

« OPERATION ANUBIS »

A world first in no scar surgery

Press release April 26th 2007

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Operation Anubis

First “no scar” surgery.

On April 2nd 2007, at the University Hospital of Strasbourg, Professor Jacques Marescaux and his team successfully performed the first no scar surgery. This first human incisionless operation was carried out using a flexible endoscope for transvaginal removal of the gallbladder (cholecystectomy) in a 30-year-old woman with symptomatic gallstones.

This world first, called “operation Anubis”, was presented last week-end in Las Vegas at the Society for the Gastrointestinal Endoscopic Surgery (SAGES) to an enthusiastic audience.

Anubis was the ancient god in Egyptian mythology who presided over mummification and accompanied the dead to the hereafter. Anubis restored Osiris to life through mummification using long, flexible instruments. The project was named after this reference.

Change is part of surgery and change is never easy to accept. At the dawn of surgery, excellence was associated with big incisions: “big scar - big surgeon”.

In 1987 Philippe Mourét performed the first laparoscopic cholecystectomy. The Anglo-Saxons countries called it the “second French revolution”: minimally invasive surgery was born representing one of the greatest surgical evolutions of the 20th century.

Since its inception in 2004 the idea of endolumenal surgery has been till now only experimental.

An important step was made by the Columbia group in New York, United States on March 20th 2007 when a hybrid transvaginal cholecystectomy was performed with the assistance of three laparoscopic trocars (New York Times, April 20th 2007- San Francisco Chronicle, April 20th 2007).

Operation Anubis performed without incision, represents an extremely important step towards totally non-invasive surgery. The next challenge will be to validate other approaches, the transgastric route being the most appealing.

The justification of this technique are: - the reduction or absence of postoperative pain- ease of access to some organs- the absence of trauma to the abdominal wall- ideal cosmetic results and the psychological advantages of eliminating the bodily trauma represented by surgery. Lastly this provides proof that there are no limits to how human ingenuity and technology can reduce the physical and emotional trauma related to the surgical act.

The successful performance of the operation at the University Hospital in Strasbourg, is the results of three years of research under the Anubis project, labelled by the “Therapeutic Innovation Biocluster”.

This success exemplifies the healthy collaboration between different agencies: the government for initiating a dynamic biocluster- a world renowned Research Institute (IRCAD-EITS University Louis Pasteur Strasbourg) - a leader in the field of minimally invasive surgery (Karl Storz Endoscope®)- and the University Hospital of Strasbourg a key element responsible for a rapid transition of research into a clinical application available to patients.

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Description of the surgical procedure

This is the first “no scar” gallbladder resection ever performed.

Date: April 2nd, 2007-04-25

Location: Bloc Chirurgical A – Hôpitaux Universitaires de Strasbourg – Place de l’hôpital – Strasbourg, France

Team: Professor Jacques Marescaux, MD, FRCS, FACS assisted by : Bernard Dallemagne, MD - Silvana Perretta, MD – Didier Mutter, MD, PhD, FACS – Arnaud Wattiez, MD – Dimitri Coumaros, MD

Partners: University Hospital of Strasbourg – Ministry of Industry – IRCAD-EITS – Karl Storz Endoscopy

Description of the operation

(Figures 1-2-3-4)

The operation was performed by a multidisciplinary team lead by Professor Marescaux together with a gastroenterologist experienced in advanced flexible endoscopy, and a gynaecologist.

The peritoneal cavity was entered through an incision in the posterior vaginal vault. The transvaginal access to the abdominal cavity and the introduction of a flexible endoscope (KARL STORZ-Endoskope®, Germany) were performed under laparoscopic control by a 2 mm needle-scope. All the procedure was carried out using a standard double channel video flexible gastroscope and standard endoscopic instruments. All the principles of laparoscopic cholecystectomy were strictly respected. At no stage of the procedure there was a need of laparoscopic assistance. No complications occurred during the procedure.

The operation consisted of gallbladder resection (cholecystectomy) performed without scars on the abdominal wall. The procedure was performed using a flexible endoscope introduced into the abdominal cavity through an incision on the vaginal wall. The gallbladder was resected using a flexible endoscope and endoscopic instruments passed through its two working channels. The only “invasion” to the abdominal wall consisted of a 2mm needle equipped with a video camera system. This needle also served for gas insufflation necessary to create a working space within the abdomen and to monitor the intrabdominal pressure throughout the procedure.

