversion rate to full or partial sternotomy was 2% and to mini-thoracotomy, 2.3%. The operative mortality rate was 0.1% and the stroke rate was 1.4%. PredischARGE echocardiography demonstrated the absence of more than mild mitral regurgitation in 97.9%. This study demonstrated the outstanding progress and immaculate results of robotic mitral valve surgery in a very high volume centre. The authors reported that the adoption of robotic mitral valve surgery has complemented their current techniques of full sternotomy, partial sternotomy or right mini-thoracotomy for mitral valve surgery. The addition of robotics has increased their armamentarium for

the treatment of mitral valve disease. A great part of the success of this robotics programme has been hypothesised to be related to the stringent selection process applied, an algorithm devised at the Cleveland Clinic to assess the suitability of patients for inclusion into the robotics programme (Fig 2, Table 2).

A larger series was reported by Murphy *et al* in Atlanta,¹⁸ with 1,257 consecutive patients undergoing robotic isolated mitral valve procedures using a more advanced totally endoscopic robotic approach. The patient cohort included those with significantly greater comorbidity than the Cleveland Clinic group, with a substantial number of the absolute exclusion criteria mentioned above not being applied in this study. Previous stroke was seen in 5.5%. New York Heart Association class IV symptoms were present in 13%. Left ventricular ejection fraction of less than 34% was seen in 5.1%. Pulmonary artery systolic pressures of greater than 50 mmHg were seen in 16.7%. Most significantly, 8.4% of the cohort had undergone previous cardiac surgery, 65.7% through sternotomy, 5.7% through right thoracotomy and 28.6% with previous robotic mitral valve surgery. The aetiology of mitral regurgitation was degenerative in 87.5% and rheumatic in 6.5% of the population. The operative strategy included femoral artery perfusion and endoaortic balloon occlusion as the preferred strategy in patients without peripheral arterial pathology. In those in whom retrograde femoral perfusion was deemed unsafe, ascending aortic cannulation through the right second intercostal space or axillary arterial cannulation were performed. Routine venous drainage was obtained through

Figure 2 Cleveland Clinic selection algorithm for robotic mitral valve surgery

AR = aortic regurgitation; CT = computed tomography; Echo = echocardiography; LV = left ventricular; mitral annular calcification; MAC = mitral annular calcification

femoral vein cannulation, either alone or in conjunction with right internal jugular venous cannulation. The totally endoscopic technique developed at Emory in Atlanta was termed the lateral endoscopic approach with robotics (LEAR) technique (Fig 3), using da Vinci S™ and Si™ models.

Concomitant procedures included tricuspid valve repair in 10.2%, closure of ASD in 13.8% and ablation for atrial fibrillation in 18.4%. Mean CPB and aortic cross-clamp times were 114 minutes and 82 minutes, respectively. The mitral valve repair rate was 93%. Ten procedures (0.2%) required conversion to median sternotomy. The operative mortality rate was 0.9% and the stroke rate was 0.7%. PredischARGE echocardiography demonstrated the absence of more than mild mitral regurgitation in 98.3%. At midterm follow-up, the reoperation rate was 3.8%. The authors

commented on the safety and efficacy of the LEAR technique, a concept which was not designed to perform a novel mitral valve procedure but was developed to use robotic technology in order to replicate conventional mitral valve surgery techniques of known functionality and durability.

The same group from Atlanta most recently reported on their experience

Figure 3 The Emory lateral endoscopic approach with robotics (LEAR) technique port placement

of 50 patients undergoing reoperative robotic mitral valve surgery, having previously undergone robotic mitral valve surgery.¹⁹ Both procedures were performed using the LEAR technique. The indications for mitral valve reoperation in this cohort were mitral regurgitation in 42 patients (84%), mitral stenosis in 5 patients (10%), recurrent micro emboli following endocarditis in 1 patient (2%) and 2 patients (4%) who had previously undergone mitral valve replacement and required re-replacement, one for endocarditis and the other for prosthetic degeneration.

The operative strategy included arterial perfusion through the femoral artery in 48 patients (96%), the axillary artery in 1 patient (2%) and the ascending aorta through the second intercostal space in 1 patient (2%). Endoaortic balloon occlusion and antegrade cardioplegia were used in all cases. The median CPB and aortic occlusion times were 115 minutes (range 93–151 minutes) and 70 minutes (range 60–109 minutes), respectively. Mitral valve re-repair was performed in 36 patients (72%), 12 (24%) previous repairs were converted to a replacement, and re-replacement was performed in 2 patients (4%). The re-repair rate was 85% in degenerative mitral valve disease. Concomitant procedures included tricuspid valve repair in four patients (8%) and ablation for atrial fibrillation in two patients (4%). There were no conversions from the LEAR technique to median sternotomy. There was no mortality, stroke, wound infection or reoperation in this cohort. Echocardiography prior to discharge revealed the absence of mitral regurgitation in 78% of cases and mild regurgitation in 33%. The authors commented

that the exposure and instrumentation in the repeat LEAR technique were essentially identical to the initial LEAR procedures. This was achieved through fewer chest wall, pleural and mediastinal adhesions compared with the more conventional robotic approach, as well as the use of endoaortic balloon occlusion, eliminating the need to expose and mobilise the ascending aorta.

