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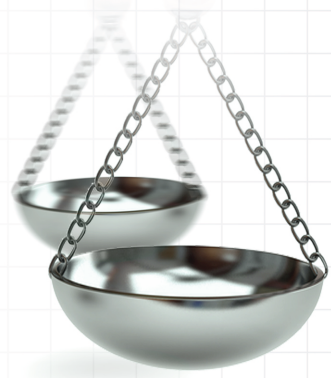

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Examples of dramatic failures and their effectiveness in modern surgical disciplines: can we learn from our mistakes?

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Innovation can be variably defined, but when applied to healthcare is often considered to be the introduction of something new, whether an idea, method or device, into an unfilled void or needy environment. Despite the introduction of many positive surgical subspecialty altering concepts/devices however, epic failures are not uncommon. These failures can be dramatic in regards to both their human and economic costs. They can also be very public or more quiet in nature. As surgical leaders in our communities and advocates for patient safety and outcomes, it remains crucial that we meet new introductions in technology and patient care with a measured level of curiosity, skepticism and science-based conclusions. The aim of an expert committee was to identify the most dominant failures in technological innovation and/or dogmatic clinical beliefs within each major surgical subspecialty. In summary, this effort was pursued to highlight the past failures and remind surgeons to remain vigilant and appropriately skeptical with regard to the introduction of new innovations and clinical beliefs within our craft.

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Innovation can be variably defined, but when applied to healthcare is often considered to be the introduction of something new, whether an idea, method or device, into an unfilled void or needy environment [1]. Innovation itself is also something that is inherent to surgical practice on a nearly daily basis [2]. As previously described in the surgical arena, innovation typically manifests as an original thought followed by surgical ingenuity, rigorous research and finally cautious introduction into the marketplace with appropriate caveats and indications. Despite the introduction of numerous positive surgical subspecialty altering concepts/devices however, significant failures are not uncommon. Comparative effectiveness over time is also essential as a concept to both judge these potential innovations, as well as ensure ongoing advances within a given field. Failures can be dramatic in regards to both their human and economic costs. For the purposes of this project, failures were defined as innovations that appeared to be revolutionary at the time of their initial introduction, but then failed the litmus test of time in regards to their clinical efficacy and/or economic efficiency. They also remind us that surgical innovations can only be regarded as truly evolutionary and comparatively effective when they pass the test of time and repeated clinical usage.

A committee that incorporated leading clinician members from multiple surgical specialties completed a detailed and comprehensive analysis of the literature within their field. The specific specialties that were selected, included surgical groups who had a high volume elective surgery footprint, as well as a significant presence within the emergency surgical arena (i.e., general surgery, surgical critical care, orthopedic surgery, neurosurgery). Each of these members were considered as an expert in their field based on local, national and international clinical and academic performance (academic and research profile, clinical experience, society involvement and reputation). These committee representatives were then required to engage in discussions among their subspecialty colleagues to arrive at a consensus selection of the single worst failure within their modern field of practice (e.g., the orthopedic example was a result of a discussion among over 40 orthopods). The aim of this group was to identify the most

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dominant failure in technological innovation and dogmatic clinical beliefs within each major surgical subspecialty. Discussions also surrounded the concept of effectiveness. This effort was pursued to highlight past failures and remind surgeons to remain vigilant and appropriately skeptical with regard to the introduction of new innovations and clinical beliefs within our craft.

Discussion

Trauma surgery & surgical critical care

All discussions surrounding traumatic hemorrhage must acknowledge the reality that modern balanced resuscitation practices have dramatically altered the traditional hemorrhage paradigm and therefore the administration of any hemostatic drug. More specifically, there has been a radical decrease in iatrogenic coagulopathy, as well as a potential amelioration in early intrinsic coagulopathy among severely injured patients [3,4]. Recombinant factor VIIa (rFVIIa) is a pharmacologic product that was originally introduced for the treatment of bleeding in hemophilic patients with known coagulation inhibitors [5,6]. Its mechanism of action was believed to be direct at the site of injury. This led to the logical theory that rFVIIa would also be capable of enhancing local hemostasis without initiating systemic activation of the entire coagulation cascade and the resulting risk of widespread inappropriate thrombosis. A number of remarkable case reports describing dramatic 'rescues' generated widespread interest among trauma clinicians [6,7].