All the principles of laparoscopic surgery were respected. The operation was performed alternating cutting and coagulating instruments for the dissection, special endoscopic scissors and endoscopic clips. Clips were used to close the artery responsible for the blood supply to the gallbladder and the cystic duct which drains bile from the gallbladder.

The image obtained by the flexible endoscope was excellent. At no stage of the procedure was there a need to switch to the conventional approach. The gallbladder was extracted through the vagina in a protected fashion using an endoscopic retrieval bag. The vaginal incision was closed with sutures.

The patient

The patient was a 30 year old woman who presented with multiple painful episodes due to gallstones. Working as an administrative assistant in a medical center she clearly understood the operative strategy leading to the incisionless removal of her gallbladder. She was informed of the limitation of this new technique and of the possibility of conversion to a laparoscopic procedure if needed.

Remarkably there was absence of any post-operative pain. Despite the uneventful postoperative course she was kept under observation for 48 hours.

Gallbladder resection (cholecystectomy): an historical reference for human ingenuity

"The abolition of pain in surgery is a chimera. It is absurd to go on seeking it. . . . Knife and pain are two words in surgery that must forever be associated in the consciousness of the patient. Dr. Alfred Velpeau (1839) French surgeon.

Change is part of surgery and change is never easy to accept.

At the dawn of surgery, excellence was associated with big incisions: "big scar - big surgeon". A surgery with no scars was an impossible reverie. Now Natural Orifices Transluminal Endoscopic Surgery (NOTES) is here, and the philosophy of surgery is doomed to be dramatically changed. Transluminal surgery has the potential to break the physical barrier between bodily trauma and surgery representing an epical revolution in surgery.

Beyond doubt, laparoscopic gallbladder resection is a model of phenomenon that changed the focus of surgery and the mindset of nearly all surgeons.

In 1882 K. Langenbuch successfully removed the gall bladder of a 43-year-old man who was suffering from cholelithiasis. His initial report was ignored. Nevertheless Langenbuch's open cholecystectomy remained the gold standard for symptomatic cholelithiasis for over a century.

In 1987, P. Mouret performed the first laparoscopic cholecystectomy with an approach that would become the standard technique within two year. His approach replaced the traditional incision with three or four ten mm incisions permitting the introduction of a camera and working instruments. Minimally invasive surgery was born representing one of the greatest surgical innovation of the 20th century. The world of general surgery was soon divided in two: a small group of enthusiastic surgeons, convinced by the superiority of laparoscopic over conventional cholecystectomy and a second very large group of surgeons with varying opinions, ranging from curiosity to frank condemnation.

The controversy was intense but short. In 1992, the NIH Consensus Development Conference Statement on gallstones and laparoscopic cholecystectomy concluded that in comparison with open cholecystectomy, laparoscopic cholecystectomy provided a safe and effective treatment for most patients and should become the treatment of choice. Since its advent minimally invasive surgery progressed rapidly. This was associated with miniaturization of both instruments and incisions from 15 to 10 to 5 mm.

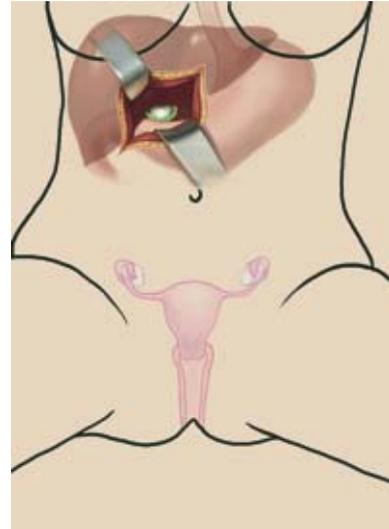
In 2001 Professor J. Marescaux performed the first transatlantic robotic cholecystectomy. This proved the feasibility of transmitting surgical gestures at a distance.

In 2004, Professor J. Marescaux was impressed by Professor A. Kalloo (John Hopkins Hospital, Baltimore) demonstrating a per-oral transgastric endoscopic exploration of the abdominal cavity in an animal model. Since then an era of exciting creativity and research has followed at a stunning rate. This experience was followed by multiple experimental programs in the United States. This gave birth to the concept of no scar surgery and the Anubis project was initiated.

