

Craniofacial

# Could Extended Reality Visualization Decrease Blood Loss in Craniofacial Surgery?

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### **Abstract**

**Background:** Blood loss is a major concern in craniofacial surgery due to extensive skeletal remodeling. Various strategies and technologies have been employed to mitigate blood loss, but the impact of Extended Reality (XR) visualization has not been extensively studied. This study investigates the effect of XR visualization on blood loss in craniofacial surgery. **Materials and Methods:** This retrospective cohort study included patients undergoing major craniofacial procedures at a tertiary academic medical center from January 2018 to February 2022. An internally developed XR system displaying Virtual Surgical Planning (VSP) data overlaid on patient anatomy was introduced in 2019. The study compared blood loss between patients who had XR-assisted surgeries (n=17) and those who did not (n=62). Primary outcome measured was calculated blood loss (ERCV%), and secondary outcomes included the incidence of sinus proximity bleeding, dural injuries, surgery duration, and transfusion volumes. **Results:** The XR-assisted group had significantly lower blood loss (43.7% vs 61.9%, P < .05). Sinus proximity bleeding during craniotomy was also significantly reduced in the XR group. More patients in the XR-assisted group avoided transfusion altogether (35% vs 24%) and tended to have fewer donor-units exposure (0.88 vs 1.34), but those trends did not reach statistical significance in our small study sample. **Conclusion:** In this pilot study, XR visualization in craniofacial surgery is associated with reduced blood loss and sinus proximity bleeding during craniotomy. While the study suggests XR can enhance surgical safety, larger, well-designed investigations are needed to confirm these results and fully understand the implications of XR technology in craniofacial surgery.

### **Keywords**

craniosynostosis, blood loss, augmented reality, extended reality, calculated blood loss, virtual surgical planning

# **Background**

Blood loss remains one of the major concerns in craniofacial interventions requiring extensive remodeling of the craniofacial skeleton. 1,2,17 Surgical maneuvers such as subperiosteal dissection, craniotomies, craniectomies, and epidural dissection entail some amount of blood loss. Several incremental strategies are used to remediate or minimize that amount, including hypotensive anesthesia, antifibrinolytics, traditional hemostatic agents (eg, Bone wax), and novel procoagulants. Technological solutions such as high-speed burr craniotomes that occlude vascular channels, footplate designs, and ultrasonic osteotomes have also been incrementally adopted.

Computer-Aided Navigation (CAN) enables less invasive procedures and is well established in neurosurgery and orthopedic surgery. CAN has demonstrated decreased blood loss in certain indications.<sup>3,4</sup> CAN often requires a specialized imaging protocol, additional radiation exposure, and specialized

spatial registration attachments that may limit its widespread applicability.

Virtual Surgical Planning involves preoperative processing of imaging data to segment out structures of interest, plan and rehearse surgical steps virtually, and fabricate patient-specific implants, models and cutting guides, albeit at a significant cost and time delay. VSP has been shown to improve surgical accuracy but has not been specifically investigated for decreasing blood loss. <sup>5,6</sup>

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Extended Reality (XR) Navigation devices have been recently proposed to increase the accuracy of various surgical procedures, including pedicle screw placement, hip and knee arthroplasties, and External Ventricular Drainage placement. XR systems have functionalities that overlap with CAN and VSP, while potentially decreasing radiation exposure, costs and cognitive load. While significant confusion exists about the nomenclature of commercial devices (Virtual Reality, Augmented Reality, Mixed Reality), the FDA uses Medical Extended Reality for these systems. 11

An internally developed XR system was introduced at our institution since 2019. The system was designed for teaching facilitation, visualizing planned osseous movements and planned bone contouring. The XR system was used for a variety of applications, including craniofacial reconstructions, facial and chest trauma, microtia repair and microsurgery. The system displays VSP data overlaid on the patient's anatomy. As part of the VSP, a segmentation of the dural anatomy and intraosseous vascular channels of the calvarium is generated and subsequently displayed in XR. These images were used to inform and guide on placement of craniotomies around major dural sinuses and emissary veins. Anecdotally, our neurosurgery colleagues reported decreased bleeding while performing craniotomies around critical areas.<sup>12</sup>

The study investigated whether the XR display of VSP in Craniofacial Surgery decreased calculated blood loss in a retrospective cohort of patients undergoing major craniofacial procedures. Secondary outcomes included the incidence of "sinus proximity" bleeding, dural injuries, duration of surgery, and overall transfusion volumes.

