Intraoperative Surgical Navigation Reduces the Surgical Time Required to Treat Acute Major Facial Fractures

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Background: Assessing bone reduction and implant placement in facial fractures is time-consuming because of limited visibility. An intraoperative navigation system allows real-time confirmation of bone positioning and implant placement on the patient's computed tomographic scan. This circumvents the visibility problem and therefore appears to shorten the surgery time. The goal of this study was therefore to determine whether intraoperative navigation reduces the surgical time required to treat patients with acute major facial fractures.

Methods: In this retrospective quasi-experimental study, 50 patients with major facial fractures were identified and randomly assigned to treatment groups. Twenty-two were treated without the use of a navigation system, and 28 were treated using navigation. The Facial frActure Severity Score (FASS) was devised to better assess and control for complexity of cases and control for possible selection bias.

Results: The FASS was directly linked to surgery time, whether or not navigation was used. An analysis of covariance demonstrated that the surgical time required to treat major facial fractures, taking into account the FASS, was reduced by 36.1 percent (124.8 minutes) when navigation was used.

Conclusions: This study compared the surgical time required to treat patients with major facial fractures, with and without a navigation system. The use of a navigation system reduced the surgical time by 36.1 percent. This is a significant improvement in reducing the length of craniomaxillofacial procedures. (*Plast. Reconstr. Surg.* 144: 923, 2019.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

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THERAPEUTIC

The operative treatment of acute major facial fractures can be very challenging. Assessing bone reduction and skeletal symmetry through remote incisions and in the context of major edema tends to be extremely time consuming. An intraoperative navigation system allows real-time confirmation of bone positioning and implant placement on a computer screen where the computed tomographic scan and corresponding three-dimensional reconstruction are displayed,[1–5] circumventing the visibility problem and possibly shortening the surgical time.

Current advances in computer-assisted surgery have qualified intraoperative navigation as a valuable surgical tool.[3,5–10] Navigation has been proven useful mostly for the treatment of secondary deformities or undated trauma,[4,8–23] oncologic resections and reconstructions,[4,8,12,13,19,24–29] and the correction of congenital deformities.[4,8,12,14,19,28–30] There are also reports for the primary treatment of localized facial fractures[5,7–10,12–14,19,20,28,29,31–39] and major fractures.[19–22,29,39,40] However, the reduction

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in surgical time for the treatment of acute major facial fractures has not been studied.

Since February of 2015, the first author has been using an intraoperative navigation system to reduce surgical time. The reduction of surgical time is possible because the intraoperative navigation system allows quicker alignment of individual bone and assessment of symmetry, and proper placement of implants such as preformed orbital floor and medial wall implants. The goal of this study was to determine whether intraoperative navigation reduces the surgical time required to treat patients with acute major facial fractures.

PATIENTS AND METHODS

In this quasi-experimental study,[41] all acute facial fractures involving the middle third and upper third of the face and skull operated on by a single surgeon in a Level I trauma hospital between January of 2013 and January of 2018 were identified through the operating room's case database. This allowed the isolation of patients operated on 2 years before and after the introduction of navigation. A Medtronic (Louisville, Colo.) StealthStation S7 navigation machine was first used for acute facial fracture treatment in February of 2015. Its use thereafter was determined solely by its availability on the preassigned operating room day, independently of the patient diagnosis or case complexity. This assignment method allowed a random attribution of cases to treatments. Cases where navigation was not used were labeled "no navigation." Cases where navigation was used were labeled "with navigation."

The research objective asks that only the most complex cases of acute major facial fractures are selected. Preoperative and postoperative computed tomographic scans were used to confirm the diagnosis for each patient. To keep only the most complex cases, cases with (1) isolated fractures and (2) multiple fractures without comminution were excluded. The final list of fractures along with the number of cases is presented in Table 1. The study was conducted in compliance with the principles of the Declaration of Helsinki and the institutional review board. Final board approval was granted on April 17, 2018.