Goodman *et al*,²⁰ from the Cleveland Clinic group, analysed their learning curve for robotic mitral valve repair. They described the hesitance, by both surgeons and healthcare systems, to adopt new, expensive and technically challenging procedures such as robotic mitral valve surgery. They sought to characterise the learning-curve portion of their experience with robotic mitral valve surgery, analysing three outcomes: operative success, patient safety and clinical effectiveness. Operative success was defined as completing the mitral valve repair as planned robotically and less than mild mitral regurgitation observed on pre-discharge echocardiography. Patient safety was defined as intraoperative and postoperative blood product use and a composite of seven postoperative complications: hospital mortality, new-onset atrial fibrillation, stroke, renal failure, sepsis, ventilator assistance for more than 24 hours and reoperation for bleeding. Clinical effectiveness was defined as postoperative intensive care unit (ICU) and hospital lengths of stay, and days from hospital discharge to return to work. Between 2006 and 2011, 404 patients underwent entirely robotic mitral valve surgery, performed by two surgeons. Learning curves were constructed by modelling surgical sequence num-

bers semiparametrically with flexible penalised spline smoothing best-fit curves. The results showed that operative times decreased, either as nearly linear (operating room time), or logarithmic (CPB and myocardial ischaemic times). In all cases, there was no significant difference in the two surgeons' learning curves.

In terms of operative success, both surgeons experienced a rise in conversion rate in the middle of their experience, predominantly as a result of endoaortic balloon occlusion complications, inadequate exposure and small femoral vessels. Less than mild mitral regurgitation was observed in 97.8% on pre-discharge echocardiography. In terms of patient safety, there was no hospital mortality, renal failure or sepsis. Composite postoperative complications decreased significantly from case 1 (17%) to case 200 (6%) to case 400 (2%). In terms of clinical effectiveness, stay in intensive care decreased from 32 to 28 to 24 hours, and hospital stay decreased from 5.2 to 4.5 to 3.8 days (for cases 1, 200, and 400, respectively). There was no significant change in return-to-work times with increasing operative experience. The authors highlighted the volume related improvement in clinical outcomes, safety and efficacy of robotic mitral valve surgery. They concluded that surgeon experience and learning ability is a significant determinant of this technical success, leading to proficiency and outcome improvement.

Coronary artery revascularisation

Bonaros *et al*²¹ presented results from 500 cases of robotic TECAB procedures. In addition to reporting outcomes, they performed univariate

analysis and binary regression modelling to identify predictors of success and safety. Success was defined as the freedom from any adverse event and conversion procedure. Safety was defined as freedom from major adverse cardiac and cerebrovascular events, major vascular injury, and long-term ventilation. The da Vinci S™ and Si™ models were used. Three 1cm ports were introduced into the left chest (or the right chest if the right coronary artery was being grafted). Arrested heart (AH-TECAB) was used in 78% and beating heart (BH-TECAB) in 22%. In the case of AH-TECAB, femoral CPB was instituted. Single-vessel, double-vessel, triple-vessel and quadruple-vessel TECAB was performed in 67%, 30%, 3% and 0.2%, respectively. The success rate was 80% and the safety rate 95%. Conversion to sternotomy was required in 10%. The independent predictors of success were single-vessel TECAB, arrested heart TECAB and cases not on a surgeon's learning curve. The only independent predictor of safety was the EuroSCORE.

Leonard *et al*²² conducted a meta-analysis assessing the current evidence of outcomes following TECAB. Eligible studies included both single-arm TECAB studies and comparative studies looking at TECAB compared with MIDCAB. Outcomes of interest for the single-arm and paired analyses were operative mortality and pooled event rate of perioperative myocardial infarction, stroke, graft patency and repeat revascularisation. A total of 17 TECAB studies with a total of 3,721 patients were analysed. From these studies, 2 comparative studies were identified, with 263 patients (69.9%) in the TECAB arm

and 113 (30.1%) in the MIDCAB arm. Notably, the majority of cases were performed with the use of CPB and antegrade cardioplegic arrest (62.1%). The weighted mean CPB and cross-clamp times were 100.4 and 67.9 minutes, respectively. The event rate for operative mortality was 0.8% in the single-arm studies and pairwise meta-analysis showed no significant difference in operative mortality between the two groups (odds ratio, OR, 0.25; 95% confidence interval, CI, 0.02–2.83). The event rate for perioperative myocardial infarction was 2.28% and pairwise meta-analysis showed no significant difference between the two groups (OR 3.09, 95% CI 0.37–26.12). The event rate for perioperative stroke was 1.5% and pairwise meta-analysis showed no difference between the two groups (OR 1.33, 95% CI 0.17–10.26). The event rate for the need for repeat revascularisation was 2.99%; pairwise meta-analysis was not performed as there were insufficient studies. The event rate for follow-up graft patency was 94.8%; pairwise meta-analysis was not performed due to an insufficient number of studies.

