

<b>Institution:</b> Nottingham Trent University (NTU)		
<b>Unit of Assessment:</b> D32 - Art and Design: History, Practice and Theory		
<b>Title of case study:</b> Transforming thoracic trauma surgery education and training by design		
<b>Period when the underpinning research was undertaken:</b> 2012 – 2020		
<b>Details of staff conducting the underpinning research from the submitting unit:</b>		
<b>Names:</b> Richard Arm  Tilak Dias Anton Ianakiev	<b>Roles</b> Lecturer & Senior Technical Advisor Senior Research Fellow Professor Professor	<b>Periods employed by submitting HEI:</b> 2009 – 2015 2015 – present 2000 – present 1990 – present
<b>Period when the claimed impact occurred:</b> 2016 – July 31, 2020		
<b>Is this case study continued from a case study submitted in 2014?</b> N		
<b>1. Summary of the impact</b>  <p>Arm's work has had a significant impact by improving thoracic surgical education and training for military and clinical practitioners working in extreme emergency environments, leading to improved clinical confidence and competence. Limited availability of cadavers, and manikins that lack a lifelike 'feel', had constrained training for thoracic trauma surgery and therefore surgeons' capacity to save lives. With industrial, clinical and military partners, NTU's Flexural Composites Laboratory used composite elastomers and additive manufacturing to create life-like thoracic manikins that make realistic training possible. By enhancing the experiential learning of lifesaving procedures for surgeons and emergency responders they have benefitted personnel in NHS trauma units and regional training hubs, the Air Ambulance Service, the Army, Navy, RAF, British special forces and NATO partners/allies. The manikins are sold commercially as PROSimbodie©, creating new employment and increased revenues for manufacturer Trauma FX (TFX).</p>		
<b>2. Underpinning research</b>  <p>As a Senior Research Fellow, Arm has led research since 2012 in the School of Art and Design's, Flexural Composites Research Laboratory, within the Advanced Textiles Research Group. The group's focus on materials means it draws upon a number of research approaches, including the craft knowledge Arm has developed working with composite elastomers and additive manufacture. In this, the group's work shares many of the characteristics of practice-based art and design research, combining embodied process with deep collaboration beyond the field. Close engagement with medical experts at the Queen's Medical Centre (QMC), Nottingham and Ministry of Defence (MOD), and expert users such as the East Midlands Air Ambulance Service has made it possible for Arm to produce 'biofidelic' simulations of human organs, characterise them systematically and prove them in clinical training settings.</p> <p>The underpinning research grew out of two grants awarded in 2012 [G1 and G2], which demonstrated and tested the potential to work with silicone polymers to create realistic simulations of the tissues of the human head and thorax – faithful to the variety of textures and structures that occur in nature. Working with surgeons at the QMC, the research was developed through the deep study of the anatomy of the thorax, including organs, tissues, and membranes. Arm used medical imaging data to build high-precision computer models and produce 3D printed moulds which he used in a sophisticated casting process to make simulations that are both anatomically correct and life-like in how they feel. It is this sequence that makes the work particularly innovative, drawing together Arm's embodied craft knowledge and the anatomical expertise of medical collaborators, to produce hyper-realistic sensual effects through a composite polymer moulding technique.</p> <p>Proof of concept research was extended through two grants [G3 and G5]. These increased the number of thoracic organs that could be realistically simulated using silicone-based materials to include rib cage, sternum, spine, skin, subcutaneous soft tissue, functioning airways, lung and heart pleura [R4 and R5]. The work was further developed to make a beating heart and arterial</p>		

system with internal blood pressure that responds realistically to surgical incisions [R1 and R3]. Funded research [G3] between 2015 and 2017, developed the material specification and production process for a whole thorax simulation which could faithfully mimic the tactile, mechanical and visual properties of human organs and tissues in situ.

Three thoracic trauma trainer prototypes were tested by medical professionals in a trauma management/surgical setting at the Army Medical Simulation Centre and Royal Centre for Defence Medicine. Tests included battle-field thoracotomy surgery as well as a variety of MOD standard operating procedures [R4 and R5]. Collaborating surgeons at the QMC and the MOD assessed the effectiveness of two prototypes. Their feedback was used to further enhance the realism of the organs and specifically the properties of the pericardium to better replicate the feel of the sac and its response to being cut by surgeons.

