Innovation in pediatric surgery: The surgical innovation continuum and the ETHICAL model

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A B S T R A C T

Innovations are indispensable to the practice and advancement of pediatric surgery. Children represent a special type of vulnerable population and must be protected since they do not have legal capacity to consent, and their parent’s judgment may be compromised in circumstances when the child is very ill or no adequate therapy exists. In an effort to protect patients, legislators could pass and enforce laws that prohibit or curtail surgical innovations and thus stifle noble advancement of the practice. The goals of this paper are, 1) To clearly define the characteristics of surgical innovation types so interventions may be classified into 1 of 3 distinct categories along a continuum: Practice Variation, Transition Zone, and Experimental Research, and 2) To propose a practical systematic method to guide surgeon decision-making when approaching interventions that fall into the “Transition Zone” category on the Surgical Intervention Continuum. The ETHICAL model allows those that know the intricacies and nuances of pediatric surgery best, the pediatric surgeons and professional pediatric surgical societies, to participate in self-regulation of innovation in a manner that safeguards patients without stifling creativity or unduly hampering surgical progress.

1. Background

Pharmaceuticals and medical devices are rigorously regulated by the FDA and an extensive, expensive, and time-consuming process is required to take a new drug from creation to market. Such a thorough and scientifically valid method is necessary to protect consumers, since the majority of new investigational medications fail to be effective, or they produce unacceptably harmful side effects [4]. There is currently no federal regulatory process for introducing new surgical procedures, and recent discussions [5–9] have raised significant concern regarding the necessity of appropriate patient protection in an era of rapid technological advancement, as well as the ethical responsibility of the surgeon to determine whether novel interventions are both safe and effective before incorporating them into one’s own practice [10]. If a novel procedure is deemed by the surgeon to be “part of patient care” it is not subject to the same regulation and rigorous oversight as is formal research involving human subjects.
However, patient protection must still be ensured during the development and implementation of new technologies and surgical approaches.

Throughout the history of surgery as a discipline, implementation of new techniques has been based on case series reports and the bestowment of knowledge from the surgeon innovator to his or her colleagues and pupils rather than through a standardized process. A surgical innovation may appear as a small deviation from the standard, such as a different way to place a clip. Or the innovation may be a more radical way of performing a procedure, such as the first laparoscopic intervention. Surgical innovations are necessary for the advancement of pediatric surgery as a field in order to create improvements in existing procedures and to address diseases that have inadequate or cumbersome therapies. While discussion with colleagues prior to surgical experimentation serves as a very important method for informal oversight, not all surgeons have access to these resources, and issues such as bias (e.g. surgeons who practice together may be more like-minded) or pressure to be agreeable (e.g. fear of retribution or wanting to “play nice in the sandbox”) may impede open, objective review of the proposed innovation.

Individual patients must be protected from excessive risks during the innovation process, and children represent a particularly vulnerable population since they do not have legal decision-making capacity. Children are unable to maturely and logically weigh the risks and benefits of a procedure in order to arrive at an appropriate conclusion that best represents their own values. Instead, the medicolegal system grants parents the authority to provide consent-by-proxy on the assumption that the parents will consider the relevant medical information presented to them and then determine which treatments are in the best interests of their child. This process can become compromised when parents “grasp at straws” with the hope that their very ill child may be cured, and their ability to objectively weigh risks versus benefits may become impaired [11]. Also, parents may not be fully aware that the proposed innovative procedure is not validated, or that the surgeon has never performed it before. In order to protect these patients from excessive risks, it is important to first define what constitutes different categories of surgical innovation, and then develop a systematic approach that makes performing each type ethically acceptable while also ensuring appropriate regulation and oversight.

