Magnetic Surgery

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I dedicate this book to my children, Xavier, Guillaume, and Maxime, and spouse, France, for all their moral support during the COVID-19 pandemic.

Foreword

From idea to reality, Professor Michel Gagner does it again. In the quest for more and more minimally invasive access, surgeons have imagined harnessing magnetic energy. Powerful magnets can be swallowed, inserted thru ports intraabdominally, or placed on the skin surface. Considering the potential is only limited by your imagination.

The World Congress of Laparoscopy, hosted by SAGES in 2018, offered a panel session entitled "Magnet Surgery: What's the Attraction?" co-chaired by Michel Gagner of Canada and Marcos Berry of Chile (Fig. 1). Topics pre-

Fig. 1 Speakers of the World Congress of Laparoscopy, hosted by SAGES in 2018, panel session entitled "Magnet Surgery: What's the Attraction?". From left to right, back row: Dr John J Vargo, Dr Michael Harrison, Dr David W Ratner, Dr Galvao Neto, Dr Homero Rivas and Dr Eric G Sheu. Front row: Dr Michel Gagner and Dr Marcos Berry

sented included physical properties and toxicity of magnets, magnetic rings for reflux, magnets for birth defects in pediatric surgery, use of magnets in flexible endoscopy, magnetic retraction, laparoendoscopic GI anastomosis, and endoscopic bowel anastomosis. The session was well attended by surgeon innovators.

On the heels of the panel, Dr. Gagner embarked on the textbook *Magnetic Surgery*. The contributors include visionary surgeons from around the world: Marcos Berry, Eric Sheu, Luigi Bonavina, Homero Rivas, and Galvo Neto. Topics focus on endoluminal and laparoscopic operations, techniques from vascular and GI anastomosis. The book demonstrates the use of magnets to treat a variety of diseases such as reflux, back pain, and fecal incontinence. The reader will learn how to retract and gain exposure, dissect tissue planes, achieve hemostasis, and create anastomosis in a totally different way. Physical properties of external surface and internal magnets are discussed. The authors emphasize the importance of partnering with industry leaders to develop novel surgical tools.

Professor Gagner has been a pioneer in MIS surgery. He has many firsts and was an early adopter of laparoscopies Whipple, endoscopic parathyroidectomy, MIS adrenalectomy, and sleeve gastrectomy. With tiny incisions, patients have experienced less pain, smaller scars, and faster recuperation. In 2017, Dr. Gagner was recognized with the SAGES George Berci Lifetime Achievement Award for Innovation in Surgery. Having advanced surgery from open to laparoscopy, to micro-laparoscopy, to SILS, NOTES, and robotic surgery, Dr. Gagner reimagines surgery now with magnets.

Magnetic Surgery is a glimpse today into what is possible with a little imagination, curiosity, and persistence. Magnets will surely enable tomorrow's surgery in ways we have yet to conceive.

Daniel B. Jones
Professor of Surgery, Harvard Medical School
Boston, MA, USA

Preface

Magnetic surgery is not new, but it is an expression that will be used more frequently in the next several decades. Indeed, China has taken this field very seriously and arranged the first international conference on magnetic surgery in Xian, China, also known as Chang'an or Eternal Peace, a famous imperial city, which had the largest palace on Earth [1]. The scientific committee was comprised of mainly Chinese nationals like Bo Wang, Jianhui Li, Jigang Bai, Rongqian Wu, Shiqi Liu, Xiaopeng Yan, Xin Zhang, Xufeng Zhang, Xuemin Liu, and Truman Cheng; Claire Elizabeth Graves and Mario F. Zaritzky from the USA; Catherine Sim Co from the Philippines; Ibrahim Uygun from Turkey; Luzia Toselli from Argentina; Tim Helge Fass from Ireland; and Vitalii Zablotskii from the Czech Republic.

Their goals are to commence regular international conferences to be held worldwide, that a Magnetic Surgery Alliance (MSA) be recognized for clinical and experimental advancements, and a book "Magnetic Surgery" discoursing the latest progresses and outlook of magnetic surgery be outlined and published. This last desideratum is fulfilled by my book *Magnetic Surgery*. This idea of a book encompassing the different concepts and designs using magnets for surgical purposes has been in my mind for several years and certainly began to materialize before the SAGES conference in Seattle, which took place at the same time as the 16th World Endoscopic Surgery met.

Dr. John H. Marks, the program chair of SAGES 2018, had contacted me to propose an innovative session of 90 minutes for SAGES 2018. This had probably been discussed during the program committee hearings in Houston, March 2017, when Jon C. Gould was chairing that group with Sallie Matthews, the SAGES executive director, and I had made suggestions to attract an international audience at the meeting. Dr. Marks had asked me to propose an innovative session, being a member of the SAGES program committee for a very long time, and I wanted to do a full session on magnetic surgery and assemble the innovators accomplishing this.

On March 26, 2017, I invited Dr. Marcos Berry from Chile to participate and be my co-moderator for that innovative session, as he was a user of magnets for laparoscopic assistance. We, in fact, had already conferred about it during SAGES 2017 in Houston, and envisioned some additional topics/speakers. So, the same day, March 26, 2017, wasting no time, I sent to Dr. Marks a first draft of the proposed session, called "All About Magnets." There was no question in my mind that all teams working on these concepts had to be invited to the table to present, foster a super discussion, and hopefully stimulate the audience about what is coming. It was Richard A. Hruska from Springer, Executive Editor of Clinical Medicine, based in New York, who officially invited me to make this book project a reality on March 20, 2018. He was involved with other SAGES books, which are great successes, and had perused the SAGES program ahead of time and was intrigued about our session. He could not join us in Seattle for the meeting, where our session took place on April 11, 2018. He suggested that as an outstanding clinician as well as a dedicated researcher and educator, I was clearly the ideal authority to be editor of such a volume and would very much like to discuss either a project developing from that session or one developing from my recent work in the field. Hence, the book was born.

