Endoscopes and helmets: yes or no?

DAVID F. JIMENEZ, M.D.

Department of Neurosurgery, The University of Texas Health Science Center at San Antonio, Texas

The authors report a limited, retrospective 2-year experience treating 18 infants with “nonendoscopic, minimally invasive calvarial vault remodeling without postoperative helmeting for sagittal synostosis.” Their analysis presents a technique that involves making 3 incisions, each measuring 3 inches in length, to remove a 2- to 3-cm wide strip of midline calvarial bone followed by bilateral barrel-stave osteotomies. The study’s mean duration of follow-up was only 16 months, the mean surgical time was 111 minutes (range 46–161 minutes), and the average length of hospital stay was 2 days. Two different means of estimated blood loss are given: 79 ml and 101.4 ml. The former does not include a patient who lost 475 ml, or 108% of her blood volume. Eighty-nine percent of the patients required a blood transfusion at the high rate of 25 ml/kg (mean weight-adjusted volume). The authors present their outcomes based on a simple 5-question parental questionnaire and postoperative cephalic indices (CIs).

Any procedure that attempts to minimize blood loss, surgical time, extensive tissue dissection, and overall trauma to the patient should be seriously considered. In this report the authors have attempted to address these issues. Their basic concept of removing a wider strip of midline bone along with bilateral barrel-stave osteotomies is not new and has been shown to produce excellent results. In their efforts not to use the visualization aid of an endoscope, they have made skin incisions totaling 9 cm and almost as long as a bicoronal incision. Furthermore, their technique has led to an unacceptably high percentage of patients (89%) requiring blood transfusions, compared to our endoscopic series of 221 cases with a transfusion rate of 7%.

An added variable was the infusion of tranexamic acid in 44% of the cases. Therefore only 10 patients are available for comparison to most other series using endoscopic techniques that did not use this adjunctive therapy. This cohort had a mean fractional blood loss of 18.4% compared to 5.3% in our series. Additionally, in the middle of the study the technique was changed and the bone removed was replaced due to the presence of “small bony defects.” This, in essence, changes the operation, and no comment is made regarding the effects of this significant change.

Outcomes were measured with the CI and a parental questionnaire. Although not a perfect tool, the CI does provide a quantitative measure of the patient’s overall head shape. It is a well-known phenomenon that patients with sagittal synostosis will improve immediately after surgery no matter which procedure is performed. The dura (and the cranium), however, is genetically programmed to resume a scaphocephalic shape within the first 2 years of life. One of the reasons that strip cranietomies have been generally abandoned is this phenomenon. Postoperative helmet therapy has been introduced with the idea of physically combating this predetermined genetic tendency. My colleagues and I have published and demonstrated that a patient’s ultimate head shape will not be finally set until he or she is at least 18 months of age.

From the age of 18 months, the patient’s CI will only drop a maximum of 3 points by the time he or she reaches his or her teenage years. The author’s mean duration of follow-up is only 16 months, and almost 40% of the patients had less than 18 months of follow-up, making the results and conclusions incomplete and invalid. Furthermore, 2 of the patients had lower CIs at 1.5 and 2 years after surgery. This, in my mind, underscores the need for helmet therapy.

The use of a biased parental questionnaire to assess outcomes is plainly unacceptable, far from a “critical appraisal” tool and an invalid way to determine “cosmetic” and postoperative results. Asking parents who have already been negatively biased toward endoscopes and helmets about their use or lack thereof in the treatment of their child is unfair and in itself biased.

In the Discussion, the authors state that “a paucity of compelling data exists to justify the de facto use of an endoscope for safety and efficacy.” A quick review of the literature points to 4 recent articles presenting 261 patients who were treated at 4 different centers using our endoscopic techniques for sagittal synostosis. All these papers showed excellent results with significant reduction in the need for blood transfusions, low surgical time, markedly decreased blood volume losses, and minimal morbidity. Moreover, our center’s current experience with 251 patients and 15 years of follow-up continue to show similar results with long-lasting excellent outcomes. As such, I believe that there are compelling data to justify the use of the endoscope for safety and efficacy.


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Lastly, I agree that the authors’ procedure needs to be standardized, improved, further investigated, and critically assessed before it can be considered as a viable surgical option.

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Disclosure

The author reports no conflict of interest.

References


Response

TODD A. MAUGANS, M.D., 1 AND IAN S. MUTCNIICK, M.D., M.S. 2

1 Division of Pediatric Neurosurgery, Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio; and 2 Division of Pediatric Neurosurgery, Kosair Children’s Hospital, Norton Neuroscience Institute, Louisville, Kentucky

We greatly appreciate the excellent review and critique of our manuscript by Dr. Jimenez. He is a pioneer in craniosynostosis surgery, leading our specialty into the realm of minimally invasive procedures. The techniques he has developed and refined over the past 15 years—endoscopically assisted craniectomies with postoperative cranial orthosis application—represent the contemporary “gold standards” for evaluating new minimally invasive craniosynostosis procedures.