1.1. Surgical Innovation Continuum: Practice Variation

Intuitively, it seems that surgical practice variation and experimental research exist at opposite poles of a continuum that can be divided into thirds (Table 1). One end of the spectrum includes Practice Variation interventions, defined as a slight deviation from a known or widely accepted truth or the currently accepted standard of care, such as a new way to tie a suture, apply a dressing, or customize a surgical plan for a particular patient’s unusual anatomy. Publication is not intended at the outset, but may occur afterward to discuss a surgical plan. A Practice Variation may eventually be entered into a research study or published as a retrospective review to determine superiority (or non-inferiority plus additional advantage such as less scarring, shorter hospital stay, or decreased pain) in order to replace the previous standard of care with an improved method and thereby foster advancement of the field. Practice Variations are critical to optimal surgical care, and are performed in the best interest of the patient. As such, “Most surgeons innovate on a daily basis tailoring therapies and operations to the intrinsic uniqueness of every patient and their disease” [13]. Due to the nature of this type of incremental surgical intervention, and the low risk typically involved, it is neither feasible nor reasonable to demand that all departures from the standard be submitted first to an IRB or similar governing body.

1.2. Surgical Innovation Continuum: Experimental Research

At the other end of the continuum is Experimental Research and involves a carefully constructed scientific study. According to the Belmont Report, research is defined as an “activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge... usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective” [14]. Informed consent to participate in the study in addition to standard surgical consent is required, and such studies in patients are often undertaken following convincing preclinical data that may include use of animal models prior to attempting first-in-human experiments.

Distinguishing characteristics of Experimental Research in surgery include, 1) The intent that society as a whole (or future patients) will benefit by increasing the body of medical knowledge, regardless of whether the individual patient benefits or not, 2) The testing of a premeditated theory or hypothesis through an appropriate research design utilizing the scientific method and ensuring statistical rigor, 3) The novel technique bears very little (minor) similarity to the current standard of care, and/or a different endpoint or outcome is expected, 4) Informed consent for the surgical procedure in addition to consent for participation in a research study is required, and 5) The safety, effectiveness, and predicted outcomes are largely unknown or hypothetical. Interventions that fall into this category are appropriately governed by institutional IRBs, research ethics, and regulatory authorities. See Table 1 for additional defining characteristics of Experimental Research innovations.

An example of an intervention that can be classified in this model as Experimental Research, Serial Transverse Enteroplasty (STEP) was first attempted and refined in animal models prior to implementation in humans [15]. The STEP procedure then progressed through several stages: 1) First-in-human attempt (or “n of 1”) with hospital IRB approval [16], 2) A small case-series that reported short-term outcomes [17], 3) An international multicenter study that utilized a data registry and reported safety and efficacy [18], 4) A comparison study of the novel procedure against the standard procedure [19], 5) A retrospective study that reported intermediate outcomes [20], 6) A subsequent study that reported long-term outcomes [21], and 7) Continued use of the data registry for intermittent reporting on safety and efficacy as use of the novel procedure becomes widespread [22]. These stages exemplify the progression of a radically new intervention from conception to integration into standard surgical care, and may represent an appropriate pathway for responsible introduction of procedures that are classified as Experimental Research.

1.3. Surgical Innovation Continuum: Transition Zone

We are then left with the middle third of our Practice Variation → Experimental Research continuum. This area has been described previously in the literature as “the gray zone,” [23,24] or “zone of innovation,” [3] and skeptics fear that surgeons performing these
types of interventions are “free to try out their innovations and ideas governed only by their ethics and their conscience” [25]. This category includes procedures which are currently not subject to the same regulations as is Human Subjects Research (called “Experimental Research” in the present model) because they are performed as part of patient care [14]. They also involve more than a minor deviation from the standard of care, but not as major a degree of deviation as does Experimental Research. Additional differences between Transition Zone and Experimental Research interventions are that Transition Zone innovations are intended to directly benefit an individual patient rather than society as a whole (or future patients), and allow the surgeon to perform the innovation in one patient if certain criteria are met, but not repeatedly in additional patients without oversight. Although both Transition Zone innovations and Experimental Research are reported in the literature, two main characteristics that separate Transition Zone innovations from Experimental Research (Table 1) are that Experimental Research involves the testing of a premeditated idea or hunch (Timing) and are intended at the outset to increase generalizable knowledge (Intent). Additionally, if the innovation has no or very little similarity to the currently accepted standard of care or a different outcome or endpoint is expected, then it should be classified as Experimental Research and subject to the same regulations that are already in place governing research involving human subjects [14]. Transition Zone interventions are also distinct from Practice Variations since the validity of the outcome is largely unknown or unproven, and the procedure differs significantly from the current standard of care, even if the same goal (e.g. gall bladder removal) would be ultimately achieved. Nevertheless, the surgeon believes the novel Transition Zone intervention will adequately address the patient’s issue based on intuition and extrapolation from previous training and experience.