### **Materials and Methods**

### Study Design

This is a retrospective cohort study of all patients undergoing major craniofacial procedures at our institution between January 2018 and February 2022. The study dates cover the introduction and increased use of Virtual Surgical Planning and Extended Reality Technologies by the senior author. The study period covers the introduction of the Extended-Reality technology into clinical practice, and includes first-in-human experience. The duration of the study was restricted to the selected dates to minimize variability due to availability of adjunct technologies, such as VSP, resolution of imaging, Tranexamic Acid, and surgical team variability.

# Setting

Children's hospital of a tertiary academic medical center. The craniofacial team consisted of a craniofacial surgeon (senior author) and 3 different pediatric neurosurgeons. The nursing and anesthesia staff were pediatric "generalists" not specifically assigned to a Craniofacial Team.



**Figure 1.** Occipital view of a segmented dural surface and intraosseous vascular channels from non-contrast enhanced CT scan DICOM data. The imprints of the dural sinuses and intracranial osseous anatomy (short thick arrows) and intra-osseous vascular lakes (long thin arrows) are clearly seen.

All patients underwent surgical procedures using standard and well described techniques. <sup>13</sup> All patients had pre-operative CT scans with volumetric bone surface reconstruction ("3D CT"). Brain MRI was obtained when clinically indicated (syndromic synostosis, Chiari etc...), and vascular imaging such as CT venogram or MRA/MRV obtained for all patients with syndromic synostosis.

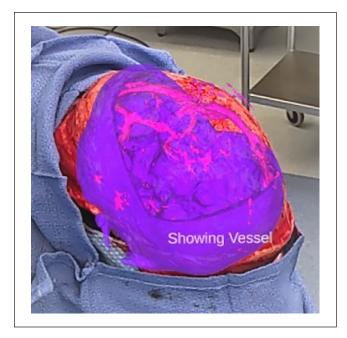
# Virtual Surgical Planning

VSP segmentation and imaging of the dural surface and intra-osseous vascular channels was performed in-house by the senior author using pre-operative imaging (Figure 1). Additional VSP for some complex craniofacial osseous movements (eg, facial bipartition, complex orbital asymmetry, etc...) was obtained in consultation with commercial provider KLS-Martin<sup>®</sup> Individual Patient Solutions. Three-dimensional surface models (manifold surfaces) are uploaded to the Extended Reality System.

# Extended Reality System

The VSP data as well as selected craniofacial landmarks are compiled into an individual patient-specific "App" that is uploaded to a Microsoft® Hololens® 2 Augmented Reality headset (Figure 2). Registration is done by assigning preselected virtual fiducials to the patient's anatomical

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**Figure 2.** Intra-operative overlay of segmented dural sinuses including superior sagittal and transverse sinuses (pink-magenta) and the planned osteotomies (Bone in purple). The patient is prone, and the scalp flaps retracted.

landmarks. The virtual fiducials are manipulated using Infrared array tracking, familiar to users of Computer-Assisted Navigation (CAN), image arrays using computer vison algorithms, or LIDAR "depth" camera, tracking hand and objects. Selection of landmarks at the periphery of the surgical field along the 4 or 6 cardinal directions is mathematically advantageous, since it ensures that the error of the hologram at the surgical site is less than the error of registering the fiducials.

For technical reasons, the system is highly accurate in the frontal plane (XY plane), and less accurate in the depth plane (Z axis). The accuracy of depth projection is critically related to an accurate measurement of the operator's InterPupillary Distance (IPD). A "walk-around" test is performed after registration to verify accuracy: The operator walks around the subject in a clockwise fashion while maintaining visual lock on the aligned hologram. If the holograms "moves" left with the operator, the system is calibrated to a larger IPD than the user's, and vice versa. IPD calibration is more accurate in a well-lit environment. Bifocal, multifocal or unusually shaped frames may affect this measurement.