Statistical Analysis

Statistics were performed with IBM SPSS Version 24 (IBM Corp., Armonk, N.Y.). The surgical time was defined as the time from skin incision to closure. The statistical analysis consisted of the following steps.

Table 1. Frequency Distribution of Facial Fracture Levels*

Facial Fracture Level	No. (%)
Le Fort I	66 (18.4)
Le Fort II	63 (17.6)
Le Fort III	56 (15.6)
Orbital roof (extracranial)	24 (6.7)
Cranial vault (intracranial)	15 (4.2)
Orbital floor/medial wall	28 (7.8)
NOE	44 (12.3)
Mandible	13 (3.6)
Zygoma	4 (1.1)
Frontal sinus	24 (6.7)
Cranial vault	21 (5.8)
Palate	3 (0.8)
Total fractures	361

NOE, naso-orbitoethmoid.
*n = 50 patients.

The complexity of cases within each group was expected to be related to the surgical time. A complexity scale was thus designed to control for possible variations of case complexity and selection bias between groups (with and without navigation), because an unequal level and distribution of case complexity between groups could lead to biased research results.

A Facial frActure Severity Score (FASS) was devised to quantify the complexity of cases, and to make sure that both groups were statistically comparable. Although the clinical diagnosis could have been used, it appeared to be too general to serve as a reliable predictor of surgical time. Instead, based on the clinical experience of the first author, eight radiologic factors seemed to clinically influence the length of a case. The radiologic factors recorded for each patient and used to compute the FASS were as follows: naso-orbitoethmoid with comminution, frontal bone/glabella with comminution, zygoma with comminution, concomitant mandible fractures with unstable occlusion and/or edentate, edentate maxilla alone, complex orbit (more than one wall), sphenoid/skull base, and cranial vault fractures. Each factor was given one point if present unilaterally, two points if present bilaterally, and no points if absent. The FASS was obtained by adding the points attributed to each factor. The FASS is a unique measure of the overall complexity of the eight empirically obtained facial fracture complexity features.

A first Levene test for equality (homogeneity) of variance in surgical time between the two treatment groups (with and without navigation) was executed. The Levene test of equality of variance tests the null hypothesis that the error variance of the dependent variable (surgical time) is equal across groups. The equality of error variance of the surgical times between the two groups is a necessary statistical condition to test for the equality of means of the surgical times between the two groups.

A Pearson correlation between FASS and surgical time was then calculated. This test was followed by partial correlations between FASS and surgical time while controlling for the treatment group to verify that FASS was associated with surgical time in both treatment groups (with and without navigation).

A second Levene test for equality of variance was conducted to compare the FASS of the patients in the two treatment groups (with and without navigation) to confirm that the two groups were equivalent in terms of FASS means and standard deviation. A concentration of less severe or more severe cases in a group versus the other group could be a threat to the validity of results. An additional *t* test was conducted to test for the equality of FASS means between groups.

An examination of the data distribution and the scatterplot of the standardized residuals of surgical time on FASS was performed to ensure that the variables were linear and normally distributed, and met the homoscedasticity criteria (variance of errors is the same at all levels), indicating that basic assumptions for a valid use of analysis of variance were met.[42]

The *t* tests were calculated to compare the means of surgical time between the two groups (with and without navigation). A criterion-related validity *t* test was also performed on the anesthesia time, defined as the total time under anesthesia care in the operating room, to confirm the validity to the surgical time measure.