Interventions in the Transition Zone can be sub-classified as either Type A, those that arise spontaneously in response to an acute problem encountered in the OR, Type B, those that attempt to address a life or limb-threatening condition and no adequate therapy currently exists, or Type C, those that are premeditated or planned, but are performed to benefit a specific patient. All surgeons that satisfy the ETHICAL model criteria are qualified to perform Type A and B Transition Zone innovations in one patient (first known attempt) in an acute situation. Type C Transition Zone innovations must first meet all ETHICAL model criteria at the level of the individual surgeon (i.e. determining for oneself if all criteria are met) as well as implementation of the model at an additional level of oversight (i.e. IRB, Dept Chair, review committee, or professional society determining if the surgeon meets all of the criteria) prior to the first-attempt in one patient. For all three types of Transition Zone innovations, all subsequent attempts utilizing the same novel intervention would follow the Experimental Research pathway, and include the requirement for appropriate expertise, background, training, oversight/IRB approval and other criteria as applicable. Table 1 and Fig. 1. Transition Zone innovations are essential to the evolution of pediatric surgery, but necessary safeguards that do not stifle progress should be employed to protect patients from unnecessary risk and provide surgeons with the confidence that they are offering appropriate care to the best of their ability. An innovation falls into the Transition Zone category by default if it does not meet the criteria for either the Practice Variation or Experimental Research

Table 1
Proposal for how to define the categories of interventions along the Surgical Innovation Continuum by specific characteristics.

<table>
<thead>
<tr>
<th>Practice Variation</th>
<th>————-</th>
<th>Transition Zone</th>
<th>————-</th>
<th>Experimental Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon Characteristics:</td>
<td>Completed ACCME training program (or equivalent)</td>
<td>Competency with critical portions of procedure</td>
<td>Experience with organ system/body cavity</td>
<td>Competency with critical portions of procedure</td>
</tr>
<tr>
<td>Equipment Characteristics:</td>
<td>FDA Approved/Cleared</td>
<td>Surgeon competent with use of all equipment required</td>
<td>New device or implant</td>
<td></td>
</tr>
<tr>
<td>Population Characteristics:</td>
<td>Procedure established for use in specific population</td>
<td>Defined in study protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Characteristics:</td>
<td>Indication: Clear indication for surgery</td>
<td>Standard for procedure</td>
<td>Standard for procedure + consent for involvement in experimental study</td>
<td></td>
</tr>
<tr>
<td>Procedure Characteristics:</td>
<td>Timing: Spontaneous</td>
<td>Major; same endpoint or outcome expected</td>
<td>Testing of premeditated theory/idea or outcome expected</td>
<td></td>
</tr>
<tr>
<td>Regulation:</td>
<td>Surgical and Medical Ethics Research Ethics, IRB approval, FDA, and/or other regulations as applicable.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Publication of Results:</td>
<td>Not Required, or post facto, if particularly interesting outcome or case.</td>
<td>Primary reason for performing study (obtain generalizable knowledge).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pediatric Surgery Examples:</td>
<td>First vessel loop management of soft tissue abscess</td>
<td>Sutureless Abdominal Wall Closure in Gastrochisis</td>
<td>Serial Transverse Enteroplasty (STEP) Proce</td>
<td></td>
</tr>
</tbody>
</table>

Degree of deviation from standard of care ————- Procedure ————-
categories. An algorithm for determining which category (Practice Variation, Transition Zone, or Experimental Research) a given innovation would be categorized into, as well as proposed regulation according to innovation type is described in Fig. 1.