SAGES 2018 was special, because the 16th World Congress of Endoscopic Surgery also took place, and had a mega audience, under the auspices of President Dr. Daniel B. Jones from Harvard Medical School. The World Congress, at the Washington State Convention Center from April 11–14, hosted surgeons from over 16 international societies, representing 6 continents, and over 80 countries. The proposed session was one of the very first morning sessions of the meeting and had a full large room audience. The final program was delivered to SAGES on August 2, 2017, with the final title [2] “Magnets in Surgery: What’s the Attraction?” After the two co-moderators welcomed the audience, the session began with a talk on “Physical Properties and Toxicity of Magnets Used for Surgical Applications” by Eric G. Sheu, MD, Boston, MA, followed by “Magnetic Rings for Reflux” from David W Rattner, MD, Boston, MA. Then we shifted to compression anastomosis with “Magnets for Birth Defects in Pediatric Surgery” by emeritus professor Michael Harrison, MD, San Francisco, CA; “Use of Magnets in Flexible Endoscopy” by John J. Vargo, MD, from the Cleveland Clinic, Cleveland, OH (with whom I had the privilege to work with while I was an attending there); followed by “Magnetic Retraction for Laparoscopic Cholecystectomy” by Homero Rivas, MD, Stanford, CA; and a similar topic on “Magnetic Retraction for Laparoscopic Sleeve Gastrectomy” by my co-moderator Marcos Berry, MD, Santiago, Chile. I presented on the topic and first patents that I have been working on since 2007, in “Laparo-endoscopic GI Anastomosis.” “Endoscopic Bowel Anastomosis” by Galvao Neto, MD, Sao Paulo, Brazil, well known in advanced bariatric endoscopic procedures, closed the session.

Strong from this base, though the session would not allow more speakers (in my mind it could have been a whole day symposium with other subjects and topics), I decided to welcome more authors on additional interesting applications of magnets in other fields of surgery, because concepts can be cross-linked easily if we all talk about them. I have been involved as co-editor on many books, but this is the first time, apart from my Ph.D. thesis, in which I am the sole editor.

I think this book, the very first of its kind, will be a breakthrough, a leap forward in a new field of surgery, to harness the power of attraction, the energy and might of magnets, a force of nature, to realize health improvements to benefit millions of patients worldwide.

Montréal, QC, Canada
Michel Gagner

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Editor and Contributors

About the Editor

Michel Gagner is a well-respected surgeon known for his contributions to laparoscopic and bariatric surgery. Born in Montreal, Quebec, Canada, he first studied at the Séminaire de Sherbrooke where he obtained a Quebec college diploma in 1978 followed by an M.D. from Université de Sherbrooke in 1982. Completing his residency in general surgery at McGill University in Montreal, during which time he conducted research studies on human lipolysis in sepsis, he went to Paris, France, to complete a fellowship in liver surgery, and he endured a second fellowship in pancreas and complex GI surgery at the Lahey Clinic in Massachusetts.

In 1990, Dr. Gagner accepted his first teaching appointment at the Université de Montréal School of Medicine as an assistant professor of surgery (Hotel-Dieu de Montreal), during which time he introduced his skills in laparoscopic surgery. As a pioneer of robot-assisted surgery, world's first laparoscopic removal of the adrenal glands, the liver, bile duct, and pancreas, he eventually made his way to the USA to practice at the Cleveland Clinic Foundation in Ohio where he co-founded the Minimally Invasive Surgery Center. There he pioneered the use of endoscopic surgery for parathyroid and thyroid tumors in humans. He then became the director of the Minimally Invasive Surgery Center at Mount Sinai School of Medicine in New York, chair of the laparoscopic division, and earned the title Franz W. Sichel Professor of Surgery. There he pioneered telesurgery with Professor Marescaux and Leroy of Strasbourg, the first transatlantic robot-assisted surgery, published in Nature in 2001. Dr. Gagner later became head of the laparoscopic and bariatric surgery section at Cornell University's Weill Medical College (New York City).

After his tenure as chief surgeon at Mount Sinai Hospital in Miami and professor of surgery at Florida International University, Dr. Gagner is now working at Sacré-Coeur Hospital, affiliated to Université de Montréal, as a professor of surgery and senior consultant. He also owns the Westmount Square Surgical Center, a private clinic specialized in bariatric surgery for weight loss and metabolic surgery for type-2 diabetes.

World renowned in laparoscopic and bariatric surgery for weight loss, the clinic of Dr. Gagner, which is located in Montreal, specializes in the laparoscopic sleeve gastrectomy, which he pioneered in 2000, as well as laparoscopic duodenal switch, which he was the first to perform in 1999, and various new innovative endoscopic treatments for obesity, type-2 diabetes, and gastro-intestinal tract disorders.

The author and co-author of more than 400 publications and 11 books, including the *Atlas of Hepato- Pancreatico-Biliary Surgery*, *Endocrine Surgery* (second edition), and *Perfect Sleeve Gastrectomy*, Dr. Gagner is also a patentee in his field, especially on new methods to treat obesity and GI anastomosis. An elected fellow of the American College of Surgeons, the Royal College of Surgeons (Canada), and the American Society for Metabolic and Bariatric Surgery (ASMBS), he is also a honorary member of the Academie Nationale de Chirurgie de France, the Association Francaise de Chirurgie, the Mexican Laparoscopic Surgery Society, the Colombian Surgical Society, the Brazilian Surgical College, the Peruvian Surgical Society, and the European Association for Endoscopic Surgery.