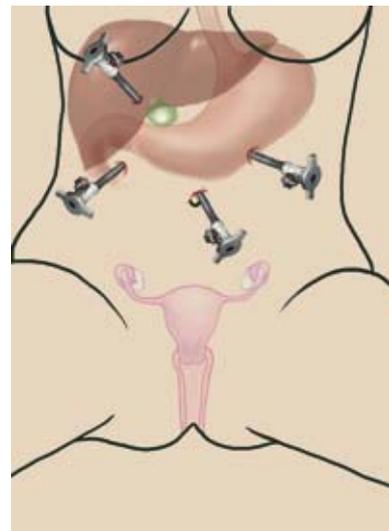
On April 2nd, 2007 Professor J. Marescaux and his team performed the first transvaginal cholecystectomy a few days after a group at Columbia university in new Your demonstrated a combined laparoscopic- endoscopic (transvaginal) cholecystectomy.

TREE SURGICAL STEPS FOR GALLBLADDER REMOVAL

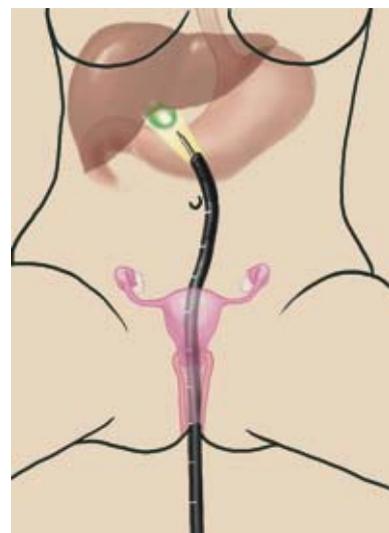
Open surgery



Laparoscopic surgery



Natural Orifices Transluminal Endoscopic Surgery



Natural orifices tranluminal endosurgery NOTES: the next revolution?

Natural Orifice Transluminal Endoscopic Surgery is a new evolution of the minimally invasive surgery concept that was initiated by laparoscopic surgery and interventional endoscopy. It consists in approaching the peritoneal cavity by an incision in the wall of a hollow intra-abdominal viscera: stomach, colon, vagina, bladder. This viscera will have been reached with a flexible endoscope introduced through a natural orifice (mouth, vagina, anus or urethra). There is therefore no longer an incision of the abdominal wall.

Described in 2004 by Dr. Anthony Kalloo of John Hopkins Hospital, this concept has seen numerous experimental works aiming at establishing its constraints and the potential solutions. The initial enthusiasm was amplified by the works of Dr. Reddy of the Asian Institute of Gastroenterology in Hyderabad who presented a clinical application of the appendectomy realized through a combined laparoscopic and transgastric route.

Amongst the different routes that were tried (transgastric, transvaginal, transcolic, transvesical), only the transvaginal route is currently valid. Indeed, numerous gynecological procedures are realised daily through the vaginal wall.

The potential advantages of transluminal surgery through natural routes are eased access, diminished surgical trauma and great cosmetic results.

Transluminal access to the abdominal cavity can be especially advantageous for an obese patient in which the developed adipose tissue makes the access through a conventional route difficult. The absence of incisions of the abdominal wall should avoid complications that frequently disturb traditional operations: infections, abscess, breaks in suturing, that often need an extra surgical procedure.

A less aggressive surgical procedure can diminish operative and post-operative stress, pains, morbidity and hospital stay. Identical advantages had been found in studies comparing laparoscopic and open surgery. We can therefore legitimately say that comparable results could be demonstrated in future studies comparing laparoscopic and transluminal surgery.

As for a cosmetic advantage, it is evident as no cutaneous incisions are associated with transluminal surgery. The absence of scars is appreciated as much by men as it is by women, as scars remind the patients of the disease that led to the surgical procedure.

To resume, **the justifications for this surgery are** : - less or no post-operative pain –eased access to certain organs – the absence of trauma to the abdominal wall – the cosmetic advantage and its corollary, no scars to remind of the operation – finally, the proof that there is no limits to human ingenuity and to technical developments in order to diminish physical and emotional traumas linked to classic surgery.

The Anubis Project: three fields of action in one: a successful example from the Competitive Centre “Therapeutic Innovations” with a global vocation.

The Competitive Centre “Therapeutic Innovations” has three fields of action.