Later grants [G4 and G6] enabled a refinement to the realism of the skin's structure and behaviour, through enhancements to simulations of the subcutaneous tissues of the face and head in the context of the impact of ballistic projectiles [R2].

### 3. References to the research

The quality of the underpinning research has been evidenced by externally peer reviewed grants and outputs which underpinned the development of processes for using polymer materials to create life-like simulations, working with medical practitioners to assess their likeness to live anatomy.

#### Key Outputs:

1. Nandasiri, G.; Ianakiev, A; Dias, T; (2020) Hyperelastic properties of platinum cured silicones and its application in active compression. *Polymers*, 12, 148. DOI:10.3390/polym120101148.
2. Mahoney, P., Carr, D., Arm, R., Gibb, I., Hunt, N., Delaney, R. (2017). Ballistic Impacts on an anatomically correct synthetic skull with a surrogate skin/soft tissue layer. *International Journal of Legal Medicine*. DOI:10.1007/s00414-017-1737-9. Online ISSN 1437-1596.
3. Arm, R.; Shahidi, A.; Dias, T., (2019). Mechanical Behaviour of Silicone Membranes Saturated with Short Strand, Loose Polyester Fibres for prosthetic and rehabilitative Surrogate Skin Applications. *Materials*. 6; 12 (22) DOI:10.3390/ma12223647.
4. Arm, R (2015) Royal Centre for Defence Medicine (MoD) Development of a Thoracic Trauma Trainer for the Advancement of Military Operational Surgical Training. Crown Copyright. Report number DMSRSG/2014/09/11 A.
5. Arm, R (2017) Centre for Defence Enterprise (MoD) Development of a Thoracic Trauma Trainer for the Advancement of Military Operational Surgical Training. Crown Copyright. Report Number DMSRSG/2014/09/11 A.

#### Grants and Commissions:

1. Queen's Medical Centre, Paediatric Department, 2012, Making an Implantable Subcutaneous Pump, GBP 4,500.
2. NTU, Advanced Medical Prosthesis NIHR i4i Project, 2012, Silicone Soft Tissue; muscles for a simulation head using embedded fibres, GBP 800.
3. Royal Centre for Defence Medicine, 2014-2017, Thoracic Trauma Trainer GBP 219,914.
4. Cranfield Defence Academy, 2016-2018, Subcutaneous Soft Tissues of the Face: Ballistic Study, GBP 14,000.
5. British Council, Newton Fund, International Collaboration, 2017, Printing Bones and Implantable Tissues, GBP 2,700.
6. Birmingham University, School of Dentistry, 2018, Soft Tissues of the Mouth, GBP 6,900.

#### 4. Details of the impact

Patients requiring a thoracotomy (opening of the chest in an emergency) typically have a low survival rate (2% - 20%) and resuscitative thoracotomy is considered an intervention of last resort to save someone's life. Hitherto, there were no effective, practical training tools that could prepare surgeons for this procedure through realistic experiential learning before they carry it out on live patients on the battlefield, at the roadside or in operating theatres. In partnership with British company Trauma FX (TFX), Arm's research produced PROSimbodie©, the only reusable surgical manikin capable of providing emergency services/surgeons with a means to train for life-saving thoracotomy procedures. The production of the whole thorax prototype led TFX, the research output license owner, to release the PROSimbodie© manikin onto the market in February 2019 [S6].



The PROSimbodie© manikin is highly valued by medical professionals because of its bio-fidelity [S1 to 4], achieved through the materials-based research outlined above. The much-enhanced realism of the whole-team training it makes possible, led to it winning the Royal College of Surgeons 'Transforming Surgical Education Award' in 2017 [S5]. The PROSimbodie© manikin also overcomes barriers to surgical training in Islamic countries, where burial practices limit the availability of cadavers [S6].

#### Improving UK and NATO field-based Military Surgery

The research has had direct impact on military surgeon training, through the development of prototypes which remain in use by defence medical simulation centres in the UK, including Army Medical Services Training Centre (AMSTC) in York and at the Royal Centre for Defence Medicine (RCDM), including the Queen Elizabeth Hospital, Birmingham. The prototypes have been used by British and German special forces during emergency aircraft evacuation training, to simulate emergency thoracotomy procedures for seriously injured military personnel on board helicopters [S6].