Dr. Gagner received a medal from the city of Marseille, France, in 2017, SAGES Pioneer in Surgical Endoscopy Award (2017), 21st Oliver H. Beahrs Professorship (Mayo Clinic 2016), Surgical innovation award from the ASMBS (2016), a 2011 Excel Award by the Society of Laparoendoscopic Surgeons, a 2010–2011 French National Assembly Award, and Medal of the City of Bordeaux, Nice, and Sete, France. He has been highlighted in many editions of Who's Who in America, Who's Who in Medicine and Healthcare, Who's Who in Science and Engineering, Who's Who in the South and Southwest, and Who's Who in the World. Married to France Lapointe, Dr. Gagner has three children (Xavier, Guillaume, and Maxime).

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1 Introduction: Ideas and People Leading to Successful Products for Patient Care Leading to Magnetic Surgery

Michel Gagner

> There is nothing more powerful in the world than the idea that came in time.
>
> Victor Hugo (1802–1855)

Compression anastomosis has come and gone in the last century, and apart from sutures and staples, there has been nothing innovative and fresh, yet we are capable of much progress. Those efforts today, are "en phase" with the movement of minimally invasive surgery that took off at the end of the eighties in the last century, especially with laparoscopic cholecystectomies between 1985 and 1988, from pioneers like Erich Muhe from Boblingen Germany, Francois Dubois from Paris, Philippe Mouret of Lyon, Jacques Perissat from Bordeaux France, Barry McKernan and William Saye in Marietta Georgia, and Eddie Joe Reddick from Nashville, USA [1]. After a year at the Lahey Clinic in complex biliary and pancreatic surgeries, I left Burlington Massachusetts for a short mini-fellowship in laparoscopic surgery with Drs Reddick, Doug Olsen, and Al Spaw from Nashville, in the hot and humid heat wave of July 1990. After my return to Montreal, I became interested in fashioning anastomosis laparoscopically in early fall of 1990, at the Hotel-Dieu de Montreal, the historic hospital affiliated with the University of Montreal, while I started my career as a young surgical attending and teaching enthusiastically, almost religiously, laparoscopic cholecystectomy to many surgeons from Eastern Canada and New England [2]. When I tried a colonic resection but was unable to make any connection with the two segments and had to exteriorize them to make a conventional anastomosis outside the abdominal wall, I was unaware that Moises Jacob and his team from Miami were also working on something similar, mainly exteriorizing the bowel segments outside the patient abdominal wall and making a hand-sewn or stapled conventional anastomosis [3]. The major inconvenience of this "laparoscopic assistance," of course, was the incision needed, decreasing the advantage of laparoscopy for the patient, causing pain, infection, and hernia risks, and possibly higher dehiscence, slower recovery, and worse cosmesis. In order to continue with the "pure" laparoscopic surgical concept and not involve open surgery, I had to do mostly left-sided colon lesion, trying to remove the specimen transanally and creating the anastomosis with laparoscopic endoloops, putting the anvil of an EEA in the proximal colon (delivered again transanally) and another endoloop closing the distal bowel, trying to make an anastomosis that would be full thickness without any parts slipping and requiring intracorporeal suturing, as needle drivers and efforts to do so were in their infancy. This prompted efforts to do compression anastomosis using the "open" BAR Valtrac device, which I worked on in a porcine model. Laparoscopic staplers were not

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available in the first years of 1990s, and nobody was doing any sort of stapled intracorporeal anastomosis until 1991–1992, except for transanal EEA end-to-end anastomosis with the circular stapler. The innovation of the laparoscopic stapler by US Surgical, led by Leon Hirsch, kind of killed the ongoing efforts of compression anastomosis at that time and put it on the backburner.

On the commercial development of the traditional open stapler and the laparoscopic form, one man stands out, Leon C. Hirsch. "Lee Hirsch" was born July 20, 1927, grew up in the Bronx, and had made his business apprenticeship in advertising, eventually creating his own company in 1948, the Lebow, Hirsch, and Windley. Several other companies followed in the 1950s, until the Soviet Union's surgical staplers were trying to make an entry in the USA market, which led to the establishment of United States Surgical Corporation in 1963, a Connecticut-based medical technology company, where Mr. Hirsch was the Founder, Chairman, and CEO of the corporation.

Since their development in 1908, surgical staplers have been utilized as a process of "mechanical suturing" in efforts to partition hollow visceral organs and fashion anastomoses in an effective and sterile methodology [4]. The concept for the surgical stapler was first exploited by Humér Hultl, a Hungarian surgeon and professor, and reconceived by Victor Fischer, a savvy Hungarian businessman and creator of surgical instruments. The design was highly praised. Nevertheless, it was too large, awkward, and costly to produce [4]. Aladár Petz, a student of Hultl, integrated two innovations to the Fischer-Hultl stapler to generate a lightweight model in 1920, which was named the "Petz clamp" [5]. Then in 1934, Friedrich of Ulm Germany fabricated the next generation of the modern-day linear stapler. In parallel, Russian staplers began to emerge in the 1950s, and one ended up on the desk of Leon C. Hirsch [4, 6].

Indeed, on a 1958 trip to the Soviet Union, Mark Ravitch learned that Russia had made headway in perfecting the surgical stapler. Ravitch had worked with and visited Russian colleagues, including Pavel Iosifovich Androsov, and then conferring with and working to convince Leon C. Hirsch. Dr. Mark Ravitch was Professor of Surgery at Johns Hopkins University, and they thought that a cartridge could be created with the Russian stapler to make it simple to use for daily gastrointestinal surgeries. Pavel Iosifovich Androsov and Alexey Alexeevich Strekopytov, both from Moscow, USSR, filed this patent on Christmas Eve December 24, 1962, 2 months after the Cuban missiles crisis, published in the gazette on May 24, 1966 and given the number 3,252, 643 for a surgical stapler that is now reminiscent of the full metal TA [7–11].