1. The Anubis Project

The title refers to Egyptian mythology, whereby Anubis realized the first mummification and gave life back to Osiris with the use of long and flexible instruments. The project aims to develop surgery via the body's natural orifices.

The Anubis Project's ambition is to position France as world leader in this new surgical technique by developing new surgical tools associated with high-level training.

Since 2005, more than 150 surgical operations have been performed at IRCAD on animal models, aiming to show the feasibility of the technique, its safety and potential.

In parallel, several prototypes of flexible endoscopes have been developed in direct collaboration with an industrial partner, Karl Storz Endoscopy.

The first successful surgical operation on a patient is the fruit of three years of research and the sharing of competences of the medico-surgical teams, engineers and industry.

2. The “Therapeutic Innovation Biocluster” Centre

Set up on 12 July 2005 and given a governing structure on 13 September 2005, fully operational by January 2006, the “Therapeutic Innovations Biocluster” has the ambition to become one of the first world clusters in the field of therapeutic innovations.

To realize this ambition, the centre selects and supports innovative co-operation projects between private and academic partners. Anubis was one of the first projects supported by the centre – it can be found in the centre's application files – and the first project to receive State financing to the tune of 2 million euros, for a project total of 7.2 million euros.

The results of this project, which have been announced today, are not only in advance of the original schedule but show that the prospects for industrial development are emblematic of the potential for successful collaboration between the public and private sectors.

3. IRCAD – EITS : European Institute of Telesurgery

Aware in 1993 of a rapid evolution from the industrial era to the Information Technology (IT) era, the Professor Jacques Marescaux created a private structure dedicated to fundamental research on cancer (IRCAD) and to the development of new technologies **in the surgical field (EITS)**.

The idea was to create a center where surgeons, doctors, researchers, engineers and computer scientists could conjugate their energy in a dedicated and dynamic institute. The challenge was to innovate and demonstrate to show the creative strength of Europe, and develop a highly rated training center as the spread these new technologies could not be conceivable without appropriate training.

The goals of the IRCAD are to elaborate and develop the surgical tools of the future and integrate technological advances to the surgical field, and manage in that way surgical procedures assisted by computers.

Since 2004, the institute has worked proprietarily on the feasibility of no scar transluminal surgery.

Besides, it was necessary to develop in parallel of this up-coming technology, an adequate environment for its training.

Thanks to exceptional training facilities (8,000 sq.m), IRCAD-EITS is able to welcome over 3,000 surgeons every year from all surgical specialities, while developing its applied research departments in the field of computer technologies and surgical robotics. IRCAD-EITS has acquired a solid reputation as a centre of excellence : Every year, we are training 3 000 surgeons coming from more than 70 different countries and we can count on the involvement of 900 international experts.

IRCAD-EITS is world renowned in surgical training, and is now one of the top surgical schools.

The first international course in transluminal surgery will be held at the IRCAD the 4 and 5th of may 2007: the course was fully booked in two days, confirming the enthusiasm of the surgeon community for a new surgical revolution full of promises.

In parallel to training in new techniques at the centre in Strasbourg, the IRCAD has created **Virtual University specialized in minimally invasive surgery**, « WEBSURG » (www.websurg.com), accessible all over the world via Internet, available in French, English, Japanese and soon in Chinese. The 70 000 monthly connections of surgeons from all around the globe witness the successfulness of the project.

During its research on robotic assisted surgery, the IRCAD was distinguished in September 2001 by successfully completing the first telesurgical operation between Strasbourg and New-York, called " Operation Lindbergh". The success of this transatlantic operation confirms the globalization of surgical procedures.

4. Karl Storz Endoscopy

Since 1945, when Dr Karl Storz created the enterprise, the name KARL STORZ is synonymous with innovation and state of the art in all fields of medical endoscopy and mini-invasive surgery. The introduction of novel instruments such as the cold light and the HOPKINS lens contributed not only to the excellent reputation of KARL STORZ in the field of endoscopy but also to the international success of the company. KARL STORZ is today represented worldwide by more than 3800 employees and 8 production sites located in Germany, Switzerland, USA, Scotland and Estonia, and 25 affiliates in 24 countries.

This Tuttlingen-based company was responsible for the development of many medical innovations in the field of minimally invasive surgery.

KARL STORZ is not just limited to the development of standard instruments and optics. Many essential contributions in the field of video-endoscopy can be attributed to KARL STORZ. With surgical endoscopic

intervention of increasing complexity, real-time imaging is essential, necessitating specially adapted high-quality video technology.