An example of a Transition Zone innovation is the sutureless abdominal wall closure to treat gastroschisis [26]. This technique arose from post-operative observation of one patient with acutely increased respiratory pressures after bowel reduction and fascial closure. In order to prevent respiratory failure and avoid the necessity of ECMO, the abdomen was reopened and a Tegaderm dressing placed over the defect. The surgical plan involved first stabilizing the patient in the NICU and then later returning to the operating room to complete the closure. However, in the interim the team noticed that this method provided a complete spontaneous closure by secondary intention in two weeks while also providing an improved cosmetic appearance and no umbilical hernia, making reoperation unnecessary. They also realized that this novel approach had the potential for use in future patients with similar respiratory complications due to increased intra-abdominal pressure as an alternative to primary fascial closure, and subsequent studies were performed. This represents a novel intervention performed in response to an acute issue to benefit a specific patient. The procedure involved a higher degree of deviation from the standard of care and increased risk as compared to a Practice Variation, but the two procedures involved an acceptably similar method and had the same endpoint (complete and satisfactory abdominal wall closure). The ETHICAL model provides a means to ethically justify performance of Transition Zone innovations that involve a higher degree deviation from standard practice (and likely, involve higher risk) in one patient in the acute setting without the requirement for additional oversight. However, it would be prudent for a surgeon to seek help from colleagues/superiors when feasible in these situations. According to the proposed model, performing the Transition Zone innovation again in future patients would require appropriate oversight (such as IRB involvement), and would follow the same regulatory pathway as innovations categorized as Experimental Research.

1.4. The ETHICAL Model: Regulation of Transition Zone Innovations

This paper proposes the ETHICAL model (Fig. 2) for approaching novel interventions that fall within the Transition Zone category as a systematic process that the prospective surgeon innovator can utilize as a guide for ethical decision-making. This model can be used in situations involving Type A and B innovations. It can also be used in Type C Innovations as an adjunct to the model proposed by Reitsma and Moreno [1], or in addition to another peer-review process, such as review by an ethics committee and/or an “innovation committee.”

First, the surgeon should be able to demonstrate Expertise in his or her specific field and have adequate knowledge of the anatomy, physiology, and basic science specific to the underlying disease process that he or she is attempting to address. This can be evidenced through board certification, continual involvement in research, academic teaching, significant contribution to the literature or other scholarly activities, or dedicated training as a surgical innovator. This

![Image of Figure 1](image-url)

Fig. 1. Regulation of Surgical Innovations by Category: Practice Variation; Experimental Research; Transition Zone: Type A = performed spontaneously in response to an acute problem encountered in the OR or similar setting, Type B = address a life or limb-threatening condition and no adequate therapy currently exists, Type C = premeditated or planned, but performed in response to an urgent problem to benefit a specific patient. *As defined by specific criteria listed in Table 1.
criterion is essential for the permissibility of approaching a surgical problem in a novel way since “One has to master all that is known about a domain to be able to change it” [27].

Second, the surgeon must possess the Technical skills required to perform the innovation such as dexterity, coordination, familiarity with the necessary instruments and materials, and practice-based training in operations that are similar to the novel procedure. For example, a surgeon who has performed thousands of hernias and is able to easily perform all of the currently recognized standard methods for repairing a hernia would likely possess the technical ability necessary to adequately and safely repair a hernia in a novel way.

Third, the surgeon should assess the probable Hazards associated with both performing and not performing the innovation, and the latter must outweigh the former in order for the surgeon to proceed (“net hazards”). For example, a surgeon would estimate the overall risk and severity of an iatrogenic injury occurring as a direct result if the new procedure were attempted. If the estimated risk of performing the new procedure is greater than the risk of not performing it, the surgeon should consider not proceeding with the novel intervention and instead provide the current standard of care or Practice Variation. The novel idea, rather than be abandoned altogether, could be funneled into the Experimental Research pathway for further exploration with appropriate animal studies, IRB involvement, and regulatory oversight as applicable.

Alternatively, if the surgeon is vexed by the decision of whether to proceed with an innovation, he or she should seek immediate advice from a colleague trained in the same field. If the hazards of not proceeding are considered significant, then the net hazards would favor, and could ethically justify, attempting the intervention as long as the other criteria of the ETHICAL model are also satisfied. The element of hazard estimation is dependent on the first element introduced: “Expert,” since being an expert in one’s field would allow the surgeon to determine the likely net hazards with a higher degree of accuracy. Under such circumstances however, the counsel of another expert or committee, depending on the specifics of the situation, would be advisable.

