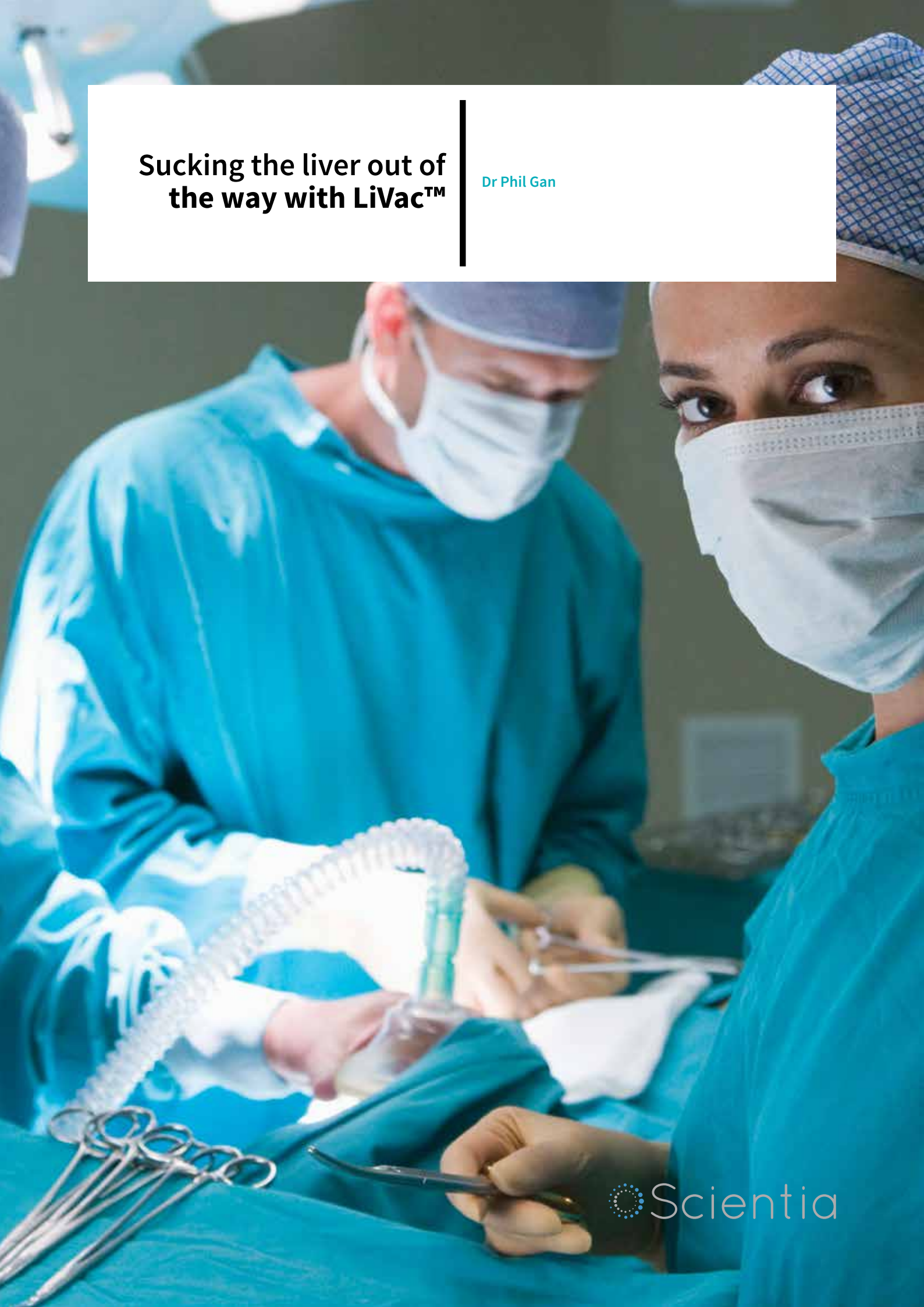
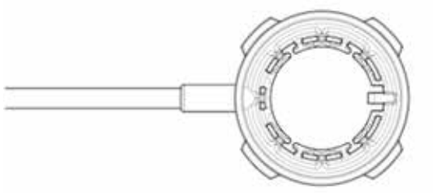
Sucking the liver out of the way with LiVac™

Dr Phil Gan



Scientia

SUCKING THE LIVER OUT OF THE WAY WITH LIVAC™



Dr Phil Gan, a general surgeon, has invented a surgical device called the LiVac™ Retractor, that has significant advantages over traditional methods during laparoscopic surgery which require the liver to be retracted.