An analysis of covariance analysis[43] was conducted on the data set using the FASS as a covariate to test the model and answer the research question. Given the relatively small number of patients in the two groups (with and without navigation) and the significant correlation between FASS and surgical time, the FASS was included in the analysis as a covariate to reduce the error variance.[44] The use of analysis of covariance is designed to identify and remove extraneous variance, thereby increasing the precision of the analysis.[42] Controlling for the covariate FASS means that the effect of FASS is statistically removed. This procedure allows for adjustment for the severity of each case, as expressed by the FASS value attributed to each patient. Thus, the results of the comparison of the surgical time with and without the navigation system takes into account the FASS values, allowing for more sensitive data analysis and a better test of surgical time comparison between the two groups. The adjusted means were used to test for a statistical difference in surgical time between the two groups (with and without navigation). The power of the analysis of covariance test was finally calculated to ensure that it met Cohen's[45] acceptability criteria.

RESULTS

One hundred twenty-two (n = 122) consecutive patients with facial fractures were identified. Seventy-two patients were excluded because they had either isolated fractures or multiple fractures without comminution. The diagnoses of these excluded cases were as follows: isolated bilateral Le Fort II (n = 4), isolated bilateral Le Fort I (n = 5), isolated orbital floor or rim (n = 13), simple zygoma (n = 20), hemi Le Fort III (n = 1), absence of comminution (n = 28), and isolated anterior table of the frontal sinus (n = 1).

There were 50 patients remaining for the study. The no-navigation group had 22 patients, whereas the with-navigation group had 28 patients. The mean patient age was 39.8 years (range, 16 to 74 years). There were 43 male (83 percent) and seven female (14 percent) patients. There was no significant difference in age (t = 0.80; df = 48; p = 0.42) or sex (t = 0.74; df = 48; p = 0.46) between the two groups (with and without navigation), meaning that the distribution of patients among groups was equivalent relative to these points. The average time between trauma and facial fixation was 8 days (range, 1 to 23 days; median, 8 days). The fracture distribution is shown in Table 1. The FASS calculated for each patient ranged from 1 to 11 (mean ± SD, 3.72 ± 2.33) (Tables 2 and 3).

The Levene test for equality of variance in surgical time between the two treatment groups (with and without navigation) revealed no significant difference in variances (F = 2.31; df = 48; p = 0.135), meaning that the error variance of the surgical times is equal between the two groups. This result allows for the equality of means of the surgical times between the two groups to be tested for.

Positive and significant Pearson correlations were found between FASS and surgical time (r = 0.623; p = 0.001) indicating that the FASS is associated with surgical time. The partial correlations calculated between the FASS and surgical time while controlling for the treatment group were also positive and significant (r = 0.715; p = 0.001), meaning that the correlations between the FASS and surgical time were similar in both groups.

Table 2. Frequency Distribution of FASS Features*

FASS Feature	Unilateral (%)	Bilateral (%)	Absent (%)
Comminution in the glabellar area	3 (6)	12 (24)	35 (70)
Comminution in the NOE area	6 (12)	11 (22)	33 (66)
Comminution in the zygoma area	20 (40)	0 (0)	30 (60)
Edentate maxilla (or unstable occlusion) associated with mandibular fracture	0 (0)	7 (14)	43 (86)
Edentate maxilla alone	0 (0)	3 (6)	47 (94)
Complex orbital fracture (>1 wall)	15 (30)	10 (20)	25 (50)
Sphenoid/base of skull fracture	23 (46)	4 (8)	23 (46)
Cranial vault fracture	9 (18)	8 (16)	33 (66)

NOE, naso-orbitoethmoid.
*$n = 50$ patients.

Table 3. Frequency Distribution of FASS*

FASS	No. of Cases (%)
1	8 (16.0)
2	9 (18.0)
3	10 (20.0)
4	10 (20.0)
5	3 (6.0)
6	4 (8.0)
7	2 (4.0)
8	1 (2.0)
9	2 (4.0)
10	0 (0.0)
11	1 (2.0)
Total	50 (100.0)

*$n = 50$ patients.