After Hirsch made an initial investment of $50,000 to make prototypes, Zanvyl Kreiger, part owner of the Baltimore Orioles baseball team and major donor to Johns Hopkins University, agreed to contribute more than $2 million in loans to the company. It took more than 3 years and $3 million to develop the first series of AUTO SUTURE staplers, which came to market in 1967. In 1967, in its first year as an operating business, USSC posted sales of just over $350,000. Fourteen years later, annual sales surpassed $100 million, and revenues reached $1 billion in 1992. In 1990, USSC launched the world's first laparoscopic clip applier, which I was happy to use for many patients, making possible a revolutionary new laparoscopic technique for gallbladder removal. The inventors Henry Bolanos, David T. Green, Lisa M. Heaton, Richard A. Mcgarry, Keith Ratcliff, and Wayne P. Young deposited the laparoscopic clip applier patent on the 18th of July 1989, with a Priority number of US07/381,265 on behalf of USSC. Most members of this team will be seen again later, for the laparoscopic stapler invention [12].

The benefits of this procedure were so dramatic that, without a randomized control trial, approximately 90% of the 600,000 gallbladder removals accomplished annually in the USA were converted to laparoscopy. Under Mr. Hirsch's leadership, USSC sales nurtured from $350,000 in its first year of sales (1967) to $1.5 billion in 1998. Zanvyl Krieger made a fortune and became a major benefactor for medicine, science, and arts in Baltimore. Ultimately USSC was acquired by Tyco International for $3.3 billion.

Certainly, in the world of compression anastomosis, the "Valtrac" by American Cyanamid, was successful. It began with Davis & Geck, a surgical/medical device company founded in 1909 by Charles T. Davis and Fred A. Geck in Brooklyn, NY, dedicated to surgical sutures, wound closure devices, and care. In 1930, during the great US Depression, the company was sold to American Cyanamid but continued as a division, later moving to Danbury, Connecticut, in the 1950s. Its most significant contribution to the surgical arena was the invention of the synthetic absorbable suture, including the Dexon (1970s), made with polyglycolic acid.

American Cyanamid, founded by Frank Washburn in 1907, was part of the Fortune 500 in the 1970s and 1980s and finally merged with American Home product in 1994, after a series of litigations for tetracycline problems and environmental damages from its manufacturing. Many of its subsidiaries ended in the hands of Pfizer, BASF, and Procter and Gamble. The Davis & Geck products and materials were sold to Sherwood, renamed Sherwood-Davis and Geck, and thereafter the CEO, David Low, tripled the sales to 1 billion dollars and retired in 1997. Tyco Corporation bought Sherwood-Davis on Dec. 22, 1997 for $1.7 billion. In an acquisition spree, Tyco International Ltd. also acquired US Surgical Corp. from Leon C. Hirsch, a maker of disposable medical sutures and staples, for nearly 3.3 billion in stock. The combination led to the creation of Covidien later in 2007, and Tyco Corporation renamed the suture line from Sherwood-Davis as Syneture. Tyco eventually decided to sell its healthcare division and Covidien, Ltd. to Medtronic plc in 2015.

The patent for the biodegradable anastomosis ring (BAR), sold under the name of Valtrac, was awarded to Thomas G. Hardy of Columbus Ohio, who had a similar nonabsorbable design, reminiscent of the Murphy button, a few years back. He was aided by Alan L. Kaganov from Danbury, Connecticut, and W. G. Pace of Columbus, Ohio, on behalf of the American Cyanamid Company, Stamford, Conn.; Appl. No. 287,500, filed on July 27, 1981 [13]. According to the patent description, the special anastomotic device was characterized by engageable locking slots supplied by mating prongs and a multiplicity of pawls carried by separate prongs which connect two ring members and retain it in a preselected position after being closed from the open position.

The Valtrac BAR accommodated different thicknesses of tissue and therefore could be used in a variety of circumstances and with pomp! The ring members and pinned prongs are so designed that they consist of a single unit that can be injection molded. The invention developed met the constraints of anastomotic surgery and provided a safe, reasonably economical, easy to use anastomotic device and was disintegratable! It was very successful for two decades but abruptly fell off after Leon C. Hirsch laparoscopic stapler developments were completed by USSC engineers. The irony is that both finally ended with the Medtronic family. The patent was called "Apparatus and method for placing staples in laparoscopic or endoscopic procedures," by inventors David T. Green of Westport, Henry Bolanos of East Norwalk, Daniel E. Alesi of New Fairfield, Keith Ratcliff of Sandy Hook, and Charles R. Sherts of Southport, all from Connecticut. This was assigned to United States Surgical Corporation of Norwalk, Connecticut with the application no. 358,64,622, filed on May 26, 1989, and issued a patent number 5,040,715 on August 20, 1991 [14]. The rest is history and led to an explosion of laparoscopic and robotic-assisted procedures for three decades [15].

The book initiates a dialog on the development of magnetic anastomosis, which is an extension of previous compression anastomosis. It is in fact an extension of the 16th World Congress of Endoscopic Surgery, SAGES, in Seattle April 11–14, 2018, during a special symposium I chaired called "Magnets In Surgery: What's The Attraction?" Many authors of the present book were presenters at that particular innovative and inaugural program. History and physical properties of using magnets are discussed in the first chapters, following with specific applications in the body. Some are simple and some are intricate. Some have led to successful companies like the development of magnet collar for gastroesophageal reflux. Indeed, I was presented with the first prototype by Pete McNerney who was the lead investor of Capital Venture, which supported the development efforts of Torax, the company that successfully led clinical trials of LINX.