Fourth, the surgeon should obtain adequate Informed consent from the child’s legal guardian prior to proceeding. This may involve stabilizing the patient in the OR and leaving the patient in the care of an appropriately trained colleague, then expeditiously discussing the net hazards with the child’s guardian, as in Type A Innovations. For all three types of Transition Zone innovations, the surgeon must be transparent in informing the guardian of the extent of his or her training and involvement in previous similar procedures and any necessary equipment, and whether he or she has never before performed the innovative procedure. If the child’s proxy is not available or refuses to grant permission, the surgeon should not proceed with the innovation, but instead provide the current standard of care or appropriate Practice Variation.

Fifth, the surgeon should be free from any Conflicts of interest, whether financial or non-financial, that may compromise the surgeon’s decision-making process for whether and how to proceed with an innovation. Examples of conflicts of interest include the use of equipment or materials for which the surgeon will benefit financially, prestige, career advancement, honors and awards, curriculum vitae enhancement, or simply the desire to be the first to perform a procedure [28,29]. It is imperative that the focus of all decision-making is on providing optimal patient care rather than on achieving any kind of secondary gain, as the potential for personal benefit in any form whether noble or ignoble can compromise objectivity and alter the clarity with which the surgeon makes key decisions.

If a possible conflict of interest exists that may significantly influence the surgeon’s decisions, it is recommended that he or she consult with a similarly trained colleague who is capable of acting as a disinterested third party. If no such person can be found, if the consulting surgeon believes a bias exists, or that it is not wise to proceed with the novel intervention for any reason, it would be advisable for the surgeon to instead perform the current standard of care or Practice Variation. The innovative idea could subsequently be shunted to the Experimental Research pathway with appropriate IRB oversight, and if necessary determination of safety and efficacy in laboratory models prior to implementation in surgical patients.

Sixth, the surgeon should devote ample time and effort in Analysis of the outcome and any relevant endpoints, and should also consider entering the innovative procedure into a formal research study for closer analysis. Immediately after the Transition Zone innovation is performed as well as after an appropriate follow-up interval, sufficient time and effort should be spent to determine what did and did not work, the reasons a particular outcome occurred, and what could be done differently in the future. This element of self-reflection encourages the surgeon to identify his or her strengths and weaknesses for future improvement and to evaluate the usefulness and safety of the novel intervention. Additionally, it is prudent that the surgeon not perform the innovative procedure on additional patients, except as part of a study (i.e. a case series) that is reviewed and approved by an IRB or similar body, in order to prevent propagation and widespread implementation of a potentially ineffective or harmful intervention.

Finally, it is important that the surgeon publish the results in the surgical Literature and/or in a peer-reviewed database regardless of whether an excellent or poor outcome occurred [30,31]. This database could be managed by each professional physician society’s ethics committee or “innovation committee” rather than using a general innovation database (i.e. national or international), since surgeons that belong to the same professional societies (i.e. otolaryngology, neuro-surgery, orthopedics, etc.) will likely perform similar types of innovations and would be best equipped to review the intricacies of these interventions. The function of the “innovation committee” would be very similar to that of current IRBs, except that it would be composed of a small group of experts in the same specific field as the surgeon, and would be responsible for reviewing and managing the innovation database/case log. Official “approval” would not be given, but instead the committee would provide “recommendations” or “guidelines” for the surgeon wishing to attempt an innovation. Database management and review by each society presents a feasible option, as each society would be responsible for a “piece of the pie” according to their area of expertise rather than one entity be responsible for analysis of every innovation entered in an immense database. Because there may be significant overlap, it would be optimal for all subspecialty societies to allow members of other societies to access their innovation database, and also provide short summaries or abstracts of cases at specific intervals (i.e. monthly, yearly) as an Innovation Report.