The system tracks the position of the surgeon's gloved hand, which is used to "position" and assign virtual fiducials, manipulate models, use virtual or real instruments, and position a "cross sectional" plane into the anatomical models. The virtual display is toggled by the surgeon's voice using pre-programmed "voice commands" and can be operated using the surgeon's gaze. The system is designed for short intermittent displays of extended-reality data to avoid

obstruction of the operator's visual field, to minimize surgeon cognitive load (eg, no complex menus), and to minimize accidental breach of sterility by avoiding use of virtual buttons (See Supplemental Appendix 1 for a short video of the registration process and operation of the system).

The Extended Reality system used for this study tracks the position of the headset in room-space using external cameras and "Inertial Monitoring Unit" (IMU), also known as "inside-out" tracking. This tracking method is sensitive to cumulative errors, therefore registration is repeated prior to each visualization of virtual data. It also doesn't track patient movement, so overlay is done on the immobile (anesthetized) patient. The specified error of registration is 1 to 3 mm (95%) and 5 mm (99%). The specified duration of accurate registration using "inside-out tracking" (<5 mm) is 90 seconds.

Anatomy "Anchors" may be attached to the patient's osseous anatomy, instruments or osseous segments (eg, an osteotomized zygoma). These can be tracked continuously ("direct tracking") using the methods described above, with a specified accuracy of 1 mm and one degree.

The software device obtained FDA-clearance in October 2022 (InraOpVSP<sup>TM</sup>, Xironetic LLC, Oklahoma City, OK, USA). An updated version of the software device with direct patient, instrument and bone segment tracking was not used on any patient in this study.

# **Participants**

The index and cohort patients were recruited from separate IRB-approved studies. The data reviewed was part of a prospectively collected database. A separate IRB approval was submitted for the review of previously collected data.

Index patients: Patients had VSP/XR at the discretion of the operating surgeon (senior author), as part of a separate study. The cases were selected for their educational values to learners (residents and medical students), or due to the complexity of the required skeletal movements.

Control cohort: All patients undergoing major Craniofacial Surgery within the study window were considered. Major procedures were defined as Cranial Vault Remodeling (CVR), Cranial Vault Distraction (CVD), Fronto-Orbital Remodeling (FOR), Fronto-Orbital Distraction (FOD), Monobloc or Fronto-Facial Distraction, Facial Bipartition or Box Osteotomies, and Craniomegaly reduction.

Patients whose surgeries did not include an intracranial portion were excluded, as well as patients that did not have a pre-operative or post-operative hematocrit or on file (see below).

### Variables and Data Sources

The patients' electronic medical records were reviewed for demographic data, weight, date of birth, date of surgery, and diagnosis. The type of surgery was retrieved from the operative note.

The presence of "Sinus Proximity" Bleeding (SPB) was defined as any mention in the operative note of visualized dural sinus injury after flap elevation, visualized bleeding from a large collateral or emissary vein, or copious bleeding after craniotomy in proximity to known dural sinus locations when the bone flap is not elevated (eg, in cranial vault distraction), typically requiring extended packing with hemostatic agents. Sinus Proximity Bleeding is further categorized as occurring during craniotomy, or during flap elevation/epidural dissection. Since visualization of extended reality data was used during intraoperative planning and execution of the craniotomies, but not for the epidural dissection, it is hypothesized that extended reality navigation use would decrease the former but not the latter.

Any mention of dural tear or injury requiring repair was noted. The starting and end times of surgery are noted to calculate duration of surgery, as well as the volume and type of transfused blood products, intraoperatively as well as post-operatively until discharge. Pre-operative hemoglobin/hematocrit, and post operative daily hemoglobin/hematocrit until discharge is noted. "Final" hematocrit was the latest value recorded prior to discharge.

Intraoperative and post-operative complications, if any, are also noted.