Pete McNerney has over 30 years of healthcare operating and venture capital experience. He co-founded Thomas, McNerney & Partners, and Coral Ventures and has been involved with The Kensington Group, Memtec North America, and Baxter Healthcare Corporation, as a certified accountant, and has a B.A. from Yale and an M.B.A. from Stanford University.

Torax Medical was founded in 2002 by Sanderling Ventures, Mayo Medical Ventures, and veteran medtech entrepreneur Todd Berg. Dr. Timothy Mills was the managing director Sanderling Ventures and chairman and co-founder of Torax Medical, headquartered in St. Paul, Minnesota. Torax matured and promoted products conceived to treat sphincter disorders utilizing its technology proposal, a sort of magnetic sphincter enhancement [16, 17]. Torax Medical was marketing the LINX® Reflux Management System for the treatment of GERD in both the USA and Europe. Previously, it raised a total of $3.5 million in Series A financing from Sanderling Ventures and Mayo Medical Ventures, and in 2005, Torax Medical Inc. had completed a $10 million Series B round of financing, led by Thomas, McNerney & Partners, Minneapolis, Minn.; Sanderling Ventures, San Mateo, California; and Mayo Medical Ventures, Rochester, Minnesota.

Torax became very successful and was acquired by Ethicon EndoSurgery, a division of Johnson and Johnson in March 2017, for an additional 102.2 million. Torax had estimated annual revenues of $15.9 million, according to a report by the Cincinnati Business Courier. The company announced that it had completed a $25 million round of Series E financing before the J&J acquisition. Other investors included Sanderling Ventures, Thomas McNerney & Partners, Accuitive Medical Ventures, Kaiser Permanente Ventures, Piper Jaffray Companies, and Mayo Clinic Ventures.

My involvement with McNerney goes back to 12 years ago, when he had invested in EndoMetabolic Solutions Inc., a company I co-founded in Minneapolis with Dave Blaeser and the late Dale Spencer, in 2007, after both were extremely successful with ev3, Inc. Interestingly enough, Covidien had acquired this company in 2010 for 2.6 billion dollars. EndoMetabolic Solutions (obesity treatment devices) had closed a $3.8 million Series A round through five investors including myself, Thomas McNerney & Partners, 3 years after it had invested in Torax. Unfortunately, Dale Spencer passed away in November 2016. Dale Spencer had been chairman of ev3, Inc., and the former CEO of SciMed Life Systems Inc., a mechanical engineer from the University of Maine by training. He was a real leader at SciMed Life Systems until the merger with Boston Scientific in 1995, and the founder of eV3, which is now a part of global medical device leader Medtronic. As a start-up mentor for me, we liked to discuss mountaineering, which we both did separately in the South American Andes. Dave Blaeser, named CEO of EndoMetabolic Solutions, has been an active leader in the medical device industry for 35 years, steering teams at Boston Scientific, Velocimed, Nidus, Endometabolic Solutions-EMS, Libra Medical, and ZIFT Medical. Most recently, he was Founder and CEO of Ideal Medical Solutions, a medical device-consulting firm, and is the new CEO of Minneapolis-based medical device company, Resolution Medical, as of May 2020. EMS was ahead of its time in terms of having the right intellectual property, but the surgical field was not mature enough and ready for its IP. A very hard "great" recession in 2008, triggered by the housing bubble, with the collapse of several US banks, unemployment from 4.7% to 10%, made a difficult environment for a multitude of start-ups at the time, causing VCs to demand more equity for valuations down by 25–50%, and the expensive costs of raising capital made it very difficult for the next round for the large human clinical trial necessary for FDA approval.

Magnets used externally on the skin surface are used for laparoscopic retraction and surgical manoeuvring inside the abdominal cavity and are successfully sold by Levita Magnetics from San Mateo California. The person behind Levita is Dr. Albert Rodriguez-Navarro, Founder and CEO, is a minimally invasive general surgeon with more than 10 years of clinical involvement and was an Assistant Professor of Medicine at the Universidad de Chile. As a medical inventor, he has multiple patents and has published in international journals, especially in the field of post-operatory pain. Levita Magnetics is evolving minimally invasive surgery by reducing the number of incisions and improving surgical outcomes, with a technology platform that will enable magnetic surgery across an array of minimally invasive surgical procedures. Levita Magnetics was founded in Chile in 2012, has been solely funded by Chilean investors and CORFO, and is currently based in Silicon Valley. The company has a robust IP portfolio and is expecting both US and European regulatory clearances for commercialization. Greg Liu, a BS and MS in Mechanical Engineering from Stanford University, has helped Dr. Rodriguez-Navarro as their Chief Operations Officer; he has 25 years of product development and operations experience. Before this appointment, he held leadership roles at Luma Therapeutics, Acclarent, Google, and Google (x) and was a founding member of Verily Life Sciences (Google).

The very interesting endoscopic developments initiated by Endometabolic Solutions of Minneapolis is continued with GI Windows of West Bridgewater, Massachusetts, and by GT Metabolic Solutions from San Jose, California. Concerning GI Windows, it is now led by Brian Tinkham CEO, and according to the company's website, he is a leader in innovation and entrepreneurship, with significant prior roles at Medtronic as Vice President of Sales and New Technologies for the GI & Hepatology division. He was the co-founder of Beacon Endoscopic (acquired by Covidien 2014) and held global marketing and sales leadership positions at Boston Scientific. He apparently replaced James Wright, the first President and CEO of GI Windows, who led the company's first clinical series data presentation in May 2016. This company is aided by Marvin Ryou, M.D., the Chief Medical Officer and co-founder of GI Windows, who is an Assistant Professor of Medicine at Harvard Medical School and Associate Physician in the Division of Gastroenterology, Hepatology, and Endoscopy at Brigham and Women's Hospital and Director of Endoscopic Innovation and Education. He is the partner of Dr. Christopher Thompson who has been also on the board of this company. Very recently, on December 12, 2019, GI Windows had announced a $14.6 million Series A financing. Asia-focused healthcare investment firm GT Healthcare Capital Partners led this financing and Silicon Valley-based Sonder Capital. Dr. Galvao Neto's chapter will be discussing their initial efforts.