The authors highlighted that the single-arm results of TECAB demonstrated very encouraging results in terms of graft patency and the need for repeat revascularisation. Meta-analysis demonstrated excellent results with TECAB in terms operative mortality, perioperative myocardial infarction or stroke and 30-day mortality, with all results comparable to MIDCAB. The clear limitation of the analysis was the small number of studies and study size, making a meaningful comparison between the techniques difficult to assess.

Another meta-analysis was performed by Wang *et al*,²³ comparing traditional CABG with TECAB. Some 16 studies comprising 1,414 patients undergoing TECAB were selected, and these were compared with the surgical arm of the Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery trial, which consisted of 897 patients undergoing CABG.²⁴ At 12 months follow-up, the rate of major adverse cardiac and cerebrovascular events (MACCE) was significantly lower in the TECAB group (OR 0.53, 95% CI 0.38–0.74), but there were no differences between the two groups in terms of hospital MACCE (OR 0.75, 95% CI 0.49–1.13), need for repeat revascularisation (OR 1.09, 95% CI 0.5–2.37) or graft stenosis/occlusion rate (OR 0.71, 95% CI 0.38–1.33). The authors highlighted the safety and efficacy of the TECAB technique. They did accept that more robust data are required to make a reliable comparison between the robotic and traditional techniques.

Other procedures

The very first robotic cardiac operation was for the repair of an ASD.¹ Most recently, Xiao *et al*²⁵ reported their institutional experience of 160 patients undergoing robotic secundum-type ASD closure. The first 54 cases were performed on the arrested heart and the subsequent 106 cases were performed on the beating heart. Concomitant tricuspid valve annuloplasty was performed in 7% and 10% of the arrested heart and beating heart groups, respectively. No mortalities or serious complications were reported and no conversion to thoracotomy or median sternotomy was required. As would be expected, the operative and CPB times were

significantly lower in the beating heart group. Postoperative echocardiography detected no residual ASD in any patient. The authors commented on the safe, effective and reliable conduct of ASD closure, specifically on the beating heart.

Li *et al*,²⁶ reported a single-institution, 23-year report of the resection of primary cardiac tumours in 228 patients. Within the cohort, there were 156 traditional open operations, 60 robotic neoplasm resections, and 12 procedures performed through mini-thoracotomy. Myxoma was the most prevalent lesion (94.8%), and the remainder were fibromas (1.3%) and lipomas (0.9%). There were no mortalities and no significant post-operative morbidity. CPB time was significantly longer in the mini-thoracotomy group than the other two

implantation. Twenty-one patients who had either had previous failure with coronary sinus lead implantation or were non-responders to conventional cardiac resynchronisation therapy underwent robotic left ventricular lead implantation. Successful implantation was conducted in all patients. There was no periprocedural mortality and no significant complications. Left ventricular pacing thresholds were excellent and remained stable at one-year follow-up. The authors commented on the safe and effective robotic technique of lead implantation as a new alternative or when conventional techniques are not suitable.

Developments in robotics

As an ever-evolving field of innovation and research, there are numerous developments in the arena of medical robotics. Arguably, the most significant

Closely related to automation is the concept of perceptual docking, which is an approach to synergistic control with the aim of achieving seamless shared control between the surgeon and the robot. The theory relies on the acquisition of knowledge from subject specific motor and perceptual behaviour through *in-situ* sensing.

In cardiac surgery, the most significant recent advancement in robotics has been the concept of organ-mounted robots. The desire to avoid CPB and to perform beating-heart minimally invasive surgery has been hampered by issues regarding safe manipulation of the heart and haemodynamic compromise. A free-standing robotic unit or a modular system attached to the operating table will encounter similar issues with regard to beating heart surgery in terms of access, manipulation, haemodynamics and heart tissue motion compensation. Consequently, organ-mounted robots have been in development. These highly flexible systems are designed for subxiphoid entry and adhere to the exterior of the heart, moving freely with it. This removes the need for manipulation of the heart and the difficulty of surgery on the beating heart. Examples of such devices include the Lamprey, a passive device that can be repositioned,²⁹ HeartLander, an inchworm-like crawling robot,³⁰ and Cerberus, a deployable flexible triangular manipulator with a moving injector head.³¹ A requirement for both the deployment of organ-mounted robots and traditional robotics is the concept of tracking. Precise tele-manipulation in a beating heart environment requires prediction of heart tissue motion, robotic control and

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groups. There were no significant differences in the cross-clamp times or other complications between the three groups. There were no significant differences in major adverse events among the three groups at six-month follow-up. The authors commented on the favourable outcomes of resection for primary cardiac tumours and the safety of minimally invasive and robotic approaches.