Many, if not most, trauma centers/systems adopted off-label use of rFVIIa within their massive transfusion protocols prior to, but in anticipation of the supporting scientific evidence expected to follow [6,8]. It was therefore both a surprise and a subspecialty-wide disappointment that the subsequent randomized trials demonstrated no practical benefit regarding the administration of rFVIIa to either blunt or penetrating trauma patients with massive blood loss [9–11]. Furthermore, other nontrauma trials even suggested that rFVIIa may induce harm to some patient groups [12].

Given the tremendous expense of rFVIIa, experts have recommended reserving its use in severe traumatic hemorrhage to 'last resort' situations (i.e., after all standard measures have failed) [13]. Although clinicians desperate to save a patient (usually in the middle of the night) will occasionally utilize rFVIIa as an ineffective final maneuver, this is the least efficacious scenario in which to expect any benefit. Acidosis severely diminishes rFVIIa's effectiveness (i.e., 90% when the pH decreases from 7.4 to 7.0) [14] and any minute utility (if present) is associated with extraordinary incremental costs [15]. In summary, although rFVIIa may be potentially helpful in low doses for reversing coagulopathy in patients with isolated traumatic brain injuries (based on a small 87 patient prospective study [16]), the manufacturer continues to search for more generalized indications. Unfortunately there is currently no sound clinical evidence to justify the use of rFVIIa as it was initially intended [11]. There is even less rationale for using rFVIIa in the context of much cheaper adjunctive medications that seem to be more helpful [17]. This discrete example of a failed medical intervention highlights the importance of large randomized studies in rigorously controlled environments.

Endocrine/pancreas surgery

Nesidioblastosis of the pancreas resulting in organic hyperinsulinemic hypoglycaemia disorder was first described in 1938 [18]. Although initially thought to be a disorder of newborns and infants, by the early 1980s, it was recognized as a rare cause of hyperinsulinemia in adults. Small series reported the resolution of hypoglycemic episodes following pancreatic resections [19,20]. In 2000, the Mayo group termed the phrase noninsulinoma pancreatogenous hypoglcemia syndrome (NIPHS) and characterized the clinical and diagnostic work-up of these patients [21]. In contrast to insulinomas, NIPHS patients had a negative 72-h fast and postprandial hypoglycemia. Utilizing calcium stimulated insulin gradients across the pancreas, gradient-directed pancreatectomies rapidly became the treatment for refractory NIPHS [22–24].

The recognition that postprandial hypoglycemia may be due to endogenous hyperinsulinemia from nesidioblastosis, led to the first report of this entity following Roux-en-Y gastric bypass surgery [25]. In this series of six patients, the authors reported on the resolution of hypoglycemia symptoms following gradient-directed pancreatectomy. They brought to light that not all postprandial symptoms in gastric bypass patients should be attributed solely to dumping syndrome. Soon after this report, others followed with the recognition of NIPHS following Roux-en-Y gastric bypass surgery and the histological confirmation of nesidioblastosis in most, but not all, pancreatic resection specimens [22,26–31]. The short-term initial results were encouraging with 67% of patients displaying a resolution of symptoms following pancreatic resection [32].

Despite this excitement, the Mayo group subsequently identified that the resolution of symptoms with pancreatic resection was not sustainable with longer follow-up. In 2010, after performing 75 gradient-directed pancreatic resections for NIPHS (out of which 70% were following gastric bypass surgery) they found in a patient-directed survey that nearly 90% of patients reported recurrent hypoglycemic symptoms [33]. In the discussion of this paper, the senior author acknowledged that except in extreme cases, their group had abandoned pancreatic resection for this condition. More specifically, dietary modifications (low carbohydrates) and medical management with diaoxide or calcium-channel antagonists should represent first line treatment. Reversal of the gastric bypass with consideration of a restrictive form of bariatric procedure should also be contemplated in medically refractory patients [34].

