

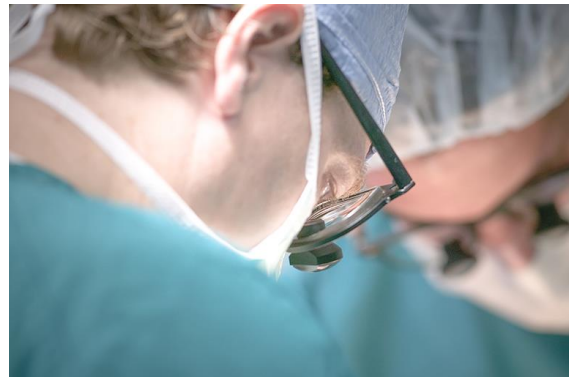
Preventing patient injury from skull clamp systems during neurosurgery

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Background

Skull clamps or pin-type head holders are routinely used during neurosurgical procedures to provide rigid fixation for the head and neck. Skull clamps enable prolonged patient immobilization with minimal risk of soft tissue injury during microsurgery and prevent eye compression and abrasion during prone positioning.¹⁻³

The three-pin skull clamp — considered the gold standard for head fixation — is viewed as safe^{2,4-6}; however, complications such as head slippage and lacerations, epidural and subdural hematomas, skull fractures, intracranial hemorrhage and air embolism can occur during its use.^{2,4} Because younger children (especially those less than 3 years old) have an increased risk of fracture and secondary hemorrhage due to skull bone thinness, alternatives to pin fixation should be considered.^{3,4,7}



Before 2016, isolated cases of complications from skull clamps such as skull fractures, epidural hematomas and lacerations had been highlighted in the literature.^{1,2,6-10} In 2016 the US Food and Drug Administration (FDA) called attention to these safety issues in a report that underscored the frequency of injuries.^{11,12} Based on more than 1,000 medical device events reported over a seven-year period, the FDA warned health care providers about the risk of skull clamps slipping before and during neurosurgery procedures. More than 700 patient injuries — including cuts, lacerations and bruising to the face and scalp, skull fractures and hematomas — were reported to the FDA.^{11,12} Events involving device slippage have not been specific to any one manufacturer or brand of devices.¹¹ The causes of skull clamp slippage or skull fracture before or during surgical procedures are multifactorial and may include mechanical failure, lack of maintenance, errors in placement of the skull clamp or adjoining parts, excessive pin pressure, and patient characteristics such as skull thickness and bone quality.^{4,11-13}

Additional events involving breakage in the skull clamp system were identified in Vizient® Patient Safety Organization (PSO) reports as well as FDA alerts and recalls.¹⁴ Neurosurgical skull clamp systems comprise a skull clamp that is pinned to the patient's head and adjoined to a base unit using a knob with a screw. The base unit is secured to the operating room table.¹¹ In some reports, the screw pin securing the skull clamp to the base unit broke in half, separating at the point where the screw threads meet the pin shaft. As a result, the skull clamp detached from the base and dropped, creating the potential for serious patient injury.¹⁴

Assessment

The Vizient PSO conducted a search of event reports involving skull clamps and analyzed 35 near-miss and adverse events voluntarily reported since 2016 to improve our understanding of the associated safety issues and contributing factors. Most of the patients involved were adults, but a few were in their teens. These events were categorized as an equipment malfunction, broken item, or unintended laceration or puncture. The issues described in reports submitted to the Vizient PSO were similar to those in the FDA reports. The majority of events (70 percent) involved the skull pin slipping out of place after being secured, causing injury to the patient's head. Pin slippage commonly occurred during patient repositioning between prone and supine positions. In other cases, the head clamp did not lock properly and swiveled while in a locked position; headrest joints or the locking handle on the base unit became loose, unlocked or could not be tightened; and connections between adjoining parts (e.g., swivel adapter and skull clamp) were stuck and could not be adjusted or disconnected. Several events involved breakage of screws or pins; for example, the screw in the knob that secures the skull clamp to the base unit broke in half, or the skull pin splintered during the procedure.

These events led to patients' heads no longer being immobilized in the skull clamp; they either slid between the pins, suddenly dropped or moved from a flexed to an extended position. These patients sustained cuts or deep lacerations to the head that required sutures or staples, or caused fractures and possible brain injury. Sometimes, the issue was identified while the procedure was being performed and the surgeon or a surgical team member had to break scrub to address the issue, delaying the procedure. In other cases, the injury was discovered at the end of the procedure. Factors contributing to failures in the system's integrity included sudden movement by the patient, positioning or application errors such as improper distribution of pressure on pin sites, inadequate tightening of knobs or locking handles, or placement issues associated with patient bone defects. Others were reported to be mechanical failures (e.g., device breakage).

Recommendations

The Vizient PSO, in collaboration with an expert advisory team, compiled leading practices to prevent errors and mechanical failures associated with the use of neurosurgical head clamp systems. To mitigate the risks of patient injury from head holder systems before and during neurosurgical procedures, health care providers should be aware of proper device maintenance, techniques for safe and proper use, and patient-specific and device placement considerations.