The second Levene test for equality of variance conducted to compare the FASS of the patients in the two treatment groups (with and without navigation) concluded in the equality of variance ($F = 0.013$; $p = 0.909$) in the severity scores. In addition, no significant difference was observed between the FASS means of the two groups (no navigation, mean ± SD, 3.41 ± 2.30; with navigation, mean ± SD, 3.96 ± 2.36; $t = 0.834$; $df = 48$; $p = 0.409$).

An examination of the data distribution and the scatterplot of the standardized residuals of surgical time on FASS indicated that basic assumptions for a valid use of analysis of variance were met.[42] The *t* test calculated to compare the means of surgical time between the two groups (with and without navigation) (Table 4) revealed significant differences ($t = 2.58$; $p = 0.013$; $df = 48$) in the means of surgical time. The surgical time was reduced by 101 minutes on average with the use of the navigation system. A criterion-related validity *t* test was also performed on the mean anesthesia time in the two groups, and similar results were obtained. The anesthesia time was significantly reduced by 100 minutes ($t = 2.48$; $p = 0.017$; $df = 48$), paralleling the surgical time reduction findings and adding validity to the research.

Table 4. Comparison of the Mean Surgical Time between the Two Groups without Controlling for Severity of Cases

Navigation Mode	No.	Mean (min)	SD (min)	Minimum	Maximum
No navigation	22	332	162	105	775
With navigation*	28	231	116	60	477

*Average time reduction with navigation, 101 min ($t = 2.58$; $df = 48$; $p = 0.013$).

Finally, an analysis of covariance analysis controlling for the FASS was conducted to compare the mean surgical time of both groups of patients (with and without navigation). The analysis of covariance results (Table 5) indicates a significant difference in mean surgical time ($F_{1,47} = 19.88$; $p = 0.000$) between the two groups, while adjusting for FASS. The adjusted means (controlling for the covariate FASS) indicate a lower surgical time in the with-navigation group (mean, 220 minutes) than in the no-navigation group (mean, 345 minutes). These results take into account the severity of each case. The power of the treatment is 0.992, above the acceptable level of 0.80 proposed by Cohen.[45] On average, the use of the navigation system has reduced the surgical time by 125 minutes, or 36.1 percent. Figures 1 and 2 demonstrate a case performed with the help of a navigation system.

DISCUSSION

When adjusted for severity with the FASS, the surgical time required to treat major facial fractures is reduced by 36.1 percent when navigation is used. In other words, not using the navigation system lengthens the surgical time by 56.6 percent.

A Medtronic S7 navigation system with a skull-mounted electromagnetic tracker was used in this study. The patient tracker measures approximately 1 cm^3. It is temporarily screwed in the skull near the temporal crest, behind the hairline, through

Table 5. Comparison of the Mean Surgical Time between the Two Groups, Controlling for Severity of Cases*

					95% CL	
Navigation Mode	**No.**	**Mean (min)**	**SE (min)**	***p***	**Lower**	**Upper**
No navigation	22	345.53†	20.88		304	388
With navigation	28	220.69†	18.50		183	258
Average surgical time reduction with navigation		124.84	27.99	0.000‡	68.52	181.16
Percentage surgical time reduction with navigation		36.13%				

CL, confidence limits.
*Analysis of covariance analysis.
†Covariates appearing in the model are evaluated at the following values: FASS = 3.72.
‡$F_{1,47} = 19.88$.

a 1.5-cm skin incision. When a bicoronal incision is performed, the tracker is placed in the same position after the bicoronal flap is done. Because of the tracker's small size, it does not interfere physically with exposure or reduction. Because it is safely secured to bone, it very rarely decalibrates during long cases.

There are many strategies for performing the virtual planning in complex fractures. The most useful technique is fracture segmentation and reduction of large fragments.[22] Mirroring[4] can be useful if the contralateral side is unaffected and virtual fracture reduction is insufficient to provide the optimal contour. A third strategy involves virtually recreating a missing plane[4] if a fracture is highly comminuted and the contralateral side cannot be used. A combination of these techniques is usually used to achieve the best virtual facial symmetry and virtual occlusion if applicable.