Amraoui *et al*²⁷ reported a series of robotically-guided left ventricular lead

development is the concept of automation, perhaps the most logical next big leap in robotics. In 2017, the Mako® (Stryker, Kalamazoo, MI) orthopaedic robotic arm was introduced, providing a glimpse of the first attempts at near automation in surgical robotics.²⁸ Using the patient's computed tomography scan, the device precisely pre-plans joint replacement while also being able to make real-time adjustments during the operation. This technology has very little applicability in the cardiac surgery arena at present.

heart tissue motion compensation. A number of different tracking devices are in development, including strain gauge-based systems, accelerometer sensors, sonomicrometer sensors and infrared devices.

Training

We have previously discussed the description of the learning curve in robotic cardiac surgery experienced by the Cleveland Clinic group. Robotic surgery is both more technically challenging and conceptually different from traditional open techniques. The transition from sternotomy to port-access surgery requires the adoption of a completely new skill set, as well as familiarity with the technology. Since its inception, there has been a slow adoption of robotic techniques in cardiac surgery. This can be hypothesised to be related to four major factors: cost; the need for significant institutional resources and infrastructure; technical demands; and most importantly, the lack of training. There are currently no recognised formal training programmes in robotic cardiac surgery. Consequently, there is a lack of mentorship and proctorship, crucial elements in the initiation of a robotics programme. Furthermore, by virtue of the sporadic nature of robotic cardiac centres, exposure to the techniques in the years of training is certainly not uniform, and in the UK almost non-existent.

To address this paucity in the exposure to robotic cardiac surgery and the uncertainty of initiating a robotics programme, a working group of experienced robotic cardiac surgeons devised a potential pathway and set of recommendations for both individual surgeons and surgical programmes

to begin or to participate in robotic cardiac surgery.³² They devised a set of criteria including robotic cardiac surgical team requirements (institutional commitment, individual leaders, dedicated teams), surgeon experience

level of surgical maturity and definition, these procedures have been mastered by a very small number of cardiac surgeons worldwide and are currently routinely performed exclusively in selected patients in a few large-volume

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requirements (competence in open and minimally invasive techniques) and robust consenting protocols that are all crucial elements of a successful programme. The report also focused on the importance of procedural and device specific education, including formal training with the equipment, the techniques and the need for dedicated fellowships to consolidate the learning.

Discussion

It has been exactly 20 years since the first telemanipulator-assisted open-heart operation was performed in Europe and since then significant technical advances in the two most commonly performed procedures (mitral valve surgery and coronary revascularisation) have been made. These have been possible only with the current use of the most updated and surgeon friendly da Vinci Si™ system and the clear identifications of the surgical pathways to accomplish both a robotic-assisted mitral valve repair and a totally endoscopic coronary revascularisation operation. Despite the fact that both these surgical procedures have probably reached their highest

US institutions or otherwise performed as ‘showcases’ by a handful of surgeons in Europe.

Robotic cardiac surgery in these selected centres has shown excellent early and midterm outcomes. There is superiority to conventional open-chest surgery in terms of cosmetics, patient satisfaction and patient reported outcome measures, reduced postoperative blood transfusion rates and the use of blood products, shorter lengths of hospital stay and a faster return to work. Despite these advantages, the current low volume of robotically assisted operations is unlikely to provide the surgical community with level-1 evidence of the superiority over minimal access mitral valve surgery, which itself has seen a much greater application in most continents, requiring significantly smaller capital investment to initiate a programme and a much smaller surgical team to be implemented in daily practice.

The lack of widespread growth of the robotic mitral procedure in most innovation prone European countries compared with the United States is

truly multifactorial and consequent to a complex algorithm that is not limited to costs or the steep learning curve. Other less quantifiable factors play a role, such as the variable level of support provided to cardiac surgery in Europe, compared with the United States, by the only robotic platform provider. The da Vinci™ platform has effectively held a monopoly in the 21st century and, as such, marketing decisions have played a role in the clinical application of the robotic system in European countries. This is a vivid example of how diffusion of innovation can be strongly (if not solely) influenced by marketing factors rather than by evidence alone.³³ The associated imbalance between diffusion of innovation and the associated evidence supporting the use of robotics in cardiac surgery is discussed in the following section.

It would be fair to assume that even if we had acquired the sought-after level-1 evidence to demonstrate the superiority of robotic-enhanced cardiac surgical revascularisation over traditional open surgery, the robotic revascularisation procedure would still have a very limited application in selected patients and selected cardiac centres, as opposed to the widespread availability and clinically established use of complex percutaneous coronary procedures. These procedures also involve the application of hybrid revascularisation techniques combining coronary artery bypass through sternotomy, mini-thoracotomy and percutaneous intervention. The established concept of heart teams and niche multidisciplinary team meetings has also seen a change in the referral pattern of coronary artery disease for revascu-

larisation. Similarly, the robotic mitral valve procedures with their capital investment, maintenance costs and complex learning curve would not withstand the more widespread use and much seamless implementation of minimal access mitral valve surgery programmes, as has been seen in Europe in recent years.