Device maintenance

- Follow the manufacturer's recommendations for cleaning, sterilization and maintenance, and schedule replacements based on device life expectancy.^{11,15} For some products — such as the Mayfield Imaging XR2 Radiolucent — the components may be damaged by steam sterilization and high heat.^{11,16}
- During cleaning, inspect and remove any components if they appear damaged (i.e., they have breaks, cracks, chips or other signs of wear) or do not function properly, and return them to the manufacturer.^{11,12}
- Keep all parts of the same system together (i.e., base, skull clamp and adjoining parts) by engraving or labeling each piece.
- Establish a schedule for quarterly inspections of the neurosurgical head holder system by your organization's manufacturer representative.¹⁵

Patient risk assessment

- Evaluate the risk of complications that can occur with the use of pin-type head holders based on the patient's age (e.g., young children and advancing age) and preexisting medical conditions (e.g., chronic renal disease and long term use of antiepileptic drugs, which contribute to poor bone health, immobility, hydrocephalus and chronically elevated intracranial pressure).^{2-4,6,7,9,10}
- Consider using nonpenetrating types of head holders in high-risk patients and children less than 3 years old.^{2,3,7}
- Compare the risks and benefits of pin fixation to the risks of using other head rests — some of which may cause skin pressure necrosis, especially during prolonged operations.^{3,7}
- Consider a computed tomography (CT) scan to assess skull thickness before using pins.^{3,4,7}

Safe and proper assembly of equipment

- Follow the manufacturer's instructions on the use of accessories for the neurosurgical head holder system¹¹; for example, do not combine with other products or limit the number of extension arms used.^{13,16}
- Do not modify the construction of the device.¹⁶
- Inspect the neurosurgical head holder system and all accessories before and after each use.^{11,15}
 - Remove defective, damaged or malfunctioning components and return them to the manufacturer for inspection and maintenance.¹¹
 - Ensure the base unit is working properly and is secured to the operating table.¹⁶
 - Prior to each use and before fixation, test the stability of the head holder system by applying a force comparable to that which will be used during the surgical procedure. Use another device if issues are identified.^{11,12}
- Follow manufacturer recommendations for assembly.
- When using the Mayfield Imaging XR2 Radiolucent:
 - Fully tighten and secure all adjustable portions of the device to prevent skull pin slippage, parts becoming loose and adjoining parts becoming disconnected. Overtightening the device's adjustment screws may result in damage to the unit.¹⁶
 - Ensure threaded connections are secure and starbursts have meshed to prevent damage and instability of the device during use.¹⁶
 - Ensure the base unit isn't overextended or overloaded, which may result in unintended movement, shortened product life or damage to the unit.¹⁶

Device selection, application and proper placement

When using a neurosurgical head holder, select the most appropriate device and technique based on the patient's age, medical history and physical characteristics to prevent injury.

- Support the patient's head and neck while applying and removing the device.^{11,12}
- Carefully position the pins in the appropriate location using the optimal pressure.⁶
- When pin fixation is necessary in young children, use the appropriate pin size and design for pediatric patients and tighten gently to obtain the appropriate pressure.^{4,6,7,9,11}
- When positioning the skull clamp pins, avoid uneven, diseased, thin or fragile bones, such as the frontal sinuses, the temporal squama, venous sinuses and previous craniotomy bone flap sites, as well as areas with major scalp vessels and nerves.^{2,3,7,10-12}
- Properly position the patient and follow the manufacturer's guidelines to ensure the three-pin fixation device is appropriately placed. When tightening the neurosurgical head holder system, apply force

that is appropriate to the thickness and bone quality of the patient's skull.¹¹

- Require a double-check of the head holder system by the surgeon or a second member of the surgical team to ensure the pins are properly placed both before the procedure and after repositioning the patient.
- For patients who will be prone during the procedure, apply the skull clamp when the surgeon is present.
- Monitor patients for signs and symptoms of skull fracture during application (e.g., loosening of the clamp, a cracking sound or no increase in pressure when the pin is being tightened),^{4,7} during the procedure (e.g., unexpected, persistent hypertension or brain swelling)³ and after use (e.g., persistent headache and nausea)^{6,9} so that providers can intervene in a timely fashion if a secondary hematoma occurs. Obtain a CT scan when symptoms are present.^{3,6,9}
- Remove the head holder while the patient is in the supine position.²

Next steps

- Increase staff awareness of possible complications of head fixation devices.
- Ensure that all surgical team staff that are involved with neurosurgical head holders are trained and demonstrate competency in their use.
- Monitor compliance with recommendations for cleaning, maintenance and application.
- Conduct a root cause analysis when events involving skull clamps occur.
- Report incidents involving neurosurgical head holder systems to the manufacturer, FDA and your PSO.¹¹

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