A skin surface registration of the system is performed with a 0.64-mm-cut computed tomographic scan performed within 24 hours of the operation to minimize surface changes from edema. Alternatively, if a bicoronal incision is performed, surface registration is performed directly on the exposed cranial bone. A successful registration gives a precision of 0.7 to 1.2 mm as reported by the system. Depending on case complexity and the time delay before the assigned operating day, a three-dimensional overlay of the reduced facial bone can also be used (Fig. 1). For simpler cases or when the operative delay is short, one can rely on on-screen measurements on standard radiographic views to assess for symmetry or expected position, as is performed with images obtained from intraoperative computed tomographic scanning.[46]

The literature on navigation use in the acute setting is scarce, with most articles describing its use for orbital fractures[7,8,31,32,34,37] and few reports of its use in fractures involving multiple facial bones in the acute setting.[22,29] We hypothesize that this is attributable to both the time-consuming preparation required for major traumatic fractures and the often short delay between the trauma and the operation. These factors make it challenging to perform the necessary preparation in time for the operating day.

A reduction in operative time using navigation has been proposed for the removal of foreign objects[47] and for secondary reconstruction.[17] One 2015 study showed no significant difference in operative time with and without intraoperative navigation in the resection of recurrent infratemporal fossa tumors.[25] Bly et al.[5] alluded to a time reduction using navigation for acute orbital fractures, but this has not been formally demonstrated before. Decreasing the operative time for major facial fractures as demonstrated here is of significant value.

There are multiple benefits to using a navigation system in the treatment of acute major facial fractures (Table 6). It allows for a safe and precise dissection, especially in cases where visibility is limited (e.g., traumatic orbital fractures).[7,37] A navigation system can also allow the rapid location of severely impacted and buried fragments such as impacted orbital rim fragments. When comminution around a bone is present and anatomical reduction cannot be obtained by simple buttressing, the bone's position can rapidly be determined with the navigation system and fixed. In bilateral cases, such as bilateral Le Fort two-thirds with comminution around the zygomas, the contralateral bone's position can quickly be made symmetric and fixed despite limited visibility. During orbital reconstruction, the navigation system can allow rapid verification of implant positioning[7] and possibly help reduce the number of secondary interventions.[5]

In addition, intraoperative navigation facilitates minimally invasive surgery. For example, in a severe panfacial fracture with zygomatic arch fractures, a bicoronal incision is often used to reduce and fix the zygomatic arches to restore adequate and symmetric projection of