# Confounding Variables

Due to its advocated effect on blood loss, 14,15 the use of Tranexamic Acid (TXA) or other fibrinolytics was noted. The use of TXA was left to the preference of the anesthesia team. A Syndromic association may increase the risk of associated vascular anomalies thus potentially blood loss. Similarly, elevated IntraCranial Pressure (ICP) may increase collateral circulation, including transcranial channels, and could similarly increase blood loss. Since navigation systems may prolong surgery, thereby prolonging "oozing" from the dura and bone edges, the duration of surgery was noted and correlated to calculated blood loss (see below). The age of the patient was similarly correlated to calculated blood loss, since older patients may bleed more from larger bone surfaces and a more developed diploe, but may bleed less in proportion to body weight, since cranial size decreases in proportion to body size as the child ages, especially after 3 years of age.

# Bias

The senior author discloses an interest as co-inventor of IntraOpVSP<sup>TM</sup> and founder of Xironetic, LLC (Oklahoma City, OK). To minimize latent bias, the data and statistics were openly reviewed and discussed by the co-authors, and statistical analyses and design reviewed by our departmental statisticians. An Excel® table containing the source data is attached in Supplemental Appendix 2.

Patient selection bias is also a concern in this paper due to the patient selection process for Extended Reality Navigation. To estimate the impact of this bias, the study cohort is examined for identifiable confounding factors.

# Study Size

No power analysis was possible due to lack of pre-existing pilot data. The study duration was limited to include a consistent perioperative management protocol, while supportive technologies such as VSP and XR use were available both to the study and the control cohorts. A minimum number of 15 study patients was recommended to generate a representative sample.

# **Quantitative Variables**

Calculated blood loss. The calculated blood loss was obtained following the methodology used by Lopez et al. <sup>16</sup> The formula incorporates pre-operative hematocrit, final postoperative hematocrit, and the transfused red blood cell volume, to estimate the Red Cell Volume (ERCV(lost)). The calculated blood loss (ERCV%) is given as a percentage of estimated Initial Red Cell Volume (ERCV(initial)) based on Weight and pre-operative hematocrit:

The Estimated Red blood Cell Volume (ERCV) lost due to blood loss is approximated to the difference between preoperative and post-operative hematocrit (Ht) multiplied by the Estimated Blood Volume (EBV) obtained by the formula:  $EBV = Weight \times 80 \, cc$ 

$$ERCV(lost) = [Ht(initial) - Ht(final)] \times EBV$$

The Estimated Red blood Cell Volume transfused is obtained by multiplying the volume transfused by 60%, which is the estimated Hematocrit of PRBC units.

$$ERCV(transfused) = PRBC(mL) \times 0.6$$

The percentage loss of ERCV is obtained by dividing the total ERCV deficit (the sum total of the two values above, ERCV(lost) + ERCV(transfused)) by the initial ERCV (Ht(initial)  $\times$  EBV)

ERCV% is used as a proxy for percentage total blood loss.

The age at operation is obtained by subtracting the date of surgery from the date of birth.

The operative time is obtained by subtracting the "Surgery End" time from the "Surgery Start" time, logged at the time of surgery, and retrieved from the Electronic Medical Record.

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**Table 1.** Study (XR) and Control (no-XR) Groups Characteristics.

Average	XR (n = 17)	No XR (n = 62)	Р
Age (mo)	70	35	.045
Male (%)	71	78	.164
Weight (kg)	24	15	.083
Elevated ICP/Papilledema n (%)	5 (29)	7 (11)	.007
Syndromic n (%)	9 (53)	18 (29)	.023
Operation types (n)			.920
FOA/Monobloc/Bipart	6	19	
Craniomegaly	0	4	
CVD/CVR	6	23	
PVD/PVR	5	16	
TXA/ACA n (%)	10 (59)	43 (69)	.127

Note. The study group included older, heavier patients and more syndromic patients with elevated IntraCranial Pressure (ICP). The operation types were diverse in scope and complexity and are grouped for comparison. There was no significant differences between the groups in the ratio of males, operation types or percentage of patients receiving antifibrinolytics. P=Marginal statistical significance. Cells with significance level below 0.05 are shaded for convenience.

### Statistical Methods

The primary outcome measurements (ECRV%) is assumed to follow a log-normal distribution. The null hypothesis supposes no difference between index and control cohorts.