In 2019, two PROSimbodie© manikins, along with the necessary trained operators, were embedded into TFX's AMSTC support contract. The prototypes are now routinely used by the British military, including when deploying their two field-hospitals. United Kingdom Special Forces medical training events in 2019, were attended by NATO partners and non-NATO allies and led to orders for PROSimbodie© manikins by the German, UAE and Israeli military, delivered by June 2020 [S6]. In 2019, PROSimbodie© manikins were used in Germany and benefited US, German, Dutch, British and Lithuanian military medics during NATO multinational field-hospital training [S6].

AMSTC confirms that PROSimbodie© has made the simulated learning experience more immersive and improved the MOD's ability to test surgeons in critical areas and against its standard operating procedures. In particular, AMSTC highlights how PROSimbodie© manikins enhance the assessment of surgeons' and team members' roles, and their behaviour, communication and coordination of critical surgical tasks [S3]. The bio-fidelity of the body, the simulated organs and their arrangement in the manikin, have enabled *'surgical teams and emergency responders to enhance the realism of exercises by practicing procedures that otherwise wouldn't be possible'* [S3]. Examples include the chest drain procedure, which requires an incision into the rib cage to admit a tube to drain blood/air out of the chest cavity, and the emergency clamshell thoracotomy, which involves opening the rib cage to access organs. Clinicians trained by AMSTC say that the thoracic anatomy in the PROSimbodie© *'gives an increased sense of realism'* that means *'they can practice the whole procedure from start to finish in an environment reflective of actual working conditions'* [S3]. During conflict, thoracic procedures are regularly carried out, but when forces are not deployed, it is important that

clinical personnel practise their skills to maintain a high level of capability. AMSTC confirms the popularity of the mannikins: *'Whenever we run simulations, clinicians ask if the PROSimbodie© are going to be used.'*



Fig. 1 Clamshell thoracotomy procedure on PROSimbodie© (Photo Arm, R.)

### Improving pre-hospital Trauma Surgery

The PROSimbodie© manikin has improved medic and paramedic training, enhancing technical skills for pre-hospital procedures by enabling emergency procedures like the clamshell thoracotomy to be practiced in life-like situations. The high-fidelity models were tested at the Royal College of Surgeons, London and by the East Midlands Air Ambulance Service in Nottingham. Consequently, the thoracic simulations are now regularly used for trauma training by first responders in the East Midlands Immediate Care Service, a multi-disciplinary team of doctors that covers the whole of the East Midlands and responds to an average of four life-threatening emergencies a day [S4]. The model improved the team's technical skills, their coordination of operational procedures and their emotional management in response to radical, traumatic and rarely seen procedures. A GP involved states *'There are many ambulance crews who've never actually seen this procedure'* [S4].

The PROSimbodie© manikin is used by British emergency services to enhance simulated training/learning and improve pre-hospital trauma care [S6]. TFX used PROSimbodie© to support Pre-Hospital Emergency Extracorporeal Life Support training for medical/clinical staff at St Bartholomew's Hospital. An example of this is Extracorporeal Membrane Oxygenation simulation which teaches emergency services staff to treat people with severe respiratory failure [S6]. Wider applications being explored include out-of-hospital trauma procedures such as emergency amputation and caesarean sections [S4]. Three UK Air Ambulance Services had purchased PROSimbodie© manikins by early 2020 [S6].

### Improving hospital-based Trauma Training and General Surgery

The PROSimbodie© manikin was tested to improve in-hospital trauma surgery and general surgery training at Queen's Medical Centre Major Trauma Unit, Nottingham, and the Aintree Hospital Simulation Centre, Liverpool [S1 and 2]. PROSimbodie© manikins overcome the limitations of using cadavers and animals (in terms of ethics, expense and accuracy) and they provide a cost-effective, reusable and more realistic model that, according to the director of the East Midlands Major Trauma Centre, has *'resulted in a change to the accuracy of our high-level training'* [S2].