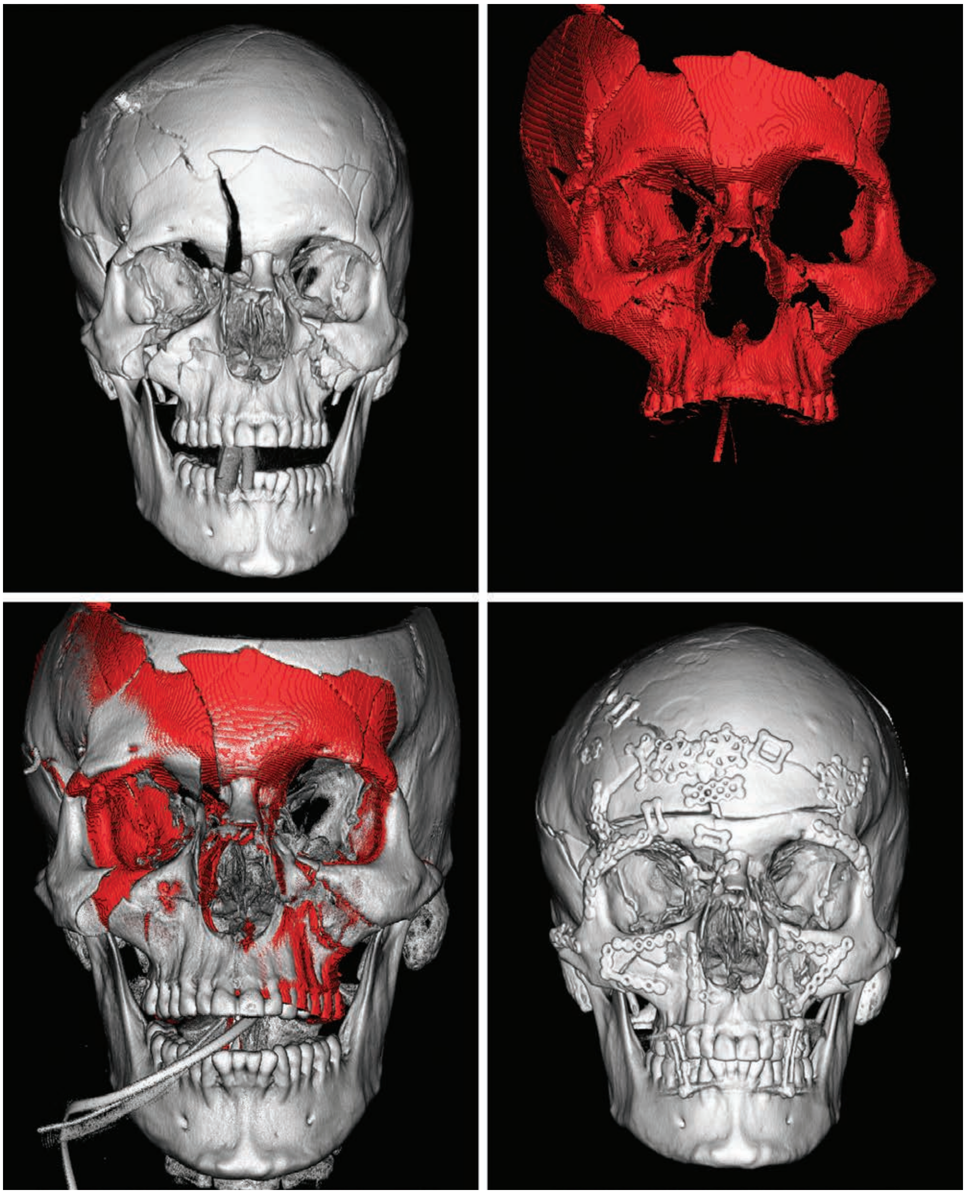

Fig. 1. A complex facial fracture treated with the help of a navigation system. A 35-year-old man with a panfacial fracture involving the middle and upper thirds of the face, and the cranial vault. (*Above*, *left*) Three-dimensional reconstruction of the facial skeleton before surgery. The FASS for this case was 9. (*Above*, *right*) The result of the virtual surgical planning in shown in *red*. (*Below*, *left*) The virtual plan is shown as a red overlay on the three-dimensional reconstruction. (*Below*, *right*) Postoperative scan. The patient underwent cranial vault reconstruction, bilateral intracranial orbital roof reconstructions through a limited bifrontal craniotomy, bilateral naso-orbitoethmoid and Le Fort I, II, and III open reduction and internal fixation, and intermaxillary fixation. The surgical time with intraoperative navigation was 7 hours 57 minutes.

the zygomas. With navigation, a bicoronal incision can be avoided by reducing the zygomatic arches in a closed manner and by determining the zygomatic bone projection with the navigation system instead. Furthermore, preexisting decompressive or traumatic craniotomies can be used to perform a cranialization instead of adding or performing a more extensive classic bifrontal craniotomy. With the navigation system, it is possible to have enough intracranial visibility to perform the intracranial work. For example, in a displaced two-table frontal sinus fracture where the entire sinus is not involved, a formal bicoronal craniotomy can sometimes