Concerning GT Metabolic Solutions, the company based in San José California, was co-founded by Dr. Michel Gagner and Thierry Thaure, in May 2020. It is a rebirth of EMS with its initial IP. Michel Gagner is the Chief Medical Officer and has spent 15 years in the USA as chief of laparoscopy or/and bariatric surgery at the Cleveland clinic, Mount Sinai School of Medicine, Weil Cornell in NYC, and chief of surgery at Mount Sinai Miami. He has more than 500 publications and 15 books in surgery and is an honorary member of the Academie Nationale de Chirurgie de France, the Association Francaise de Chirurgie, the Mexican Laparoscopic Surgery Society, the Colombian Surgical Society, the Brazilian Surgical College, the Peruvian Surgical Society, and the European Association for Endoscopic Surgery. Dr. Gagner also has received a 2017 City of Marseille, France, Medal, SAGES Pioneer in Surgical Endoscopy Award (2017), 21st Oliver H. Beahrs Professorship (Mayo Clinic 2016), Surgical innovation award from the ASMBS (2016), a 2011 Excel Award by the Society of Laparoendoscopic Surgeons, a 2010–2011 French National Assembly Award, and Medal of the City of Bordeaux, Nice and Sete, France.

Concerning Thierry Thaure, the Chief Executive Officer, who has over 35 years experience in medtech, is an entrepreneur and CEO. He demonstrated repeated successes in building businesses with disruptive technologies and driving their market expansions. He was previously CEO & Co-founder of Cephea Valve Technologies –

purchased by Abbott in 2020 for $200 M, CEO of EndoGastric Solutions, a private company leader in NOTES, launched technology SVP of Accuray, a leader in radiosurgery had taken them public, and was the founding VP of Sales & Marketing of Intuitive Surgical, a leader in surgical robotic, and had a key management roles at Guidant, Origin Medsystems, and Edwards Life Science. The company is also supported by key engineers like Hal Heitzmann, the Chief Technical Officer and previously Senior VP, R&D & Engineering, and Distinguished Scientist at Glaukos Corporation (GKOS, NYSE). He also held positions as Sr. Distinguished Engineer at Edwards Lifesciences and as VP, R&D at four medical device start-ups. He holds over 100 US and International patents and applications. He holds a Ph.D. in Molecular Biophysics and Biochemistry from Yale University. Todd Krinke is the VP Development and Lead Engineer; he held Principal and Senior Engineering positions at Conventus Orthopaedics, Travanti Pharma, St. Jude Medical, and Hutchinson Technology; he holds a Bachelor of Science, Aerospace Engineering & Mechanics, from University of Minnesota – Twin Cities. The initial team is extremely promising, "on ne change pas une equipe qui gagne."

With this book my hope is that the reader will be inspired about the future of surgery, pushing boundaries in the mid twenty-first century and beyond, all to create more minimally invasive procedures and interventions than we did with laparoscopic surgery at the end of the twentieth century. It appears that the surgical gestures of creating anastomosis will be delayed (I call this "DAT" for delayed anastomosis technologies), while creating a positive new tunnelling will disperse the negative effects of creating connections in the body, with fewer acute leaks, infections, strictures, and ulcerations and with a reduced inflammatory response. This is occurring with gradual wound healing, a slow and steady connection permitting optimal collagen deposition, and creating strength without foreign body reaction; that is DAT!

> Until you spread your wings, you'll have no idea how far you can fly.
>
> Napoleon Bonaparte

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Physical Properties, Toxicity, and Physiological Effects of Magnets

2

James N. Luo and Eric G. Sheu

Brief History of Magnets

Magnets have been a part of human civilization for millennia. The ancient Greeks described the magnetic lodestone as early as the sixth century B.C. According to legend, a Greek shepherd named Magnes, while living in the region of Magnesia, first noticed that metallic debris and even the tip of his staff were attracted to the rock on which he was standing. He then dug up what is perhaps the earliest recorded example of lodestone. The term "lodestone" itself is believed to have derived from the Anglo-Saxon meaning "leading stone." The Greek region of Magnesia, where the shepherd is said to have first found the lodestone, also gives root to the modern term magnet.

The ancient Chinese first made reference to lodestone around the fourth century B.C., where they described lodestone's ability to attract iron and other metallic objects to itself. These early civilizations continued to experiment with this mysterious material. By the twelfth century, the Chinese began to use the lodestone for navigation when they realized that one end of the object reliably points toward one direction (north) [1]. The industrial usefulness of the magnet continued to expand in the subsequent centuries, and today, it is an indispensable part of modern society.

Lodestone, or magnetite, is a class of substance collectively known as ferrites. Ferrites have the characteristic of being ferromagnetic, which includes the ability for spontaneous magnetization. Unlike other ferromagnetic metals, ferrites have relatively low electrical conductivity. This low electrical conductivity allows them to become an important part of the electronic industry.

What Is a Magnet?

Broadly, and intuitively defined, a magnet is a material that exerts an attractive or repulsive force on another object. The scale of this magnetic force ranges from the subatomic to the intergalactic. Individual subatomic particles exert a magnetic force and in turn experiences a magnetic force exerted by a neighboring particle [2]. The earth itself can be viewed as a magnet, and it is the largest magnet with which we come into daily contact [3].