Any technological advances which reduce the amount of trauma caused by surgical procedures can enhance patient recovery and help to minimise complications. Laparoscopic, or 'keyhole' surgery, has allowed many procedures to be performed without the need for major incisions (laparotomy). Although this has proved a major advancement, surgeons are constantly trying to improve their techniques, such as by reducing the number and size of incisions required for a particular operation. Dr Philip Gan is a general surgeon based in Australia, who has made such an advancement through the invention of an innovative piece of technology called the LiVac™ Retractor.

Issues with retracting the liver

The liver, our largest internal organ, must often be retracted, or moved out of the way during laparoscopic operations to allow the surgeon access to particular parts of the body. The left lobe of the liver is retracted for surgery performed on the stomach, while the right lobe is retracted to allow access to the gallbladder and right kidney. A device called a Nathanson retractor, which has been in use for decades, consists of a curved and bended steel rod, is traditionally used for retracting the left lobe of the liver. The retractor is inserted through an incision in the epigastrium (the central region of the abdomen just below the rib cage) and placed under the liver before being fixed to a frame bolted to the operating table. Retractors may be held in place during the operation by a surgical assistant, who may also be operating the laparoscope. These methods require an incision and/or port specifically to insert the retractor.

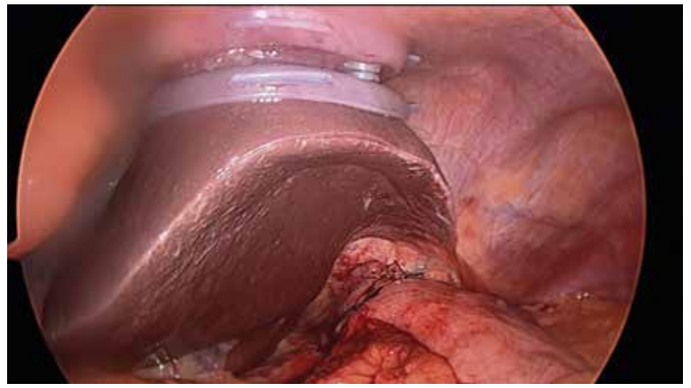
The pressure exerted by the retractor can congest the internal vasculature of the liver, leading to tissue trauma from disturbance of the blood supply and subsequent re-perfusion injury. This damage can occur in varying degrees of severity, ranging from mild tissue congestion all the way up to rare reports of liver necrosis and death. Increased time periods for which the tissue is compressed results in higher risk of liver injury, as well as a subsequent inflammatory response which makes the patient feel unwell.

Retraction techniques can also include suturing (stitching) of the liver or gall bladder to the abdominal wall, which may cause undesirable tissue trauma.

From ideas to prototypes

'In any field, if you are not moving forward, then you are going backwards. Innovation is the catchword of the moment, and not without good reason', says Dr Philip Gan. During surgery, Dr Gan observed the left lobe of a liver which had adhered to the diaphragm from surface tension alone, and saw an ingenious way to move the field of surgery forward. 'It occurred to me that if surface tension alone could hold up the left lobe of the liver, then so too could suction.' Over the next few years, his idea developed into the LiVac™ Retractor (Liver Vacuum), which after lodging a provisional patent in 2010, he produced with the help of an Australian medical device manufacturer and engineering company, Ingeneus Pty Ltd. Dr Anabela Correia, a specialist in the commercialisation of medical technology, and a number of consultants in the industry also assisted over the subsequent years.

'The LiVac™ Retractor is the only retractor which attaches to the superior surface of the liver, whilst also being hands-free and not requiring any additional incisions.'



The device is a collapsible, soft, ring-shaped object made of silicone, attached to suction tubing. When attached to a regulated source of suction, a vacuum is created in the space inside the ring. The retractor is placed in apposition between the liver and the diaphragm, and suction is then applied to the LiVac™ Retractor. This then mimics the effect which Dr Gan had originally observed, in adhering the liver to the diaphragm. Compared with hand held retractors, the surgical assistant would instead be able to give their full attention to optimising the view through use of the laparoscope. No attachment to a fixed frame is required when using the LiVac™, since once the suction is applied, the diaphragm takes the weight of the liver, rather than its weight being taken by an attachment to external apparatus. The LiVac™ suction tubing can exit alongside existing ports and therefore a dedicated incision is also not required, as it would be when using the Nathanson retractor.