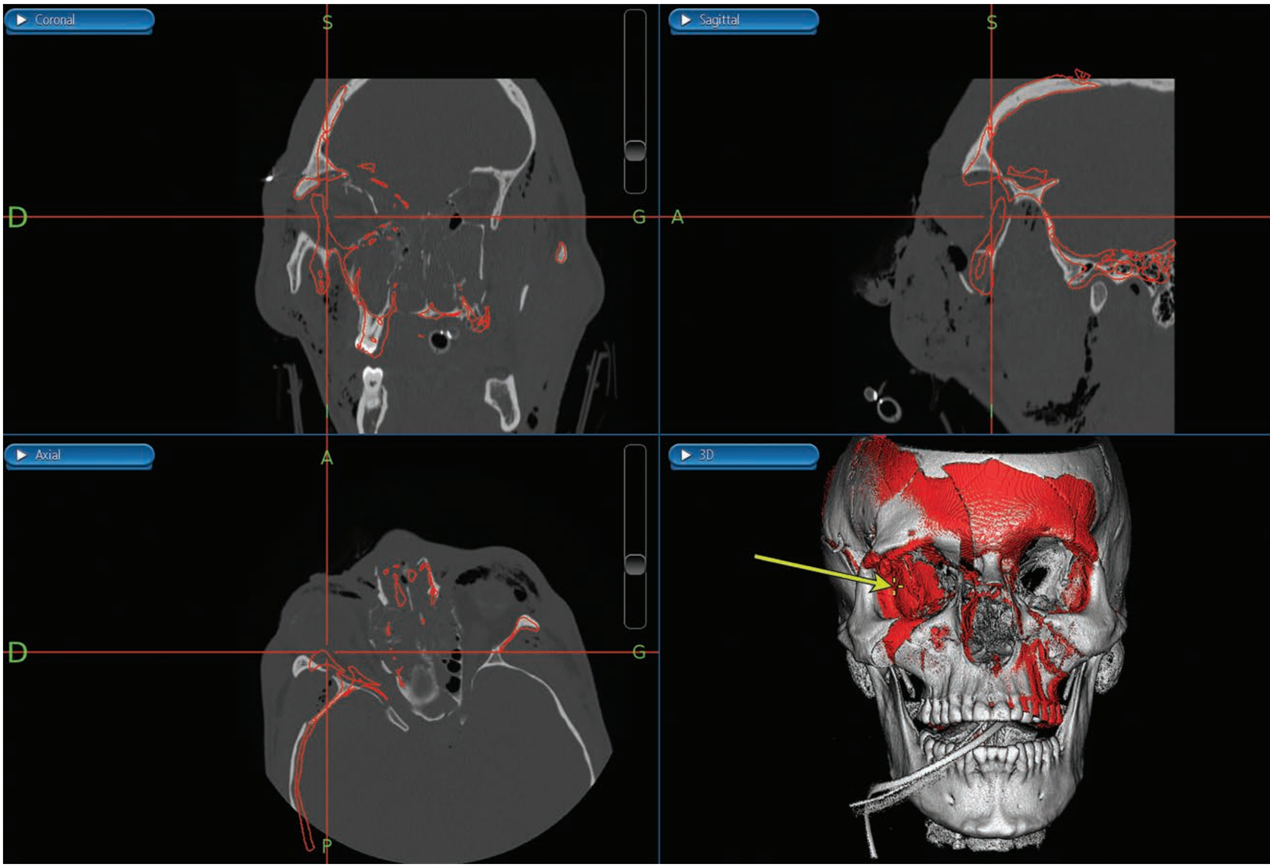

Fig. 2. Navigation system interface. The screen is split in four views: coronal, sagittal, axial, and three-dimensional. The surgical plan is overlaid in red in all four views. To reposition a bone, a surgical probe is held on a desired landmark of the reduced fractured bone. Its position relative to the surgical plan is checked in real time on the screen. Once the reduction is satisfactory, plating of the fractured bone is performed without the need to reconfirm bone position through all surgical incisions or reexposing the contralateral bone to ensure symmetry, saving significant surgical time. The probe tip is shown in the three-dimensional view (*yellow arrow*). The cross-hair markers in the three other views also display the location of the surgical probe. Positioning of a mesh or implant is performed in a similar manner.