Since the original report 10 years ago, NIPHS is now recognized as a rare complication of bariatric gastric bypass surgery, with a reported incidence of 0.2% [35]. However with the increased worldwide utilization of bariatric surgery, and the fact that the Roux-en-Y gastric bypass was the most common bariatric operation performed in 2008, this entity remains clinically relevant [36]. Although initially treated in a similar fashion to adult onset nesidioblastosis, treatment of NIPHS following gastric bypass requires a different therapeutic approach. Several possible mechanisms regarding the induction of nesidioblastosis following bypass surgery have been postulated. These include inappropriate growth factors release, altered gut hormonal signaling, adaptive responses to serve dumping syndrome and obesity induced β-cell hypertrophy [34]. The surgical therapy for these patients must therefore be directed at the cause, not the end organ. As a result, reversal of the disruptive GI tract should be the first consideration for medically refractory NIPHS. This example of surgical failure following initially promising publications reminds us of the importance of long-term follow-up and continued re-evaluation of our outcomes.

Colorectal/anorectal surgery

Fistula-in-ano occurs commonly following perianal and isciorectal abscesses, with an incidence of 30–50%. Simple fistulas can be effectively treated by primary fistulotomy, with a low risk of incontinence. Complex fistulas however, are significantly more challenging, as a fistulotomy in these patients carries a much higher risk of fecal incontinence. Many treatment strategies have been developed to treat fistula-in-ano over the years, but most have suffered from high recurrence rates.

An incredibly promising technique in the management of fistula-in-ano was the introduction of the anal fistula plug. Surgisis (Cook Surgical Inc., IN, USA), a bioabsorbable xenograft made from porcine intestinal submucosa, was fashioned into a conical plug that was then drawn through the fistula tract and secured into the internal opening of the fistula itself. The first report of the anal fistula plug for treatment was a comparative study of 25 patients with complex fistula-in-ano [37]. More specifically, ten patients were treated with fibrin glue injection, and 15 with the anal fistula plug. The authors reported an 87% healing rate in the fistula plug group, leading to great enthusiasm for this technique. Many surgeons immediately began using the fistula plug as their primary treatment modality for complex fistulas.

Several case series with variable healing rates were then subsequently published, leading to a consensus conference in Chicago in 2007 that outlined key procedural components [38]. These included patient selection, preoperative preparation, intraoperative management and postoperative care. Following this meeting, a number of clinical trials and additional case series began reporting extremely disappointing results. Safar and colleagues published a poor 13.9% success rate among 35 patients [39]. Two randomized controlled trials then reported recurrence rates in their fistula plug groups of 80%, and 71% in a comparison with endorectal advancement flaps [40,41]. In only a few years, this superb technological hope for a persistently troublesome clinical problem had transitioned from a heavily supported research and development phase to a product that is now used sparingly when other options are unavailable or fail, and with a far less optimistic outcome and a call for yet more research into efficacy [42].

Hernia surgery

Although observation of hernias remains reasonable in some circumstances [43], hernia surgery has been revolutionized by the invention of mesh products. Whether inguinal or ventral/incisional, the proper application of mesh products has reduced recurrence rates dramatically (by 10–50% respectively) [44,45]. Although tension-free techniques such as the Lichtenstein repair, and more recently the introduction of biologic mesh products from both human cadaver and/or porcine sources, have also resulted in giant leaps forward, not all mesh products have performed favorably in the longer timeframe. The most notorious example of this epic failure in development has been polytetrafluorethylene (PTFE or Teflon) mesh in the context of ventral/incisional hernia repairs. While PTFE mesh products have a long history, they became extremely popular only in the late 1990s with the incorporation of a