In our manuscript, we have presented our preliminary experience with a minimally invasive technique for the treatment of sagittal synostosis that varies in 2 important ways from Dr. Jimenez’s procedure. First, we did not use the endoscope for visualization. Second, we did not use postoperative cranial helmeting. In this respect, we have attempted to further “minimalize” a minimally invasive procedure and simplify the postoperative care of patients with nonsyndromic isolated sagittal synostosis.

Safety, efficacy of deformity correction, and parental satisfaction were our primary outcome measures.

Safety is paramount for all surgical procedures. There was no significant morbidity in our series and none of our patients died. Although Dr. Jimenez did not dispute this, he did express concern about reported blood loss in our patient population. While minimization of blood loss is a primary goal of minimally invasive procedures, there is no established “acceptable blood loss” for such procedures. Estimated blood loss (EBL) is exactly that: estimated. Surgeon and anesthesiologist estimation is notoriously unreliable, generally biased toward underestimating actual blood loss. In another project from our group, we demonstrated a statistically significant correlation between calculated blood loss (based on red cell mass determinations via preoperative and postoperative hemoglobin levels) and observed EBL. The patients we report on in this current manuscript were also included in that analysis and report. Because of fastidious monitoring of blood loss via direct volumetric measurements and surgical sponge weighing as well as correlating with calculated blood loss, we believe our reported EBL to be accurate, albeit higher than reported by Dr. Jimenez and others. It is not clear that the EBL was so carefully measured in other series referenced by Dr. Jimenez.

Although transfusion of blood products should be minimized for patients undergoing surgical procedures, the decision to initiate a transfusion is complicated. This may depend on EBL; objective estimates of red cell mass, such as hemoglobin and hematocrit levels; transfusion thresholds espoused by anesthesiologist, surgeon, and critical care medicine specialists; patient factors such as heart rate, blood pressure, pallor, and oxygen saturation; and parental concerns for risks of transfusion versus risks of severe anemia. In our institution, we maintain a bias toward early intraoperative transfusion. We have been unwilling to subject patients to immediate postoperative hematocrit levels as low as 10%, as reported by Jimenez et al. We believe that the contemporary risk of transfusion-related complications is low, and that this counterbalances the risk of producing a morbid or fatal outcome (including processes such as disseminated intravascular coagulopathy that can result in death) for an elective procedure. As at other institutions, we are continuously revisiting this issue.

Dr. Jimenez agrees that our primary objective of the normalizing the CI was achieved. He commented negatively about the follow-up interval in our patient group. We referenced the single manuscript existing in the literature that reports robust data specific to stabilization of deformity correction following craniosynostosis procedures without postoperative helmeting. These data more appropriately apply to our cohort than Dr. Jimenez’s and indicate that stabilization occurs around 6 months postoperatively. Similarly, the concept that a patient with sagittal synostosis is “genetically programmed to resume a scaphocephalic shape” before 2 years of age is speculative, as it is based on molecular biology observations and experiments in nonhuman species. We certainly agree that longer follow-up of our patients is essential; however, we believe that deformity correction in our patient population will be maintained.
We agree with Dr. Jimenez that a parental questionnaire has limited utility for evaluating outcomes as it is not a scientifically rigorous research tool. We present these data merely to demonstrate general parental satisfaction. The craniofacial surgery community must work diligently to create meaningful subjective and objective outcome measures.

We want to emphasize that there are important differences between our surgical technique and that of Dr. Jimenez. We believe these elements are responsible for our patients’ rapid and sustained improvement in CI, without the need for externally applied forces via cranial orthoses. Our use of accurate, radially oriented barrel staving cuts in the parietal bones, releases at the coronal and lambdoid sutures, and cuts into the occiput to allow reduction of the posterior bulb all differ from Dr. Jimenez’s technique. These surgical manipulations recapitulate the procedure that we described for open calvarial vault remodeling, also performed without postoperative helmeting and producing excellent results. Furthermore, our total incision length is less than half the length of a standard bicoronal incision, and not “almost as long as” one, as stated by Dr. Jimenez.

Finally, we never set out to challenge the safety or efficacy of Dr. Jimenez’s technique. We are simply stating that a simpler approach to sagittal craniosynostosis may be possible. We emphasized that our series is preliminary and limited in patient numbers. Yet, we remind Dr. Jimenez that he reported on just 4 patients when he introduced his “endoscopic craniectomy for early surgical correction of sagittal craniosynostosis” in this journal in 1998. Since then, he has refined and standardized his technique, has achieved significantly lower reported blood losses and transfusion volumes, and has confirmed that his corrections are sustained in most patients. In our manuscript, we report on our early experience with a similarly novel iteration of minimally invasive cranial surgery for sagittal craniosynostosis; we trust that it is worthy of similar careful consideration by the neurosurgical community.

References


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