Mean and standard deviations are calculated for each subgroup. A comparison of variance test was not performed, instead, variance was assumed to be different and Welch a *t*-test was used for group/subgroup comparison. One-tailed and two-tailed tests are used as appropriate. For binary variables, a binomial test is used.

For the main study outcome, it is hypothesized that the use of extended-reality system and antifibrinolytics would result in smaller ERCV and ERCV% loss. A one-tailed Welch t-test is used with statistical significance set at P < .05.

Statistical test are performed using Excel® with Data Analysis package (Microsoft® Redmond, WA). Statistical significance is set at .05.

### Results

Between December 2018 and February 2023, 82 patient charts were reviewed. Two patients were excluded due to lack of a major intracranial component to their surgery. Eighty patients were included in the categorical analysis. Seventy-nine patient charts were included in the calculated blood loss statistical analysis: One patient was excluded from calculations of ERCV due to absence of a preoperative hematocrit.

The study group consisted of 17 patients that had preoperative VSP and intra-operative overlay of their data in XR. Sixty-two patients had pre-operative standard 3D CT, with

**Table 2.** Primary Outcomes on Blood Loss and Blood Component Replacement.

Average	XR (n = 17)	no-XR (n = 62)	Р
ERCV%	43.7	61.9	.046
Transfusion (mL/kg)	14.65	22.28	.082
No transfusion (%)	35.3	24.2	.093
# of donor units exposure	0.88	1.34	.070
Pre-Ht (%)	38.4	35.7	.030
Post-Ht (%)	32.5	30.4	.048
Delta-Ht	5.9	5.3	.646
IntraOperative PRBC in mL (SD)	268 (140)	326 (277)	.162
Average ERCV in mL (SD)	131 (132)	165 (198)	.200

Note. "ERCV": Estimated Red Cell Volume, calculated using a formula described in the text, as a proxy for percentage blood volume loss. "No Transfusion": Patients in each group that did not require a transfusion. "# of Donor Units Exposure": total number of Packed Cells, FFP and Platelet units transfused divided by the number of patients in each group. "Pre-Ht/Post-Ht": Average Preoperative/Postoperative Hematocrit. "Delta Ht": Drop in hematocrit between pre-operative and last postoperative. Intra-Operative transfusion requirements and group average ERCV are also shown. SD = Standard Deviation. P: Marginal statistical significance, given in the right-most column. ERCV% was lower for the study group (XR), and the difference was statistically significant. Pre-operative and post-operative hematocrit levels were higher in the study group, which consisted of older patients, but the drop between pre-operative and postoperative ("Delta-Ht") was similar. Intra-operative transfusion volumes and average total Red Cell Volume transfused were both slightly lower in the study group, but did not reach statistical significance, possibly due to their older age and higher body weight. Cells with significance below 0.05 are shaded in yellow, while cells with significance between 0.05 and 0.1 are shaded in a lighter gray-yellow.

MRI or VSP as indicated clinically, but did not have intraoperative overlay, and were used as a control group. One patient had preoperative planning (XR "App") but no documentation was found for intraoperative use of the XR system, and was included in the control group.

Group characteristics including patient demographics, Syndromic Association, elevated ICP, Operation Types, and TXA use are listed in Table 1.

The full list of associated diagnoses is detailed in Supplemental Appendix 2. Sixteen patients had confirmed elevations of Intra-Cranial Pressure. Single suture involvement was found in 34 cases (Sagittal n = 20, Metopic n = 6, Coronal n=4, Lambdoid n=4), while non-syndromic multiple -suture synostosis was found in 16 patients. Seventeen patients had identifiable Syndromic Synostosis: Seven patients had Crouzon Syndrome (FGFR2 mutation), two patients had Crouzon with Acanthosis Nigricans (FGFR3), two patients had ERF-related craniosynostosis, two patients had Muenke Syndrome, one patient had Pfeiffer's, one patient had Apert's, one patient had Jackson-Weiss, and one patient had Noonan's. Four patients had Tessier Craniofacial clefts, four patients had Craniomegaly, and three patients had shunt-related craniosynostosis with slit ventricles.

Table 3. Secondary Outcomes: Comparison of Study Versus
Control Groups, With Significance in the Right Column.