Mitral valve repair for degenerative mitral regurgitation and CABG for left main stem or three-vessel coronary artery disease have long been the gold standard. This accolade has been merited and has been validated through RCTs, demonstrating the superior clinical outcomes, efficacy and long-term results of the techniques. The much faster evolution of non-robotic enhanced minimally invasive cardiac surgery has challenged the existing dogmas and the gold standards of practice.

Minimally invasive techniques began with the concepts of innovation and progression firmly at their forefront. These techniques began by attempting to offer equivalent and comparable clinical outcomes, with the clear cosmetic superiority and the intuitive functional benefit of a smaller soft-tissue incision compared with the full sternotomy routinely produced in traditional surgery, with potentially reduced postoperative pain and disability, shorter lengths of hospital stay and quicker return to work. These, however, would be at the cost of the learning of new techniques and the associated impact of this learning curve on outcomes, the cost of new equipment and infrastructure and longer operative times. With the evolution and progression of these techniques came encouraging clinical outcomes.

Success with each innovative advancement led to approval within the surgical community and diffusion of innovation, a concept that describes the processes, reasons and the rate at which new ideas and technology spreads. Its function is based on four major elements, the innovation itself, communication channels, time and a social framework. The cardiac surgical community provides an ideal receptive medium as a framework and network of communication. A widespread uptake of new minimally invasive non-robotic techniques has been seen in most European countries rather than robotic techniques over the past ten years. The existence of multiple surgeons with large surgical volumes and with no increased hospital costs has translated into excellent clinical outcomes with minimally invasive techniques. The learning curves of these techniques have been well negotiated and this has resulted in reduced operative times compared with traditional open surgical techniques and the possibility of minimally invasive techniques of not only equalling but surpassing the established traditional methods. We do believe that the next ten years will see the establishment of minimal access valvular surgery in most UK centres and, in fact, we may not see a resurgence of robotic cardiac surgery in the UK or other European countries.

Outcome reporting has become increasingly subtle in recent years, moving progressively away from mortality rates alone and focusing more on morbidity, disability and patient-reported outcome measures. With these ideas in focus, the finer margins of improved outcomes observed with minimally invasive sur-

gery, such as reduced length of stay, quicker return to work and earning, institutional clinical effectiveness and frugality have become increasingly important. Innovation in the techniques has driven this transition in outcome reporting and analysis. With these significant principles in place, the cardiac surgical arena provides an ideal host for the deployment of minimal access technologies. In a receptive environment ready for innovation and progression, with robust communication and social frameworks, increasingly focusing on subtler surgical and institutional outcome measures, the finer marginal gains provided by such technological advances can be suitably amplified.

The current clinical applications of robotic cardiac surgery are predominantly in two main areas as described above, mitral valve surgery and coronary revascularisation. The nature of the use of the robot in these two procedures leads, however, to two very different entities. The progression that mitral valve surgery has experienced has been that of access: sternotomy, mini-thoracotomy, port access. The actual techniques of mitral valve surgery (ie mitral valve repair) have seen some alterations, although have generally remained constant. Robotic mitral valve surgery produces the exact same surgical outcome, treating the same mitral valve pathology to that of traditional sternotomy, albeit rather stringent selection processes do exist.

In contrast, coronary artery bypass surgery has evolved, not so much in terms of access, but more so in the conduct of the operation itself. Off-pump, on-pump, beating-heart, fibrillating-heart and cardioplegic arrest

have all been used. Robotic coronary artery surgery takes two major forms. In the first, the left internal thoracic artery is harvested robotically and then, through a small thoracotomy, a coronary anastomosis is performed. In the second, the entire procedure is undertaken robotically using port access (TECAB). There is currently no available clinical evidence to support the use of a TECAB approach over robotic MIDCAB. The former is a more complex procedure and is only suitable for selected patients. Even in large volume series, TECAB does seem to require longer operative times and to carry a considerable conversion rate to variable open techniques with the current available da Vinci Si™ system.

In the field of coronary revascularisation, the exponential growth and widespread availability of percutaneous catheter interventions, even in

increasingly higher-risk patients with more complex coronary anatomy, including left main stem disease, who are being treated percutaneously, has been and will remain a significant limiting factor in both the referral patterns and the expansion of robotic coronary revascularisation. In recent years, a large wave of financial investment has been aimed towards the development of various percutaneous techniques aiming to treat mitral valve disease (other than traditional mitral balloon valvuloplasty). The percutaneous 'mitral toolkit' is likely to expand and take hospital resources away from competitive and expensive robotic surgical approaches and will continue to challenge the justification of robotic surgery compared with minimal access surgical techniques. These minimally invasive techniques will in turn become more easily incorporated into the training

Figure 4 Barriers to randomised controlled trials in surgery including the evaluation of robotics in cardiac surgery

surgical curriculum as they will have more widespread availability and clinical applicability.