be spared because the cranialization can be performed with the navigation system through an already existing traumatic or adjacent decompressive craniotomy.[48]

Table 6. Benefits of Using an Intraoperative Navigation System for the Treatment of Facial Fractures

Minimally invasive approaches
Cranialization through an existing decompressive craniotomy
Smaller craniotomy through the comminuted fracture site, avoiding a bifrontal craniotomy
Can avoid bicoronal incisions
Safe dissection
Identification of fragments
Confirmation of bone reduction despite limited visibility
Reduction according to virtual surgical planning
Confirmation of facial symmetry
Confirmation of implant placement
Shorter operating time: 36.1% surgical time reduction

The authors do not have experience with intraoperative computed tomographic scanning[46,49] and therefore cannot compare both technologies. However, the following advantages of navigation can be considered. First, repeated radiation-free measures can be taken to assess and reassess bone[22] or implant positioning. Second, the navigation pointer can be used in real time to reduce a bone and hold it in place while it is plated. Third, most navigation systems allow an image overlay of the operating plan on the original computed tomographic images, which allows for confirmation that reduction is as intended. Fourth, the system does not take up much space in an operating room or in storage. Fifth, it does not require a special radiolucent operating table and therefore works with the current operating room setup.

Our hospital system has been supportive of acquiring a dedicated navigation system for craniomaxillofacial use and has placed it as a top priority. The results from this study have helped support this project. Other factors that need to be taken into account to evaluate the costs of a navigation system include the cost of the capital equipment, disposables (e.g., navigation pointers, trackers), virtual planning, and possible inefficiency during the learning curve.

This study carries some limitations. Navigation systems are usually not designed specifically for craniomaxillofacial use. Currently, to plan, set up, and execute the procedure asks for a significant effort from the surgeon and an engineering team, particularly the first time the navigation system is used. This might improve as system designers develop interest in the craniomaxillofacial field, as is the case for neurosurgery; ear, nose, and throat surgery; and spine surgery, where the surgeon can plan the surgery and set up the equipment autonomously and relatively painlessly.[50] There is also a learning curve for understanding the intraoperative capabilities of the system and adapting the operative workflow. Dry-laboratory practice is essential before using a new technology. Furthermore, prospective randomized studies to evaluate the different outcomes could be undertaken.

This study does not measure surgical accuracy as a symmetry score and normative reference values have yet to be determined for use with major facial fractures patients. Kim et al.[22] have attempted to demonstrate the accuracy of navigation in the treatment of major facial fractures by comparing five pairs of points between the postoperative scan and the virtual plan. They found that the accuracy was 1.49 ± 0.27 mm. Although not measured in this study because of the absence of a virtual surgical plan for some patients and the simplified measurement system used by Kim et al., the qualitative assessment of results appears satisfactory.

In this study, a significant surgical time reduction has been observed for lengthy cases, but further studies are needed to investigate the possibility of similar reductions in surgical time for shorter cases. The authors are very enthusiastic with the clinical results obtained with navigation and suggest that further studies on the accuracy and robustness of navigation systems should be undertaken.

CONCLUSIONS

This quasi-experimental study compared the surgical time required to treat patients with acute major facial fractures, with and without a navigation system. A Facial frActure Severity Score was devised to better assess the complexity of cases and control for possible selection bias. Taking into account the FASS for each patient, the surgical time required to treat major facial fractures was found to be reduced by 36.1 percent when navigation was used. Therefore, the use of a navigation system has a significant contribution in reducing the surgical time required to treat complex craniomaxillofacial cases.

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