One QMC consultant described the training opportunities afforded by the PROSimbodie© as *'critical'*, enabling staff to *'practice in a no risk environment rather than being trained in a high-risk environment i.e. live surgery'*. The PROSimbodie© manikin has enhanced simulated training in emergency care. In January 2020, TFX delivered training with PROSimbodie© to Watford Emergency Department (West Hertfordshire NHS Trust). This involved nurses, consultants and other staff members taking their Certificate of Eligibility for Specialist Registration. University Hospital of Wales, Cardiff purchased a PROSimbodie© manikin in 2019, to teach medical trainees/staff at Cardiff University School of Medicine and Wales Air Ambulance Service [S6].

### Commercial impact via the commercialisation of the PROSimbodie© manikin

The production of whole thorax prototypes led the industrial collaborator and research output license owner TFX to commercialise a new product, the PROSimbodie© manikin, for emergency



surgical training, which came onto the market in February 2019. This directly led TFX to create a new department at their manufacturing facility in Yorkshire, with one new senior, highly skilled position and three graduate roles. The facility expanded from 2,500 to 7500sq/ft to meet need production demand [S6]. The PROSimbodie© manikin delivered £900,000 in turnover to TFX up to July 2020 [S6]. Sales were further supported when the research work was featured on BBC Radio 4's Today Programme, broadcast from NTU in February 2020 [S8]. The TFX licence agreement with NTU committed the company to manufacture and retail 25 units by July 2020, in fact 30 units were achieved [S6]. Several accessories and consumable products have also been developed and manufactured through collaboration with TFX to support PROSimbodie© manikin customers. Examples include replaceable skin/fat, pericardium, repair kits and training manuals.

In February 2020, Water Street Healthcare Partners (WSHP), a US-based healthcare strategic investor, merged TFX, Prometheus Medical (PROSimbodie© manikin retailer) and North Carolina's Combat Medical, (emergency medical solutions provider for military and law enforcement agencies), to form a new company called Safeguard Medical [S6 and 7]. TFX MD confirmed *'PROSimbodie©'s one product that's been instrumental in influencing our merger with Safeguard medical, to access large US medical and military markets.'* The Chief Executive Officer of WSHP stated, *'This merger is an important first step toward our goal of building a global leader dedicated to developing life-saving products and teaching emergency medical skills for any environment and every skill level'* [S7].

## 5. Sources to corroborate the impact

**S1:** Consultant Neurosurgeon Queens Medical Centre QMC, Nottingham and Professor of Paediatric Neurology corroborates PROSimbodie© is embedded in trauma simulation training, enhancing realism through the bio-fidelity of the lifelike thoracic model.

**S2:** Consultant Hepatobiliary and Director of the East Midlands Major Trauma Centre, QMC, Nottingham corroborates how PROSimbodie© enhances experiential learning of general surgery skills and use of surgical tools in a no-risk environment.

**S3:** Exercise Planner, tri-services army medical trauma training at the Army Medical Services Training Centre, York corroborates PROSimbodie© has enhanced MOD's simulation training, expanding MOD capability to testing surgeons and medical professionals technical competence against standard operating procedures, confirming clinicians enthusiasm for the use of the trainer to enhance learning during simulated exercises.

**S4:** GP at University of Nottingham and volunteer at East Midlands Immediate Care Service (EMIC) corroborates benefits to EMIC emergency responders through exposure to rarely practiced procedures prior to use of PROSimbodie©, enhancing technical skills in thoracotomy procedures and emotional management of traumatic procedures.

**S5:** RCS Technology Showcase, Surgeon Educator's Day Friday 17<sup>th</sup> March 2017, Transforming Surgical Education Award Certificate.

**S6:** Managing Director, Trauma FX (TFX) corroborates PROSimbodie© has underpinned TFX merger with Safeguard Medical, led to an expansion of their production capacity. DMSG (Defence medical services group) are an umbrella branch of the military that oversees all aspect of military medical spending and deployment. The DMSG code (DSMRSG20140911) links the end product to the research directly and may be regarded as an accreditation from the MoD.

**S7:** <https://www.prometheusmedical.co.uk/news/prometheus-medical-trauma-fx-and-combat-medical-join-forces> corroborates merger of TFX, Prometheus Medical, Combat Medical under Safeguard Medical group.

**S8:** BBC's Today Programme (7<sup>th</sup> February 2020) <https://www.ntu.ac.uk/about-us/news/news-articles/2020/02/bbcs-today-programme-broadcasts-from-nottingham-trent-university>.