Diffusion of innovation and the evidence base

As discussed previously, there is a growing body of evidence demonstrating the safety and feasibility of robotic cardiac surgery in selected cases, although a robust evidence base for its comparative effectiveness over non-robotic (open and minimally invasive) approaches is still lacking. A number of barriers have been implicated for the paucity of RCTs in surgery, including the evaluation of robotics in cardiac surgery.³⁴ These barriers are summarised in Fig 4.

ing the high penetration rate of this technology in minimally invasive cardiac surgery.³⁹

Various reasons have been postulated for the imbalance between implementation and the associated evidence base in robotic cardiac surgery.⁴⁰ In the absence of clear evidence of superiority, the primary driver of diffusion most likely relates to marketing.⁴¹ Indeed, the robotic industry's marketing strategy has not only been intense but has adapted over the years to target not only surgeons (business-to-business model) but more recently also patients directly (business-to-consumer model) to enhance demand.^{42,43} Both surgeons and patients have been re-

scale, non-randomised clinical studies to authorise market approval.^{34,41} At the same time, medical device performance is heavily reliant on operator skill and experience thus further confounding the role of comparative trials (including RCTs) in this context.⁴⁵

The third reason relates to the short product life of innovative medical devices including robotics. The generation of high-level evidence requires time but the dynamic nature of the sector would make the technology redundant before its long-term efficacy is known.⁴⁶ Consequently, and in contrast to other more 'streamlined' healthcare sectors such as the pharmaceutical industry, evidence may actually follow (rather than precede) implementation, which is precisely the case for robotics in cardiac surgery.

To balance the need for greater rigor in the evaluation and surveillance of complex medical devices, the FDA has introduced a medical device post-market surveillance plan, known as the Medical Device Epidemiology Network.⁴⁷ Post-market surveillance offers the opportunity of overcoming limitations by leveraging the intelligence derived from the analysis of big data extracted from a variety of real-world datasets, including national and international registries, claims data and electronic healthcare records.⁴⁸ Machine learning tools can be applied to complement traditional analytical methods to provide real-time, evidence-based, personalised answers.⁴⁹ In this way, the gap between implementation and evidence can be bridged without delaying the process or compromising patient safety. An international registry infrastructure for cardiovascular

When it comes to novel surgical technologies, perception can often act as a more powerful driver than evidence in promoting adoption

Despite the lack of evidence regarding clinical superiority and the fact that robotic cardiac surgery has been consistently shown to be costlier and more time consuming compared with conventional approaches, cardiac surgery represents one of the largest markets in the field of robotic surgery.^{33,35,36} It thus becomes apparent that the diffusion of robotic cardiac surgery has outpaced the evidence supporting it.³⁷ In the United States alone, more than 1,700 cardiac procedures are performed annually, with no decline seen over the past decade.³⁸ Moreover, of all minimally invasive mitral valve repairs, 35.5% are performed robotically, indicat-

ported to embrace novel technologies before their merits and weaknesses are fully understood, with robotic surgery considered a prime example of this phenomenon.⁴⁴ Thus, when it comes to novel surgical technologies, perception can often act as a more powerful driver than evidence in promoting adoption.

The second reason for the implementation-evidence imbalance may relate to the difficulties associated with evaluating medical devices. The numerous barriers to surgical RCTs illustrated in Fig 4 are also recognised by regulatory bodies, which, as a result, are generally satisfied by small

device post-market surveillance was established in 2011 by the FDA,⁴⁷ although there is not yet a dedicated international registry for robotics in cardiac surgery.

Conclusions

Excellent outcomes in both mitral valve surgery and coronary artery revascularisation are observed with the use of robotic technology in a handful of surgical programmes. These programmes are supported by unique marketing strategies and investments, large volumes of patients and consequently, the ability to select ideal patients for individual surgical approaches.

Unfortunately, these robotically assisted procedures have been applied in a very selective patient cohort, leading to tremendous heterogeneity in any comparative analysis between the two techniques. The benefits observed are reductions in postoperative morbidity including blood loss, pain, length of intensive care and hospital stay, an earlier return to work and institutional clinical effectiveness. Again, these benefits have been exclusively shown in large, single-institution, non-randomised clinical series.

The two well-established robotic cardiac surgical procedures have not witnessed the same widespread clinical application as other established non-cardiac robotic procedures in the 21st century. The creation of a successful robotic cardiac surgical programme comes with significant costs, requires a considerable volume of work to overcome the inevitable learning curve and carries longer robotic operative times. It also requires infrastructural and cultural change

within the institution, both of which are most unrealistic in the currently financially constrained NHS.