second layer (polypropylene) to create a composite mesh product [46]. This product was initially touted by industry as a 'revolution in design and performance', but it became clear in the subsequent decade that mesh migration, and more importantly prosthetic infection, was far too common [47]. There is no other example within the abdominal wall domain that is more dramatic, as an entire generation of surgeons who had inserted these PTFE-based products, then had to remove them from hostile fields at alarming rates. This in turn, led to a substantially more complex hernia/abdominal wall defect than at the initial presentation/procedure, and prompted a clear abandonment of these PTFE-based composite products by most thoughtful surgeons. The poor performance of the composite mesh was then even further compounded when its structure was altered to include the Kugel variation [48]. This provided the theoretic advantage of a stiff ring surrounding the mesh that 'popped' open following insertion through a smaller incision. The introduction of this product was met with increased reports of patient abdominal pain and a subsequent international class action lawsuit that is currently pending.

From an ethical point of view, the repeated introduction of new mesh products with limited research continues to deliver a mixture of successes and failures. This reality represents a failure of not only some research ethics boards to prevent futile studies, but more importantly, of the inability to have all new products carefully and cautiously reviewed by a multidisciplinary 'new technologies' hospital/health region working group. Even ignoring the associated incidence of pain and/or infection, the true performance of mesh innovations with respect to hernia recurrence is often unclear for up to a decade following insertion.

Vascular surgery

Infrainguinal arterial disease is a leading cause of limb loss [49,50]. Despite endovascular advancements, surgical bypass is frequently necessary for revascularization in critical limb ischemia. Graft failure requiring revision for limb salvage exposes the tenuous vasculopath to a 4.8% major wound complication rate, 4.7% myocardial infarction rate and 2.7% perioperative mortality rate [51].

In general, vessel inflow, outflow and the conduit itself determine the success of a bypass. A desirable conduit maintains patency while resisting degeneration. It is affordable, readily obtainable, easily manipulated and infection resistant. Autogenous greater saphenous vein (GSV) is the gold standard but its frequent prior use commonly leaves the surgeon searching for other viable conduit options. Arm veins are often of inadequate diameter, autogenous arteries are typically too short, and femoral vein harvest is complex and morbid. Prosthetic grafts are infection prone and have poor infrageniculate patency [52,53].

As an alternative, biografts (allografts and zenografts) have been developed over an extended period [54,55]. Despite the reality that fresh grafts are difficult to store, modern cryopreserved or chemically pretreated biografts [56,57] were reported as accessible, infection resistant, high fidelity conduits. In 1993, Shah and colleagues demonstrated 1-year patency rates of 66% using cryopreserved saphenous vein allografts [58]. These high clinical patency rates appeared to promise that biografts would become the primary alternative conduit in the setting of inadequate autogenous GSV.

Unfortunately, the limitations of biografts have become more evident over time and included inherent immunogenicity, poor patency, aneurysmal degeneration and high cost [59]. The recipient immune response contributes to conduit thrombosis and degeneration. Cryopreservation and chemical pretreatment techniques have met with limited success in preventing this reaction. These techniques further contribute to graft failure by inciting endothelial damage and loss [60]. Use of immune modulating medications, such as cyclosporine, in the setting of ulceration or infection is hazardous and does not appear to improve patency [59,61,62]. Perioperative anticoagulation has not convincingly improved conduit longevity and brings an associated increased risk of bleeding complications.

Unfortunately, with more study, 1-year biograft patency rates were rarely reported to be higher than 30–37% and as low as 13% in some potentially poorly selected patients [63,64]. Even more concerning, the few biografts that have maintained patency remain at significant risk of aneurysmal degeneration secondary to cellular changes resulting from enzymatic preparation, as well as the recipient immune response after implantation. This increases the risk of both distal thrombo-embolism and devastating arterial rupture. Finally, the cost of biografts can be prohibitive at over US$6000 for 20 cm of commercially available vein.

As a result of this complete reversal from promise to reality, when GSV is not available alternative autologous veins remain preferable over biografts for infrageniculate bypass [65]. Currently, biograft use for infrainguinal revascularization should be limited to the replacement of infected prosthetic material when lacking autogenous conduit options. In this circumstance, many argue that given the associated surgical morbidity and mortality, repeat attempts at bypass are not only futile, but harmful, when compared with the definitive treatment option of limb

amputation. Despite 100 years of massive investment and refinement, biologic conduits have dramatically failed to fulfill the repeated promises that they once offered.