Average	XR (n = 17)	no-XR (n = 62)	Р
Duration of surgery (min) (SD)	162 (78)	145 (81)	.431
Sinus proximity bleeding (%)	0	17	.043
Durotomy (%)	29	17	.093

Note. Duration of Surgery (operative times), not including anesthesia time, extracted from EMR. The mean duration is given in minutes, with standard deviation in parentheses. Sinus proximity bleeding is defined in the text, including copious venous bleeding in the region of the major dural sinuses, and directly observed sinus bleeding. The results are given in percentages. "Durotomy" refers to partial or total dural tears. A notable trend was observed for increased findings of dural injuries in the study group, without reaching statistical significance. Sinus Proximity Bleeding was observed more commonly in the control group, and that difference reached statistical significance. Operative times were not significantly different between study and control group. Cells with significance below 0.05 are shaded in yellow, while cells with significance between 0.05 and 0.1 are shaded in a lighter gray-yellow.

The primary outcomes of the study are shown in Table 2. The calculated red cell volume loss was 43.7% for the study ("XR") group, and 61.9% for the control ("no-XR") group. This difference reached statistical significance (P=.04).

Other relevant trends were observed but did not reach the significance level: 35% of patients in the study group did not require a transfusion, while 24% in the control group did (P=.09 ns). Patients in the XR group were exposed to an average of 0.88 donors, while those in the control (no-XR) group were exposed to 1.34 donors on average (P=.07 ns).

The pre- and post-operative hematocrit levels are also shown in Table 2. The study group had higher pre-operative ("pre-Ht") and post-operative ("post-Ht") levels than the control (no-XR) group. One outlier in the XR group had a pre-operative hematocrit of 56 due to right-to-left cardiac shunt, and was included in the study. However, the drop between pre-operative and post-operative levels were identical between groups ("Delta-Ht").

Secondary outcomes are shown in Table 3. Sinus proximity bleeding (SBP) was observed in one patient (1/17) in the study group, that occurred during epidural dissection and elevation of the bone flap, and 11/62 in the control group (P=.06). When only SBP during craniotomy is included, the difference between groups is statistically significant (P<.05).

A trend for increased risk of dural injuries, whether partial or full thickness, was observed in the study (XR) group (29% vs 17%, P=0.09).

Tranexamic Acid and other Anti-Fibrinolytics (AF; Table 4) had a smaller impact on ERCV%, which did not reach statistical significance (60.17% [AF, n=26] vs 50.33% [no-AF, n=53], P=.18 Welch t-test, one-tailed). In the XR group, 10 out of 17 patients had received TXA, with an average ERCV% of 46%, versus 40% for those in the XR group that did not (P=ns).

**Table 4.** ERCV% of Patients That Received AntiFibrinolytics (AF) Within the Study Group (XR), Control Group (no-XR), and the Whole Population (Total).

ERCV%	XR (n = 17)	no-XR (n = 62)	Total (n = 79)
AF (n = 53) no-AF (n = 26)	46 (n = 10) 40 (n = 7)	65 (n=43) 55 (n=19)	60 50 P=.18

Note. 53 patients in total received antifibrinolytics intraoperatively, 51 of which received Tranexamic acid (TXA), the other two receiving AminoCaproic Acid (ACA). It is important to note that the groups were not randomized, thus a selection bias toward higher acuity surgeries receiving AF could explain the higher numbers observed in the group that received AF.

Operative time was not significantly different between the study and control groups: Average (Standard Deviation): 161.9 (77.84) minutes versus 144.75 (80.82) minutes, P=.43.

### **Discussion**

A prone patient with exposed calvarium has few anatomical landmarks for anatomical orientation. XRN, by visualizing the dural and intra-osseous vascular channels, registered and overlaid on the patient's anatomy, could facilitate the cognitive task of transferring imaging data to the surgical field, possibly improving the surgeon's ability to plan and perform safe craniotomies. <sup>17</sup> Despite the limitations of the study, the data points to a possibly significant decrease in blood loss in the group that received VSP+XRN navigation, as well as a possible causative explanation, with fewer "Sinus Proximity Bleeding" events observed. While the use of traditional navigation and VSP have been independently investigated to decrease blood loss in craniofacial surgery, <sup>3-6</sup> to our knowledge, this is the first report of the benefit of combining Extended Reality navigation with VSP for this purpose.