We postulate that the UK will finally experience a surge in non-robotic minimal access procedures, albeit much later than most European countries. These techniques will deservedly take the leading role in the surgical treatment of isolated valve surgery while new percutaneous transcatheter techniques will undergo rigorous scientific and clinical testing to prove their safety, efficacy and increased value of care compared with the current well-established minimal access surgical techniques.

References

1. Carpentier A, Loulmet D, Aupecle B *et al*. Computer assisted open heart surgery. First case operated on with success. *C R Acad Sci III* 1998; **321**: 437–442.
2. Carpentier A, Loulmet D, Aupecle B *et al*. Computer-assisted cardiac surgery. *Lancet* 1999; **353**: 379–380.
3. Mohr FW, Onnasch JF, Falk V *et al*. The evolution of minimally invasive valve surgery – 2-year experience. *Eur J Cardiothorac Surg* 1999; **15**: 233–238.
4. Mohr FW, Falk V, Diegeler A *et al*. Computer-enhanced coronary artery bypass surgery. *J Thorac Cardiovasc Surg* 1999; **117**: 1,212–1,214.
5. Loulmet D, Carpentier A, d'Attellis N *et al*. Endoscopic coronary artery bypass grafting with the aid of robotic assisted instruments. *J Thorac Cardiovasc Surg* 1999; **118**: 4–10.
6. Reichenspurner H, Damiano RJ, Mack M *et al*. Use of the voice controlled and computer-assisted surgical system ZEUS for endoscopic coronary artery bypass grafting. *J Thorac Cardiovasc Surg* 1999; **118**: 11–16.
7. Falk V, Walther T, Autschbach R *et al*. Robot-assisted minimally invasive solo mitral valve operation. *J Thorac Cardiovasc Surg* 1998; **115**: 470–471.
8. Nifong LW, Chu VF, Bailey BM *et al*. Robotic mitral valve repair: experience with the da Vinci system. *Ann Thorac Surg* 2003; **75**: 438–442.
9. Nifong LW, Chitwood WR, Pappas PS *et al*. Robotic mitral valve surgery: a United States multicenter trial. *J Thorac Cardiovasc Surg* 2005; **129**: 1,395–1,404.
10. Deeba S, Aggarwal R, Sains P *et al*. Cardiac robotics: a review and St Mary's experience. *Int J Med Robot* 2006; **2**: 16–20.
11. Falk V, McLoughlin J, Guthart G *et al*. Dexterity enhancement in endoscopic surgery by a computer controlled mechanical wrist. *Minim Invasive Ther Allied Technol* 1999; **8**: 235–242.
12. Gupta V, Reddy NP, Batur P. Forces in laparoscopic surgical tools. *Presence* 1997; **6**: 218–228.
13. Macedo JA, Kaber DB, Endsley MR *et al*. The effect of automated compensation for incongruent axes on teleoperator performance. *Hum Factors* 1998; **40**: 541–553.
14. Hanna GB, Cuschieri A. Influence of the optical axis-to-target view angle on endoscopic performance. *Surg Endosc* 1999; **4**: 371–374.
15. Taylor RH, Lavallee S, Burdea GC *et al*. *Computer-integrated Surgery: Technology and Clinical Applications*. Cambridge, MA: Massachusetts Institute of Technology Press; 1996.
16. Vannier MW, Haller JW. Navigation in diagnosis and therapy. *Eur J Radiol* 1999; **31**: 132–140.
17. Gillinov AM, Mihaljevic T, Javadikasgari H *et al*. Early results of robotically assisted mitral valve surgery: analysis of the first 1000 cases. *J Thorac Cardiovasc Surg* 2018; **155**: 82–91.
18. Murphy DA, Moss E, Binongo J *et al*. The expanding role of endoscopic robotics in mitral valve surgery: 1257 consecutive procedures. *Ann Thorac Surg* 2015; **100**: 1,675–1,681.
19. Murphy DA, Moss E, Miller J, Halkos ME. Repeat robotic endoscopic mitral valve operation: a safe and effective strategy. *Ann Thorac Surg* 2018; **105**: 1,704–1,709.
20. Goodman A, Koprivanac M, Kelava M *et al*. Robotic mitral valve repair: the learning curve. *Innovations* 2017; **12**: 390–397.
21. Bonaros N, Schachner T, Lehr E *et al*. Five hundred cases of robotic totally endoscopic coronary artery bypass grafting: predictors of success and safety. *Ann Thorac Surg* 2013; **96**: 803–812.
22. Leonard JR, Rahouma M, Abouarab AA *et al*. Totally endoscopic coronary artery bypass surgery: a meta-analysis of the current evidence. *Int J Cardiol* 2018; **261**: 42–46.
23. Wang S, Zhou J, Cai JF. Traditional coronary artery bypass graft versus totally endoscopic coronary artery bypass graft or robot-assisted coronary artery bypass graft – meta-analysis of 16 studies. *Eur Rev Med Pharmacol Sci* 2014; **18**: 790–797.
24. Serruys PW, Morice MC, Kappetein AP *et al*. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *N Eng J Med* 2009; **360**: 961–972.
25. Xiao C, Gao C, Yang M *et al*. Totally robotic atrial septal defect closure: 7-year single-institution experience and follow-up. *Interact Cardiovasc Thorac Surg* 2014; **19**: 933–937.
26. Li S, Gao Ch. Surgical experience of primary cardiac tumours: single-institution 23-year report. *Med Sci Monit* 2017; **23**: 2,111–2,117.
27. Amraoui S, Labrousse L, Sohal M *et al*. Alternative to left ventricular lead implantation through the coronary sinus: 1-year experience with a minimally invasive and robotically guided approach. *Europace* 2017; **19**: 88–95.
28. Sandle P, Hirschler B. *Robotic knee surgery competition heats up*. *Scientific American* 2017; 13 July. <https://www.scientificamerican.com/article/robotic-knee-surgery-competition-heats-up> (cited July 2018).
29. Wood NA, Schwartzman D, Zenati MA, Riviere CN. Physiological motion modeling for organ-mounted robots. *Int J Med Robot* 2017; **13**(4).
30. Patronik NA, Ota T, Riviere CN. Synchronization of epicardial crawling robot with heartbeat and respiration for improved safety and efficiency of locomotion. *Int J Med Robot* 2012; **8**: 254–266.
31. Costanza AD, Breault MS, Wood NA *et al*. Parallel force/position control of an epicardial parallel wire robot. *IEEE Robot Autom Lett* 2016; **1**: 1,186–1,191.
32. Rodriguez E, Nifong LW, Bonatti J *et al*. Pathway for surgeons and programs to establish and maintain a successful robotic-assisted adult cardiac surgery program. *Ann Thorac Surg* 2016; **102**: 340–344.
33. Garas G, Cingolani I, Panzarasa P *et al*. Network analysis of surgical innovation: measuring value and the virality of diffusion in robotic surgery. *PLoS One* 2017; **12**: e0183332.
34. Garas G, Ibrahim A, Ashrafian H *et al*. Evidence-based surgery: barriers, solutions, and the role of evidence synthesis. *World J Surg* 2012; **36**: 1,723–1,731.
35. Athanasiou T, Ashrafian H, Rowland SP, Casula R. Robotic cardiac surgery: advanced minimally invasive technology hindered by barriers to adoption. *Future Cardiol* 2011; **7**: 511–522.
36. Intuitive Surgery, Inc. da Vinci Surgery. *Cardiac conditions*. 2018. <http://www.davincisurgery.com/da-vinci-cardiac> (cited July 2018).
37. Lerner JC, Robertson DC, Goldstein SM. Case studies on forecasting for innovative technologies: frequent revisions improve accuracy. *Health Aff* 2015; **34**: 311–318.
38. Pettinari M, Navarra E, Noirhomme P, Gutermann H. The state of robotic cardiac surgery in Europe. *Ann Cardiothorac Surg* 2017; **6**: 1–8.
39. Chitwood WR. Robotic cardiac surgery by 2031. *Tex Heart Inst J* 2011; **38**: 691–693.
40. Wright JD. Robotic-assisted surgery:

- balancing evidence and implementation. *JAMA* 2017; **318**: 1,545–1,547.
41. Wong KA, Hodgson L, Garas G *et al*. How can cardiothoracic and vascular medical devices stay in the market? *Interact Cardiovasc Thorac Surg* 2016; **23**: 940–948.
 42. Teece DJ. Business models, business strategy and innovation. *Long Range Planning* 2010; **43**: 172–194.
 43. Turley LW. A comparison of advertising content: business to business versus consumer services. *J Advert* 2013; **26**: 39–48.
 44. Barbash GI, Glied SA. New technology and health care costs – the case of robot-assisted surgery. *N Engl J Med* 2010; **363**: 701–704.
 45. World Health Organization. *Increasing Complexity of Medical Technology and Consequences for Training and Outcome of Care. Medical Devices: Managing the Mismatch*. Geneva: WHO; 2010.
 46. Avorn J. Regulation of devices. *BMJ* 2010; **341**: c5730.
 47. Sedrakyan A, Marinac-Dabic D, Holmes DR. The international registry infrastructure for cardiovascular device evaluation and surveillance. *JAMA* 2013; **310**: 257–259.
 48. Resnic FS, Normand SL. Postmarketing surveillance of medical devices – filling in the gaps. *N Engl J Med* 2012; **366**: 875–877.
 49. Ross JS, Bates J, Parzynski CS *et al* Can machine learning complement traditional medical device surveillance? A case study of dual-chamber implantable cardioverter-defibrillators. *Med Devices* 2017; **10**: 165–188.