The present work of the company focuses on OR1, the concept of an 'intelligent' operating room which allows for the integration of different technologies into a single control center. This concept centralises the control of various surgical instruments and other equipment into a single touch screen or vocal command.

OR1 also offers the possibility of telemedicine, telementoring and video-conference. This system is ideal for situations when a surgeon requires the advice of an expert, which can be transmitted in a virtual fashion.

In addition to medical instruments for humans, KARL STORZ also produces optics and instruments for veterinary medicine and industrial applications.

5. University Hospitals of Strasbourg

Located in the heart of Alsace, the University Hospital of Strasbourg has become a vast collection of seven establishments offering a 2696 hospital beds and employs 11000 people with an annual operating budget of 684,58 millions of euros.

The University Hospital of Strasbourg serves three missions: healthcare, education and research.

Classified in the 5th rank of the French University Hospital Center, the University Hospital of Strasbourg performs 35.640 major surgical intervention per year in 60 operating rooms. Furthermore 796 464 out patients are seen yearly.

The University Hospital of Strasbourg is responsible for teaching 1100 students.

Accredited by the National Institute of Health without restriction in 2005, our Regional University Hospital Center (CHRU) is dynamic and striving to achieve the highest levels of health care delivery at all times. Patients have access to state of the art technology and clinical care.

Perspectives

1. Clinical applications

Experience has shown that surgical ingenuity had boundless limits.

In 1987, when Philippe Moret described laparoscopic surgery of the gall bladder, the vast majority of surgeons considered that, in view of its technological limitations, this technique would be reserved for very precise and limited cases.

Twenty years later, more than 80% of cholecystectomies of all origin are carried out by laparoscopic approach.

In 1991, when surgical teams described laparoscopic surgery of digestive tract cancers, scepticism was intense. In 2007, however, the scientific community recommends laparoscopic surgery for colon cancer.

Transluminal access to the abdominal cavity has opened up a new era, the limits of which are still difficult to define.

Since the initial description of this new surgical approach by Kalloo in 2004, numerous operations have been developed on animals: liver biopsies, digestive anastomoses, ligation of urine ducts, removal of the spleen, of the uterus. All these operations were of an experimental nature. Surgeons were looking at the technique's potential, but also and especially at its limitations, so that they could contribute to the growth of technical innovation.

It is quite possible that only a few of these operations will become clinically feasible. It is also certain that other development possibilities have not yet been imagined.

Laparoscopic surgery has become a replacement for conventional surgery; transluminal endoscopic surgery will bring new therapeutic concepts.

Transluminal surgery will initially be favoured for the treatment of benign infections. Their frequency and socio-economic consequences will be the motor for technological development. If the hypothesis of a reduction in the aggressiveness of surgery is confirmed, it cannot be excluded that several operations could be repeated with ease, with no consequences for the patient, as is the case today for endoscopy. Operations performed on an out-patient basis could well be imagined.

The treatment of obesity by transluminal surgery will certainly be amongst the most important development priorities in national health programmes.

Gastro-oesophagus reflux syndrome, appendicitis, removal of benign liver tumours, of the adrenal gland or other viscera will rapidly find a solution with this new approach.

Cancerous pathologies will be approached with caution, but also with an open mind.

2. Virtual Reality, Augmented Reality and Robotics applied to N.O.T.E.S

The success of Natural Orifice Transluminal Endoscopic Surgery is dependant on the efficiency, security and reproductibility of the surgical gesture. Apart from the need for the development of new instruments, several other limitations exist which means that this surgery remains difficult to perform efficiently.

The first difficulty of this gesture is the loss of several senses. For instance, the reduction in the sense of touch already noted in laparoscopic surgery is here greatly increased by the length of the flexible instrument. It is then almost impossible to know by this sense alone when an instrument touches an organ. In current robotic surgery, this lack of force feedback has been solved by accurate stereoscopic vision. This stereoscopic vision is achieved thanks to the use of two cameras which would be complex to accomplish. Another possibility is to use virtual reality and augmented reality. Indeed, virtual reality techniques allow a pre-operative 3D visualization of the patient that can be manipulated in real time through the use of a patient-specific surgical simulation (figure 1).