Thoracic surgery

Gastroesophageal reflux disease (GERD) is a complex disease that affects millions of patients worldwide. Treatment options include lifestyle changes, medications, endoluminal therapies and surgical interventions. In an effort to address the many challenges in managing a spectrum of GERD patients, an increasing number of innovative therapies have been introduced over the last three decades. Although the management of GERD with a partial or full fundoplication remains the mainstay of surgical treatment, the evolution of these approaches has not been without its challenges. As Sir Ronald Belsey is quoted as saying regarding antireflux operations: *"The battlefields of surgery are littered with the remains of new operations, which floundered and perished in the follow-up clinic"* [66].

One of the most impressive GERD treatment failures was the Angelchik prosthesis. The Angelchik prosthesis is a C-shaped silicone ring that was first implanted in 1973 [67]. In the initial report on 46 patients, this device was favored over other antireflux procedures because of the standardized and comparatively simple technique for inserting the prosthesis [67]. The ring is fitted around the gastroesophageal junction and secured in place with Dacron tape. By 1983, it was estimated that over 10,000 of the devices had been inserted worldwide [68]. Within a relatively short period of time however, complications arose that included dysphagia and erosion into adjacent structures [68]. The most common complication remains migration of the prosthesis due to untying or breakage of the Dacron straps. Three types of prosthesis migration have been reported: migration proximally into the chest, migration distally over the body of the stomach, and migration in the abdominal or pelvic cavity [69]. Corrective surgery with extraction of the prosthesis is often required with successful laparoscopic removal of a migrated Angelchik prosthesis being reported [70]. Due to these complications, the use of the prosthesis was all but abandoned in favor of fundoplication surgery approximately 15 years after its introduction [71].

On a similar note, a new prosthesis has recently been introduced into the market for the treatment of GERD (LINX® Reflux Management System)[72]. This device uses a thread of interlinked titanium beads with magnetic cores. The beads are linked together in a ring around the gastroesophageal junction using magnetic attraction to increase the lower esophageal pressure at rest. During swallowing, the magnetic bond is temporarily broken allowing the food bolus to pass. Although preliminary case series reports suggest favorable short-term results with this technology [73], only time will truly tell if this apparatus will prove to be effective or, like the ill-fated Angelchik prosthesis before it, be relegated to the graveyard of failed antireflux therapies.

Orthopedic surgery

The epidemic of osteoporosis (OP) has resulted in fragility fractures being more common than heart attack, stroke and breast cancer combined. It is estimated that one in two women and one in four men over the age of 50 years will suffer from an OP fracture [74]. OP commonly results in bone loss at a fracture site due to impaction and to significant challenges for stable implant fixation, as the pullout strength of screw instrumentation is largely reliant on host bone density. As a result, investigating strategies for bone augmentation, such as bone cement, has become a high priority.

Polymethylmethacrylate (PMMA) cement is commonly used for both total hip and knee prostheses [75], as well as for percutaneous injection in vertebroplasty and kyphoplasty. PMMA undergoes an exothermic reaction during polymerization, which raises concern for local thermal necrosis, especially when PMMA is used near neural elements in spine fixation [76,77]. PMMA migration also presents a risk of neurologic and soft tissue damage and embolism [78–81]. PMMA contraction with curing may compromise stability due to potential gapping at the bone interface [82]. Finally, the mismatch between cancellous bone and stiffer PMMA may cause stress shielding at the cement-bone interface, which can result in bone resorption or fracture [83,84].

