



Neurosurgical Forum
LETTERS TO THE EDITOR

Systematic and safe approaches to innovation in pediatric pinning

TO THE EDITOR: We read with interest the article by LoPresti and colleagues,¹ which provides an overview of the standard techniques and history of “pinning” to immobilize the head, with considerations specific to pediatric neurosurgery (LoPresti MA, Nguyen J, Lam SK. Pinning in pediatric neurosurgery: the modified rubber stopper technique. *J Neurosurg Pediatr.* 2020;26[1]:98–103). We agree with many of their observations, including limiting the use of pins when possible and using pediatric pins and/or applying less force in younger children (age < 5 years). The development of electromagnetic-based neuronavigation systems has allowed alternatives to rigid immobilization of the head in many circumstances, and this is not discussed in the article.

We took particular interest in their modification of the classic Mayfield clamp system with a rubber stopper from a medication bottle or Vacutainer, which was first reported back in 1996, as an adaptation to the application of a Leksell frame to facilitate the biopsy of a thalamic lesion in a 5-month-old patient.^{1,2} The authors purport that this reduces the risk of “plunging” (when a pin fractures the skull with potentially disastrous consequences) or pin slippage due to reduced pressure. The risks reported related to the rubber stopper modification include pressure on the skin from the stopper, which the authors report as not being a significant issue.

While an innovative solution and one that must be considered, especially in settings in which alternative immobilization systems are unavailable, apart from the two reports cited, we could not find any literature attesting to the safety of this modification and believe that this raises a number of important issues.

The first has to do with liability and usage outside of the indications for use. Importantly, while there are no age limits in the manufacturer’s documentation or FDA approval, the manufacturer’s indication for use states:

The [clamp] is placed on the patient’s skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid

fixation is necessary. The accessories provided with the skull clamp also allow it to be used where stabilization is desired instead of complete fixation.^{3,4}

Importantly, the documentation specifically states that the device should only be used with other Mayfield products and that the design of the device should not be altered.⁴ Therefore, the authors’ modification, while innovative, could put both the patient and clinician at risk in terms of risk and liability if complications were to occur.

The second issue surrounds the lack of systematic evaluation of the benefits and risks of this modification. Seemingly, the authors of this study use this modification in their routine practice, but benefits and risks have not been assessed in the peer-reviewed literature. In addition, we could not find any technical evaluation (either in simulations or models) of the effects of this modification.

Innovative minor alterations to existing medical devices, like the one we are discussing here, have the potential to have a dramatic impact on patient care and outcomes, and the issues we raise here should not discourage innovators from making such advances. Conversely, we encourage systematic evaluation of surgical innovation and new medical devices via established frameworks such as the IDEAL Framework (Idea, Development, Exploration, Assessment, Long-Term Follow-Up, Improving the Quality of Research in Surgery) and its medical device-specific framework, the IDEAL-D framework.^{5,6} Modifications of this type would require a small amount of preclinical study (stage 0) to identify the need for such modifications and perform some basic laboratory testing to ensure that the clamp characteristics are not detrimentally altered by the modification with the rubber stopper. Although the first-in-human (stage 1) studies have already occurred, IDEAL-D suggests that, in other cases, such modifications should be registered to ensure adequate oversight before progressing to further evaluation via small-scale prospective use (stage 2), larger prospective studies (stage 3), and longer-term evaluation (stage 4).⁶ While seemingly an onerous task to take such a small modification through all of these stages, this framework provides a systematic approach to ensure that medical device innovation proceeds in a safe and pragmatic manner.

We definitely see the benefit of this particular technique and would welcome a systematic evaluation to ensure that

patients and clinicians benefit maximally from such innovative and simple modifications.

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Disclosures

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Response

We thank the authors for their interest and insightful feedback on our article. Our technical paper serves as a review of the various modalities, adjustments, and considerations when pinning the skull in pediatric neurosurgery. The authors bring up valuable considerations to discuss.

The authors highlight the development of electromagnetic neuronavigation in affording alternatives to fixed head immobilization devices (HIDs). This is absolutely true; the benefits include intraoperative guidance with baseline navigational imaging while avoiding the risks of pinning.¹ Disadvantages include the higher costs as-

sociated with disposable probes and tracers, tradeoff of accuracy compared with rigid fixation, and risk of sterility breaches if movement occurs intraoperatively.¹ Thus, while revolutionary in regard to pinning, it is not without caveats.

Additionally, the authors discuss the safety and liability of modifications to standard pinning techniques, including the modified rubber stopper technique. We agree with the authors in underscoring the importance of safe patient care and the role that systematic, regulated safety and efficacy studies play in innovations. While innovation often stems from adapting or building upon existing technology, the next steps to further expand this or other techniques would include partnership with HID product development branches, legal/liability considerations, engagement with potential patients and families, and larger-scale studies in the field. While we postulate that this modification may help minimize the risk of skull fractures related to pinning in the vulnerable pediatric population and minimize potential damage to the skin from pin scything or slippage, further study is warranted. Indeed, frameworks for surgical innovation begin with a single case that initiates the spirit of inquiry and descriptive studies in idea and development phases; continuing larger-scale work occurs in exploration, assessment, and long-term study stages.²

We are grateful for the opportunity to expand on our review in this letter and discuss the formal study of innovation with modifications to existing practices and devices. We thank the authors for constructive and insightful feedback, and we aim to be consistently thoughtful and informative in contributing to responsible innovation in the field of pediatric neurosurgery.

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