In addition, augmented reality techniques superimpose this 3D image on the real image (figure 2). Thanks to augmented reality it is thus possible to compensate the lack of the sense of touch with a visualization of these forces or by providing an artificial 3D view included transparency.

One of the other main difficulties of NOTES is the loss of orientation due to the flexibility and length of the optic. However, the flexibility allows us to see and work on the same target from several different directions without having to turn the flexible endoscope but only by defining the parameters of the two possible rotations of the flexible end-tip of the fibroscope.

Such difficulties could be solved by combining robotics and augmented reality. Indeed, robotics could control with a high precision the end-tip of the flexible endoscope and instruments. What is more, recent developments performed at IRCAD by Professor De Mathelin's AVR robotic team demonstrates that it is also possible to control in real-time and automatically the whole flexible endoscope in order to keep a selected target in the center of the endoscopic view.

In a near future, by combining robotics and augmented reality, it will be possible to overcome the current limitations of NOTES and perform extremely safe procedures with no scars.

Biography – Professor Jacques MARESCAUX

Jacques Marescaux was born on August 4, 1948. His parents were both university teachers. He quickly set his sights on a medical career and his passion increased as he advanced in his medical studies. This commitment was apparent in his ranking at the top of his class each year, including the top score on the internship exam in 1971

As an intern he was shaped by the life-giving potential of gynaecology, the exacting focus of the orthopaedic surgery, the precision of the cardiovascular surgery and the diversity of visceral surgery.

Upon completing his internship, he decided that surgery could never be an end in itself and could not be disassociated from scientific studies, in particular applied in clinical research. This led him to join a team of researchers at INSERM, the French Institute of Health and Medical Research.

Thanks to this exceptional scientific collaboration, he was able to apply and obtain a position as University Professor extremely early in his career, at the age of 32, in the Digestive Surgery Department.

Professor Marescaux rapidly established his initial contacts with the business world, which was largely and unfairly kept at a distance by the French University Community, despite the substantial logistic resources available. Indeed, the world of business excelled in the same areas that underpin the development of medical research: efficiency, unyielding, professionalism and a profound sense of ethics.

In 1992, he decided to create a truly innovative structure for teaching and research. On the one hand, this enabled him to pursue research beyond the somewhat uniform criteria of state-run institutions, inspired largely by research in basic disciplines and thus far removed from the issues facing surgeons. Equally important, this structure provided a platform capable of initiating technological revolutions, rather than simply experiencing their impact. Advanced communications resources create cultural and political challenges on a truly global scale, and Professor Marescaux was firmly convinced that surgeons could not only play a role in this information revolution, but also act as a high-profile ambassador.

These ideas came to fruition with the inauguration in June 1994 of IRCAD (Institut de Recherche contre les Cancers de l'Appareil Digestif – Institute for Research into Cancer of the Digestive System) and ETIS (European Institute of Telesurgery). Here basic science researchers, technicians, computer engineers and teachers from around the world could work together to drive advances.

In 2004, attracted by transluminal surgery through natural orifice, he initiated the ANUBIS Project supported by the French Ministry of Industry and in close collaboration with Karl Storz Group.

In 2007, IRCAD is at the origin of approximate 1 950 international and scientific publications and communications and trains more than 3000 surgeons coming from all over the world.

Professor J. Marescaux, Chairman Department Digestive and Endocrine Surgery, University Hospital of Strasbourg since 1989, President IRCAD/EITS since 1994, Member of numerous International Scientific Associations: -Founding Member of the French Society of Endocrine Surgeons – Secretary of the French Society of Digestive Surgery – Founding Member of the French Association of Hepatobiliary and Transplantation Surgery – President of the Scientific Council of the Commission d'Evaluation de l'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES from 1997-2000) – Member of the National Council of Universities – Member of the Board of Directors of the French Society of Laparoscopic Surgery – Member of the Scientific Committee of the European Association for Endoscopic Surgery – Member of the International Society of Surgery – Member of the European Society of Telemedicine – Member of the International Organization for statistical studies in the field of Oesophageal Disease – Member of the International Association of Endocrine Surgeons – Member of the International Gastric Cancer Association – Member of the National Academy of Surgery – Corresponding Member of the National Academy of Medicine – Honorary Member of Royal College of Surgeons of England – Member of the European Surgical Association – Member of the Society of American Gastrointestinal Endoscopic Surgeons.