In order to appreciate the important role that magnets play in the modern life, and in modern medicine, several basic principles of magnetism must be noted. The magnetic properties of an object derive from the magnetic properties of its constituent atoms. A substance is said to

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be *diamagnetic* if its constituent atoms do not possess free magnetic dipole moments [4]. These substances have a negative magnetic susceptibility that is independent of the strength of any external magnetic field or of temperature. On the other hand, a substance is said to be *paramagnetic* if its constituent atoms have free magnetic dipole moments [4]. Even in these paramagnetic atoms, their magnetic dipole moments are normally oriented randomly, and thus they have no net magnetization. When in the presence of an external magnetic field, these dipole moments no longer orient randomly and are instead oriented toward or away from the external magnetic source, and a net positive magnetization is produced. These substances in turn have a positive magnetic susceptibility.

Whether a potentially magnetic substance exhibits macroscopic magnetic properties depends on the arrangement of the atomic magnetic dipoles. If the atomic dipoles align in parallel throughout a large volume of any matter, then these net magnetic dipole moments will be additive, and the substance will exhibit *ferromagnetism* [5]. However, if nearly equal numbers of atomic magnetic dipole moments of similar magnitude align themselves in opposite orientation, and thus cancelling each other out, then the substance will have no permanent macroscopic magnetic property. These substances are referred to as *antiferromagnetic* [5]. Therefore, a ferromagnetic material is any material that contains *permanent atomic magnetic dipole moments* that spontaneously orient themselves in a *parallel* fashion even in the absence of an external magnetic field.

All magnets, from the smallest magnetic dipole moment to the household refrigerator magnet to the earth itself, have an inherent directionality, or pole. A given magnetic material has its strongest magnetic forces at the poles. Traditionally, because the earth's magnetic poles are located north and south, thereby attracting the corresponding poles of other magnets, the two magnetic poles are grossly referred to as *north* and *south* [6] (Fig. 2.1).

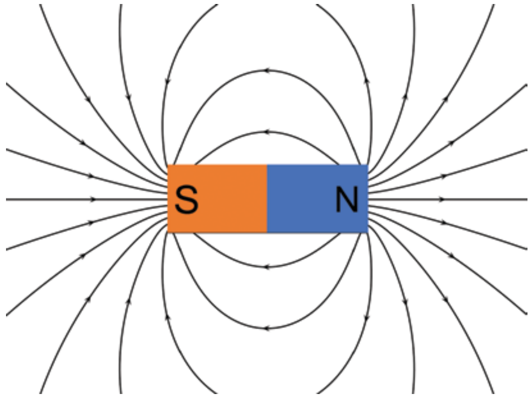

Fig. 2.1 Magnetic field lines. All magnetic objects have an inherent directionality, with the strongest forces at the poles. Traditionally, because the earth's magnetic poles are located north and south, the two magnetic poles are grossly referred to as *north* and *south*

Properties of Magnets

There are numerous characteristics that are important in understanding the usefulness of magnets, and a complete overview of these properties is beyond the scope of this text. Nonetheless, three of these parameters are crucial in evaluating the medical usefulness of a magnet. They are *energy product, coercivity*, and the *Curie constant.*

Energy Product

The energy product is a composite parameter determined by the strength of the magnet and the coercivity. This is the most frequently used and important parameter in evaluating the usefulness of a magnet [7]. The strength of a magnet depends on its constituent elements. As previously described, each atom in a magnetic substance has its own magnetic dipole moment, and the ultimate macroscopic magnetic strength is the resultant sum of the individual atomic moments. The energy product is measured in Gauss Oersted (GOe), or Joules/meter^3 (SI). One megaGOe (MGOe) is one million Gauss Oersted. For industrial use, the "strength" of a magnet is graded from N35 to N52. A magnet with a grade of N40 has a maximum energy product of 45 MGOe. As

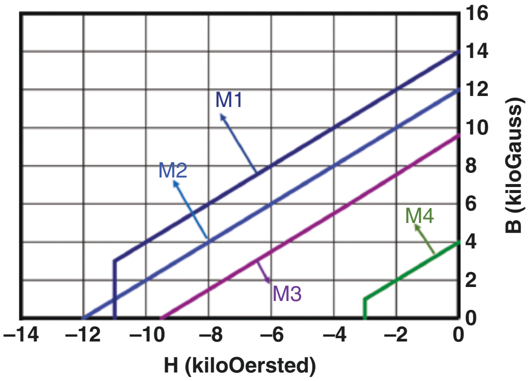

Fig. 2.2 Demagnetization curve (BH curve) of several hypothetical magnetic materials. The curve measures the strength of a given magnet and the force required to demagnetize it. The maximum energy product of a magnetic substance is the product of the B and H values along the curve (MGOe). Each magnetic substance has its unique demagnetization curve. *M* magnet. ("Magnetic field of an ideal cylindrical magnet with its axis of symmetry inside the image plane." by Geek3, Wikimedia Commons is licensed under CC BY-SA 3.0 and was partially modified)

the grade of the magnet increases, the strength of the magnet also increases.

The N grading system is based on the demagnetization curve (aka. BH Curve) (Fig. 2.2). This curve measures the strength of the magnet and the force required to demagnetize it. On the abscissa is the "H" value, which is measured in kilooersted, and on the ordinate is the "B" value, which is measured in kilogauss. The maximum energy product of a magnetic substance is the product of the B and H values along the curve; thus it bears the unit of MGOe [8]. Each magnetic substance has its unique demagnetization curve. While this grading system gives an overview of the strength of a particular magnetic substance, it is not a sufficient descriptor. A magnet's ultimate usefulness depends on a variety of other factors including the intended application, the shape, the cost, and the thickness of the final product.