As an alternative, Kryptonite™, a calcium triglyceride biological bone cement was developed as an expanding bone void filler with osteoconductive and adhesive properties (Doctors Research Group Inc., CT, USA) [85–87]. Kryptonite is mixed intraoperatively to form an adhesive paste that then sets to form a rigid porous polymer. The polymerization reaction is normothermic and releases carbon dioxide, which forms pores that produce volume expansion, a unique property when contrasted to PMMA [88]. In biomechanical testing, superior pullout strength was achieved with Kryptonite over PMMA in spine pedicle models [88]. Kryptonite was also shown to be superior for peak bending, shear and compressive yield stresses in a cadaveric radius fracture model. Kryptonite expanded into the trabecular bone significantly more than PMMA [83]. In a clinical series, Kryptonite was injected percutaneously

along with Kishner-wires at various fracture sites and fracture consolidation was achieved in all 12 patients [89]. Kryptonite promised to be a valuable advancement for fragility fracture care.

Unfortunately Kryptonite was recalled by Health Canada in 2012 for product safety concerns. The cement's preclinical testing was conducted mainly in cadaveric models at ambient temperature. Further evaluation found that the strength and stiffness of this product decreased by approximately half when conducted at body temperature. The US FDA also recalled Kryptonite in 2012 for use in repairing cranial defects. While Kryptonite had impressive fixation strength, the setting time for the cement was up to 30 min, followed by further hardening for up to 24 h, making it unsuitable for clinical use. The failure of this advanced product and several prior biologic bone cements (i.e., Norion XR) begs for continued evidence-based research and reinforces the importance of tempering excitement in nonliving human models across all subspecialties.

Neurosurgery

A dated but incredibly dramatic example of failed promise within the neurosurgical arena surrounds the use of extracranial-to-intracranial (EC–IC) bypass arterial anastomosis to reduce the rate of stroke in patients with symptomatic atherosclerotic lesions of the internal carotid artery and middle cerebral artery. The first EC–IC bypass was performed in 1967. With the hypothesis that the occurrence of stroke ultimately possessed a hemodynamic pathophysiology, EC–IC bypass rapidly became an extremely common operation for stroke prevention. Graft patency rates were often above 90% and surgical morbidity was generally low. The EC–IC approach to stroke prevention was quickly challenged however because of concerns that it did not address the thromboembolic origin of most transient ischemic attacks and stroke in patients with symptomatic atherosclerotic lesions of the internal carotid artery [90].

An international multicenter randomized trial initiated in 1977 successfully enrolled 1377 patients who were randomized to either EC–IC bypass or best medical therapy (mean follow-up of 56 months). In 1985, the EC/IC Bypass Study Group reported their results in a paper entitled 'Failure of EC–IC Arterial Bypass to Reduce the Risk of Ischemic Stroke'. More specifically, nonfatal and fatal stroke actually occurred with both greater frequently and earlier in surgical patients, in spite of a 96% postoperative graft patency rate. [91] Although this study was a well-designed multicenter, multidisciplinary effort, it was also criticized for a number of flaws that included mixing high and low risk patients together, as well as the exclusion of a large number of patients who were potential candidates at participating centers because they were felt to be too high risk for medical therapy. An initial strong reaction from some in the neurosurgical community to these shortcomings argued that EC–IC bypass still had a role in the treatment of selected patients with hemodynamic insufficiency, or as a component of treatment for some patients with complex cerebral aneurysms [92–98]. Although the controversy regarding minor aspects of the EC–IC trial persist, the 1985 study effectively ended the use of EC–IC bypass as a routine stoke prevention surgery [99–103]. This was a seminal neurosurgical clinical trial [95].

The elimination of the EC–IC operation for stroke prevention did not however result in the abdication of surgery for stroke prevention. The North American Symptomatic Carotid Endarterectomy Trial Study Group published the results of their randomized clinical trial in 1998. This demonstrated a significant reduction in stroke risk with carotid endarterectomy for symptomatic patients with moderate or severe internal carotid artery stenosis [104,105]. Additional clinical trials have continued, evaluating the role of carotid endarterectomy in asymptomatic patients, as well as the interaction of carotid stenting in those with both symptomatic and asymptomatic carotid artery disease [105,106]. These neurosurgical examples act as a convincing reminder of the value of a well designed randomized surgical clinical trial and importance of persistent effort to identify the 'correct' surgical solution.