The LiVac™ Retractor is produced in two sizes, large (78mm diameter) and small (56mm), with the smaller version being suitable for retraction of the left lobe and the larger size being more suited to retraction of the right lobe. The collapsible nature of the LiVac™ Retractor means that incisions through which the retractor is inserted do not need to measure the entire width of the ring. In fact, retractors of either size can be inserted through the lumen of a 15mm port or the tract created by a 12mm port. The LiVac™ Retractor is also disposable, which is a desirable specification for most pieces of surgical equipment, as it guarantees sterility.

Trials and testing

Dr Gan and Ingeneus developed prototypes, and by 2012 the device was ready to be tested on laboratory animals at the University of Melbourne Veterinary School. The tests proved successful and the results were later published in the medical journal, *Surgical Endoscopy*. However, it can be difficult to extrapolate from animal tests into how a surgical device may perform in humans, due to the anatomical differences between the livers of humans and those of animals such as pigs and sheep. The next stage of testing therefore needed to be performed on human patients, which is a considerably more complex process than animal testing.

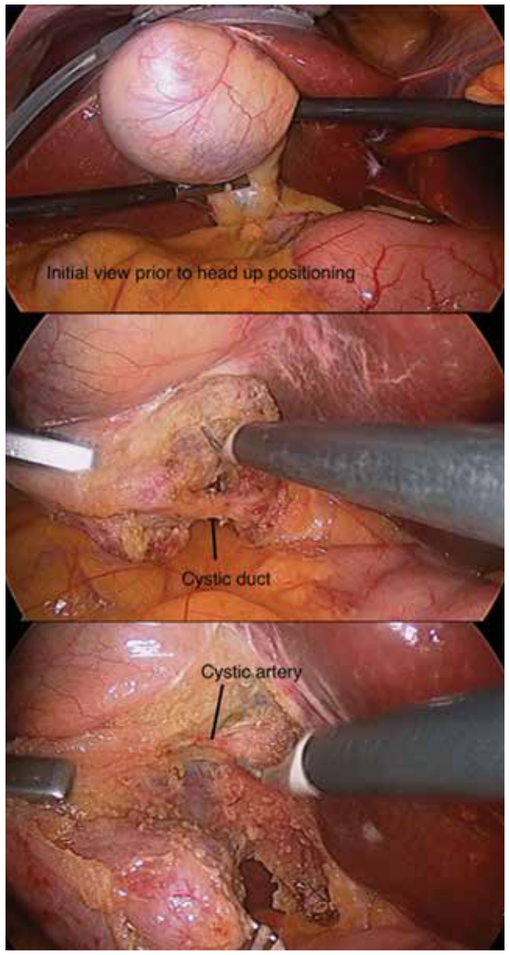
In 2013, Dr Gan's team successfully applied to a highly competitive, match-funded Australian Federal Government grant program for commercialisation. With the money secured for an in-human trial, his team then addressed the legal, ethical and scientific requirements necessary for clinical testing of medical devices. Two committees, the national St John of God Healthcare Ethics Committee and the Ethics Committee of Southwest Healthcare approved the trials.

Impressively, the development of the trial protocol, patient recruitment, surgery and follow up were conducted within the grant's short time-frame, which was less than one year. One three-port hiatus hernia repair with anterior fundoplication, three single-incision gall-bladder surgeries, three reduced-port (3) gall-bladder surgeries and three reduced-port (3) gastric band operations were performed. The term 'reduced port' refers to the smaller number of incisions which would normally be required to perform the operation. The patients' recovery and any complications were carefully monitored and reviewed by independent trial coordinators, as well as the operations themselves being video recorded. No device-related adverse events were observed and all performance milestones were achieved. No bleeding, lacerations or tears were observed and livers displayed only embossing, which flattened a few minutes after removing the retractor, leaving only bruising.

The results were presented at several high-profile, international surgical conferences in 2014 and 2015 (the European Association for Endoscopic Surgery (EAES) 14th World Congress in Paris, June 2014, the 2nd International Consensus Conference on Laparoscopic Liver Resection (ICCLLR) in Iwate, Japan in October 2014 and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Congress in Vienna, Austria, in August 2015), and also published in Surgical Endoscopy.