A central database of innovations and their outcomes that is sponsored and reviewed by each specialty society and not publically

| E | Expertise |
| T | Technical skills |
| H | Hazards |
| I | Informed consent |
| C | Conflict of interest |
| A | Analysis |
| L | Literature |

Fig. 2. Summary of the ETHICAL Model.
accessible could provide a mechanism for alerting other potential surgeon innovators who may have been planning to use a similar approach and didn’t realize that it had already been attempted. The database would provide information on the pitfalls or negative outcomes already encountered, and could help physicians avoid subjecting additional patients to the risk of the same procedure. If a surgeon searches the database and finds a procedure similar to the one he or she is hoping to attempt and it is already logged and labeled in the database as resulting in a poor outcome, then the surgeon should refrain from doing the same procedure. However, if after careful review and consideration the surgeon believes that their own attempt could result in a better outcome, then the provider would have the ability to appeal to the sponsoring society’s innovation or ethics committee with a proposal and rationale for performing the previously failed innovation. Reasons that may justify further attempts could include but not be limited to: possessing a different skill set than the original team, a subsequent improvement in the procedure or equipment, or addressing pitfalls encountered by predecessors. Another benefit of publishing in the literature or a peer-reviewed database, and knowing that one’s actions in the operating room will be available for review, is that it would likely motivate the surgeon to operate within their level of expertise as “The best antidote to cavalier surgical experimentation is outcome transparency” [32].

Going forward, the ETHICAL model recommends for Transition Zone innovations that demonstrate promising results in the first patient and could provide a potentially beneficial approach for future patients to undergo further analysis (such as a case series study, formal research, etc.) with appropriate oversight prior to implementation in subsequent patient(s) to mitigate dissemination of ineffective or harmful techniques prior to translation into standard surgical practice. Regarding different types of innovations that fall into the Transition Zone, the first attempt doesn’t require additional oversight for Type A and B, although collegial consult is strongly encouraged. Type C Transition Zone innovations do require oversight/approval for the first attempt, and subsequent attempts should be funneled through the Experimental Research regulatory pathway. Please see Fig. 1 (dotted arrows) for a schematic depicting the shunting of subsequent attempts through the Experimental Research regulatory pathway.

2. Discussion

Innovations are indispensable to the practice and advancement of pediatric surgery. Children represent a special type of vulnerable population and must be protected since they do not have legal capacity to consent, and their parent’s judgment may be compromised in circumstances when the child is very ill or no adequate therapy exists. Although a continuum, including a portion called the “Zone of Innovation” [3] has been described previously in the literature, to the author’s knowledge no previous model has been developed that attempts to define three categories of surgical innovations along the continuum according to specific intervention characteristics. The ETHICAL model also provides a novel, easy to remember pneumonic to aid in implementation of the model in clinical scenarios. The ETHICAL model has the potential to serve as an objective and standardized method for determining when to proceed with an innovation, proposes appropriate means for oversight/ regulation based on specific characteristics of a given intervention, encourages responsible practice, and is universally applicable across all surgical specialties and geographic locations. It can be employed in the clinical setting for any intervention to help guide surgeon decision-making with a one-patient-at-a-time approach. In other words, the model addresses the question, “What should be done now for this specific patient?” and is equally applicable regardless of the commonality the underlying disease process. Other possible uses of the ETHICAL model include situations such as the implementation of a novel procedure or equipment that other surgeons have used successfully and are becoming standard of care, but that an individual surgeon will be using for the first time in their own practice. Perhaps when publishing in the literature and/or a database, surgeon innovators could declare how the ETHICAL model criteria were satisfied as a reasonable substitute for IRB approval when performing novel interventions that are part of patient care and not clearly definable as Experimental Research. This could serve as a way to help mitigate rogue surgeons from attempting innovations that they are not qualified to perform, or that should have clearly undergone IRB review (for example, attempting a high-risk procedure to test a premeditated hunch or hypothesis in a situation that is not acute). It can also be used in disciplines beyond pediatric surgery, since all elements of the model are applicable to other fields. While the model is conceptual and has not yet been tested in clinical practice, it has been applied to historical cases during the model’s development and refining stages in order to create a feasible model for guiding surgical decision-making. The author recognizes that because of the nature of surgical practice, proposed guidance models are likely to undergo subsequent iterations as the field advances and application of the model evolves. Testing the model prospectively in a case series study and at its completion reporting performance metrics would provide valuable data to promote additional fine-tuning, and strategies for testing the model are currently underway. The ETHICAL model is intended to serve as a starting point in working toward a comprehensive model to guide surgical innovation that allows those that know the intricacies and nuances of pediatric surgery best, the pediatric surgeons and professional pediatric surgical societies to participate in self-regulation of innovations in a manner that safeguards patients without stifling creativity or unduly hampering surgical progress.

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