Conclusion

As described, examples of failed technologies and dogmatic beliefs that have been introduced into the common daily workplace of the surgeon are numerous. Similar to clinician-based developments/updates in treatment algorithms [107], there is a superficial belief that most products are developed by industry with the aim of improving patient care and outcomes. This notion must be balanced against the realities of shareholder profit, limited preintroduction research and product testing, and finally surgeon bias toward the influence of a given company and/or product. As surgical leaders in our communities and advocates for patient safety and outcomes, it remains crucial that we meet new introductions in technology and patient care with a measured level of curiosity, skepticism and science-based conclusions. This mandates us to not only ensure scientifically rigorous studies of adequate power, but also long-term follow-up and continued re-evaluation of both our own practices and the available

technologies we employ. While multiple different methodologies provide nuanced opportunities to achieve this goal (society guidelines [1] and publication commentaries [108]), the importance of the local/regional 'New Technologies' assessment committee cannot be over stated. This multidisciplinary group is typically responsible for evaluating all proposed new introductions based on the evidence for both clinical efficacy and economic benefits, as well as evaluating all competing institutional priorities and capacities. Despite failing to achieve long-term acceptance, some technologies will still be modified and then reintroduced following a pause within their evolution. Although this process is an important central tenet to progress within all industries, it also fits well within the umbrella of a New Technologies review. As an interested, responsible and engaged collective, we can prevent many of these failures from recurring in the future.

Future perspective

We believe that the introduction of new technologies will meet increasing resistance over the next decade by a more common mandatory requisite for granular and detailed analyses performed by 'New Technology' boards within most healthcare systems. The renewed focus on quality and economic responsibility will assist in ensuring patients (and healthcare systems) are stewarded through a process with more transparency and accountability.

Executive summary

- Innovation is defined as an introduction of something new, whether an idea, method or device, into an unfilled void or needy environment.
- Failures within the introduction of new technologies are not uncommon.
- An experienced committee of surgical specialists identified some of the most impressive failures in innovation within their modern surgical subspecialties.
- Despite tremendous development costs and early introduction, recombinant factor VIIa was a failure at slowing ongoing traumatic hemorrhage.
- Partial pancreatectomy was advocated for the treatment of Nesidioblastosis on the strength of a small single center patient series. This proved to be unnecessary with long-term follow-up.
- Despite significant initial industry advocates and a consensus conference, the utility of anal fistula plugs for complex fistula-in-ano was eventually shown to be poor.
- Although the intuitive excitement of adding a second synthetic layer to minimize intraperitoneal adhesions for a standard mesh allowed the extremely rapid and widespread uptake of this technology, terrible long-term performance and infections highlighted a lack of initial due diligence.
- While the introduction of vascular biografts was initially met with tremendous clinical excitement, massive financial industry investment and perpetual refinement, these devices remain helpful in only a few specific instances.
- The widespread suffering associated with gastroesophageal reflux disease among the general population led to the development of the Angelchik prosthesis. This device was inserted in over 10,000 patients only to lead to dramatic long-term complications such as dysphagia and esophageal perforations in many.
- Similarly, the epidemic of osteoporosis with subsequent fractures and the need for bone augmentation drove significant investment into the creation of a novel bone cement. Kryptonite was eventually recalled by multiple governments for safety concerns that included failures caused by the inappropriate extrapolation from cadaveric models at ambient temperature to living humans.
- Stroke prevention remains one of our utmost important public health goals. The elimination of the extracranial-to-intracranial bypass was a classic example of the adoption of an invasive surgical procedure with failed results.
- New Technology committees are critical within healthcare to enhance the safety of introducing novel devices/technologies that may impact patients in a negative manner.
- As an interested, responsible and engaged surgeon, we can prevent many of these failures from recurring in the future.

Author's contributions

All authors were involved in designing and confirming the topic content within each subsection. All authors drafted, edited and revised their individual subspecialty/specialty sections. All authors also revised the entire manuscript for critical appraisal and intellectual content. All authors read and approved the final manuscript.

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