Fewer patients in the study group required a blood transfusion, and those that were transfused received smaller volumes per body weight, but these trends did not reach statistical significance in our small study sample. Notably, patients in the study group tended to be exposed to fewer donor units. Several authors have focused on efforts to decrease the number of units transfused, thereby donor exposure. In major craniofacial procedures, a "first unit" may be required to replace the blood lost to elevation of the scalp flaps, performing the sub-pericranial dissection and the craniotomies, a "necessary cost of craniofacial exposure." It is possible that VSP+XRN may decrease the need for the "second unit" by decreasing sinus injuries or untoward intraoperative events.

Several confounding factors must be considered when interpreting this data. Previous literature has reported that age and weight are associated with decreased percentage blood loss (ERCV%), while increased duration of surgery was associated with increased percentage blood loss (ERCV%). <sup>18</sup>

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The patients in the study group were older and heavier, which could partly explain their lower blood loss. However, they were more likely to be syndromic, have elevated ICP, and have slightly longer operative times, all factors that can increase blood loss. Similarly, the patients that had XRN+VSP were selected by the main author for their complexity and "educational value," their surgeries were slightly longer, and more complex. The relative impact of these confounders should be assessed in follow-up studies with logistic regression models and larger samples from a multicenter study.

Another relevant observation is the trend toward higher durotomies in the study group. While this could be attributed to the higher prevalence of patients with elevated IntraCranial Pressure (ICP) or Syndromic diagnoses in the study group, other factors should be considered, such as "overconfidence" or "over-reliance" on the XRN system. To note, obstruction of the operating surgeon's and the assistant surgeons' visual fields is a hazard considered in the design of the AR system, and mitigated by simple "voice commands" that clear out the visual field completely. The XRN system is designed to be visualized intermittently, for planning or verifying, and we strongly discourage XR visualizations during active steps of surgery, both for the operating and assistant surgeons. The XR system was not worn by the operating neurosurgeon when craniotomies and durotomies were performed.

The use of AntiFibrinolytics (AF) was not associated with a decrease in average ERCV% blood loss. In this study population, AF use was associated with an ERCV% of 60% on average, compared to 50% for those that did not (P=.18 ns). Most of the patients received Tranexamic Acid, and only two received AminoCaproic Acid. Since the groups were not randomized, that difference could be due to selection bias by the operating surgeon or anesthesiologist, selecting higher complexity patients to receive AF. Extrapolating from published reports<sup>1,19</sup> about TXA efficacy, a 10% ERCV% decrease is expected with its use. Notably, the magnitude of reduction of ERCV% loss associated with XRN+VSP use (62%-43% ERCV%=19%) is almost double that reported with TXA use, emphasizing the need for broader multicenter studies on this promising technology.

Extended Reality is a novel technology that has several advantages, but also several potential limitations, including increasing the surgeon's cognitive load,<sup>20</sup> obstruction of the surgeon's visual field,<sup>21</sup> "overconfidence" or over-reliance on the system,<sup>22</sup> and "Cybersickness."<sup>23</sup> No major untoward effect is reported in this study. A trend toward higher incidence of durotomies was observed but did not reach statistical significance. Several other technological limitations, such as depth perception,<sup>24</sup> projection accuracy<sup>25</sup> and covisualization methods continue to improve.

The main limitations of this study were its retrospective nature, limited numbers, and lack of randomization. The results of this pilot study indicate a potential for VSP+XRN to decrease blood loss in craniofacial surgeries and invites larger multicenter investigations into its implications. Our

initial results provide useful initial estimates for future power analyses. The original data is included in this report for use by researchers.

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# **Declaration of Conflicting Interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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# **Ethical Approval**

The study was approved under institutional IRB (HSC 14181 and HSC 17254).

### **Informed Consent**

Informed consent obtained from all participants.

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# Supplemental Material

Supplemental material for this article is available online.

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