Coercivity

Coercivity is the strength required of an external magnetic field in order to demagnetize a substance [7]. In essence, it measures how well a magnet stays a magnet. A material with a high coercivity means that it will require a higher external magnetic field for the substance to lose its magnetism. Recall that the macroscopic magnetic strength of a substance is the sum total of the individual atomic dipole moments, properly aligned. A high coercivity requires a crystal structure where the individual constituent dipole moments are oriented in such a way that its stability requires a high amount of external force to disrupt. Magnets resist demagnetization by imposing a high energy requirement to realign their atomic dipole moments. Accordingly, the coercivity of a magnetic product can be influence by the size, shape, as well as the orientation of its component molecules [9].

Curie Constant

Curie constant measures how the magnetic substance withstands heat. A magnet's ability to remain magnetic depends on the external energy required to disrupt the alignment of its dipole moments. In most ferromagnetic substance, the spontaneous alignment of these dipole moments is resisted by random external thermal forces. Thus, as these "disrupting forces" strengthen with rising temperature, the magnetic susceptibility of a ferromagnetic substance correspondingly decreases. In the late nineteenth century, the French physicist Pierre Curie (one half of the famous duo) first reported the observation that for many magnetic substance, their magnetic susceptibility is inversely related to the absolute temperature (T, Kelvin) [10]. His equation, $\chi = C/T$, where χ is the magnetic susceptibility, C is Curie constant, and T is absolute temperature. From this simple equation, it becomes apparent that the theoretical magnetic susceptibility of a ferromagnetic substance becomes infinite as the temperature approaches absolute zero. Today, the Curie constant is an important industrial parameter for magnet evaluation. How well a magnet can withstand heat significantly influences where and how it can be used.

Rare-Earth Magnets

By the nature of their chemical behavior, transition elements such as iron and cobalt have large magnetic dipole moments and are thus frequently used for their ferromagnetic properties. However, transition elements by their elemental nature often do not have high coercivity, and their industrial usefulness is significantly enhanced if their magnetocrystalline structure can be stabilized without diluting their magnetic dipole moments [7]. A handful of heavy elements on the periodic table have emerged as the ideal candidates for this task.

Rare-earth elements (REE) are a group of elements that includes the lanthanide series, lanthanum, scandium, and yttrium [11] (Fig. 2.3). Their misleading name notwithstanding, *rare-earth* elements are in reality not particularly rare. The REE's reserves in the earth's crust are 1600 times more abundant than silver and 3200 times more abundant than gold [11]. REE exist in a variety of minerals (e.g., haides, carbonates, oxides, phosphates, silicates, etc.) and are frequently used for industrial purposes. For example, the dominant REE, cerium, is used in catalytic converters, allowing them to run at higher temperatures. Lanthanum is used in telescope lenses, and gadolinium is a familiar contrast material in magnetic resonance imaging [12, 13].

Prior to the widespread use of REE in industrial magnets, transition metal (e.g., samarium and cobalt)-based magnets were the best available magnets. The original SmCo5 was discovered in the 1960s and play an important role in the postwar industrial economy [7]. Early iterations of REE-based magnets used a binary structure of REE-iron, and the common REE candidates were terbium, dysprosium, and samarium. Incorporation of these REEs gave the magnet much higher coercivity. Subsequent work led to the development of more complex structures, and ultimately the REE-iron-boron structure was developed.

Today, the most important industrial magnets, especially in medical use, are neodymium-based. Several attributes of neodymium-iron-boron (Nd-Fe-B) magnets make them particularly attractive for medical and industrial use. Neodymium magnets are significantly stronger than many of the other commonly encountered magnets. Nd-Fe-B can produce a maximum energy product of 474 kJ/M^3 [9]. At its surface, neodymium magnets can generate magnetic

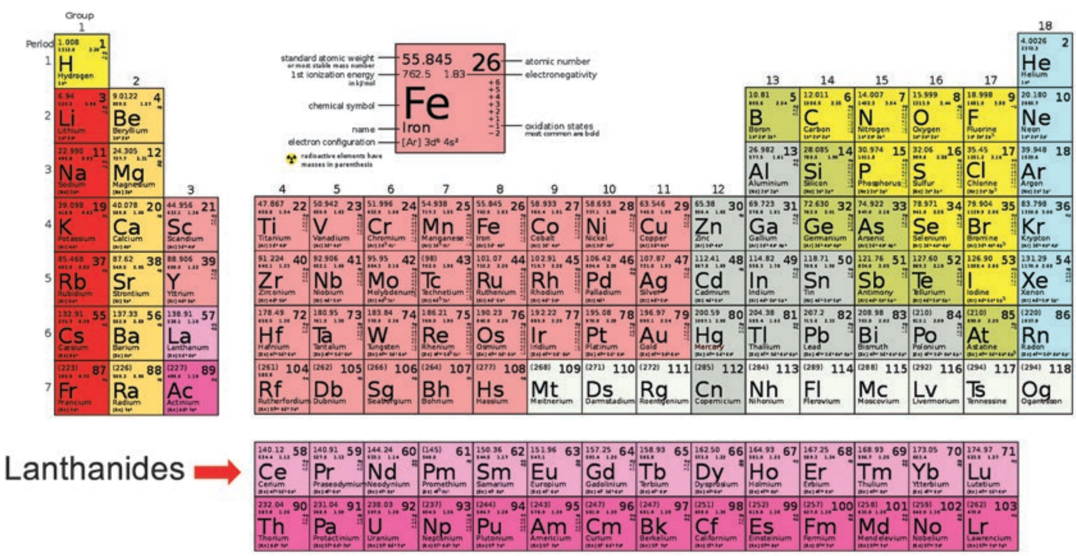

Fig. 2.3 Periodic table of elements. Rare-earth elements (REE) include the lanthanide series, lanthanum, scandium, and yttrium. ("Periodic table of the elements" by 2012rc, Wikimedia Commons is licensed under CC BY 3.0 and was partially modified)