Regulatory approval came in late 2014 with listing on the Australian Register of Therapeutic Goods (ARTG) and issuance of a European Conformity (CE Mark) certificate.

Dr Gan was pleased to receive a letter of congratulations from the current Premier of Victoria at the time, Dr Denis Napthine.



The LiVac™ retractor in practice

Dr Gan has subsequently used the LiVac™ Retractor as his standard retractor in gastric and gall-bladder surgeries. 'I have used it on many different types of liver, including severely fatty livers, which are the ones most prone to retraction injuries as they are so soft and friable', says Gan. He has also been able to directly observe the effect of the LiVac™ in patients who have, for one reason or another, had to undergo other laparoscopic procedures. One, for example, required an appendectomy six weeks after a laparoscopic three-port cholecystectomy (gall-bladder removal surgery) which involved liver retraction using the LiVac™ Retractor. No visible mark was seen on the patient's liver. Similarly, none the other patients he has needed to re-laparoscope have shown any residual marks on the liver.

'In any field, if you are not moving forward, then you are going backwards'

In two patients who required liver biopsies during other operations in which the LiVac™ Retractor was used, core biopsies were taken from retracted and non-retracted parts of the liver then sent to pathologists separately, blinding the pathologist as to where each core was taken from. The pathologist was unable to differentiate between the two samples in these two patients.

Dr Gan describes a laparoscopic Nissen Fundoplication, used to treat gastro-esophageal reflux disease, which was performed on a teenage girl, 'using a combination of the LiVac™ retractor with a Hasson port, two 5mm ports and a needlescopic 2.3mm grasper, leading to very insignificant scarring, little pain and most importantly, a very happy patient.'

The future of LiVac™

The future of Dr Gan's business appears bright, as patents have now been granted in Australia, New Zealand, the USA, Japan and China, and with patents pending in a number of other countries including the EU. The LiVac™ Retractor is still a new technology in the surgical field and awareness of this invention is just starting to grow. Using the LiVac Retractor does not change the fundamental techniques used during surgery. However, as with any new technology, there is a learning curve and support is available for surgeons interested in using the device.

The company's priority is to introduce the LiVac™ Retractor to interested early adopters, innovative surgeons who share the goal of truly minimally invasive surgery. When these surgeons have built up their experience with the LiVac™ retractor, then it will be time to do a comparative clinical trial with the Nathanson Retractor. Surgeons themselves may also come up with ideas and applications that can be incorporated into future developments.

It is important for surgeons to have options to choose from when performing surgery, based on the anatomy of the individual patient, such as their BMI, liver size, shape and pathology. On this natural variability and importance of a range of options, Dr Gan says, 'Laparoscopic surgery can be done in very different ways, from using multiple large calibre ports to few mini-laparoscopic incisions, and choosing the least invasive, yet safest, approach for a particular patient makes a difference.' The LiVac™ Retractor increases the options available to surgeons by providing a retractor that does not require an additional incision, is hands free and is gentle on the liver.

DR PHILIP GAN, DR ANABELA CORREIA & JUDY BINGHAM

Meet the researchers

Dr Philip Gan began studying medicine at the University of Melbourne in 1985, and became a Fellow of the Royal Australasian College of Surgeons in 2001. Dr Gan currently works as a consultant general surgeon at the St John of God and Southwest Healthcare Hospitals, Warrnambool, and the Portland District Hospital. He has a keen interest in minimally invasive laparoscopic surgery, including laparoscopic colorectal resections, hernia repairs, cholecystectomy, bariatric surgery, fundoplication and splenectomy (largest 2.6kg).

Dr Anabela Correia achieved her PhD in Medicine from Monash University and runs her own technology commercialisation business. She has over 10 years of experience in the field of commercialisation of medical technology and has worked as General Manager of Ipernica Ltd, senior consultant at PricewaterhouseCoopers and Commercial Business Development Manager at Monash Commercial.

Judy Bingham BPharm, FSHP, MHSc, GAICD. Judy Bingham is a registered pharmacist who worked in hospital pharmacy, medical affairs in the pharmaceutical industry and as a senior director for an international clinical research organisation before establishing her own consulting company, Easington. Judy now provides regulatory and clinical strategy, planning and management services, supporting medical technology companies to bring innovative new product to global markets

CONTACT

E: philip@livac.com.au
T: (+61) 408493286
W: http://www.livac.com.au

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