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Accuracy of surgical navigation for patient-specific reconstructions of orbital fractures: a systematic review and meta-analysis

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Summary

Objective: This systematic review and meta-analysis aimed to review the recent literature on the technical accuracy of surgical navigation for patient-specific reconstruction of orbital fractures using a patient-specific implant, and to compare surgical navigation with conventional techniques.

Materials and methods: A systematic literature search was conducted in PubMed (Medline), Embase, Web of Science, and Cochrane (Core Collection) databases on May 16, 2023. Literature comparing surgical navigation with a conventional method using postoperative three-dimensional computed tomography imaging was collected. Only articles that studied at least one of the following outcomes were included: technical accuracy (angular accuracy, linear accuracy, volumetric accuracy, and degree of enophthalmos), preoperative and perioperative times, need for revision, complications, and total cost of the intervention. MINORS criteria were used to evaluate the quality of the articles.

Results: After screening 3733 articles, 696 patients from 27 studies were included. A meta-analysis was conducted to evaluate volumetric accuracy and revision rates. Meta-analysis proved a significant better volumetric accuracy (0.93 cm^3 ± 0.47 cm^3) when surgical navigation was used compared with conventional surgery (2.17 cm^3 ± 1.35 cm^3). No meta-analysis of linear accuracy, angular accuracy, or enophthalmos was possible due to methodological heterogeneity. Surgical navigation had a revision rate of 4.9%, which was significantly lower than that of the conventional surgery (17%). Costs were increased when surgical navigation was used.

Conclusion: Studies with higher MINORS scores demonstrated enhanced volumetric precision compared with traditional approaches. Surgical navigation has proven effective in reducing revision rates compared to conventional approaches, despite increased costs.

Keywords

Orbital fractures; orbital implants; surgical navigation systems; technical accuracy; virtual surgical planning; surgery, computer-assisted

1. Introduction

The bony orbit is a key structure of the midface that plays an important esthetic role. Owing to its position, the orbit is involved in 25-50% of midface fractures [1]. These fractures can result in functional and esthetic problems such as diplopia, enophthalmos, hypoglobus, and facial asymmetry, consequently leading to diminished health-related quality of life [2]. Indications for surgical management include diplopia resulting from entrapment of extraocular muscles, enophthalmos or exophthalmos resulting from orbital volume alteration, and extensive orbital fractures with a fractured area exceeding 2 cm² or comprising over 50% of the total orbital floor area [3, 4]. Surgical navigation (SN) is suggested for different types of orbital wall fractures as well as for more extended midfacial bony trauma [5, 6]. The surgical procedure is typically performed using a small incision with little visibility and frequently, the implant position cannot be confirmed by direct visualization [3, 7, 8]. Therefore, SN is a promising technique for improving surgical orientation and accuracy in this narrow operative field [5, 7, 9].

There are three essential components of SN: a surgical probe, a localizer, and a computed tomography (CT) dataset [15]. In analogy to an automotive global positioning system (GPS), the probe functions as a vehicle, reflecting infrared or electromagnetic waves to the localizer. The localizer can be seen as a “GPS satellite”. The computed tomography dataset functions as a “road map”[16].

The concept of SN was first described in 1908, further developed in the 1990s for neurosurgery, and is now widely accepted for different craniofacial procedures [6, 10]. The use of SN in post-traumatic orbital surgery was first described in 2002 and is reported to be the most frequent indication for craniofacial surgery (72% of cases) [11, 12].
Precise reconstruction is possible when combined with patient-specific implants (PSI) and intraoperative three-dimensional (3D) computed tomography (CT) imaging [7, 13]. However, this technique is mostly used in academic settings, and up to 82% of surgeons do not use it in orbital surgeries [14].

There is a learning curve and necessary preoperative planning and setup times. Additionally, financial costs are an important consideration [5, 18]. SN can only be successful if there is an accurate preoperative virtual surgical planning and a high-resolution digital CT dataset [19]. Despite increased radiation, additional intraoperative 3D CT imaging can provide immediate feedback to the surgeon about the potential discrepancy between the digital plan and the result of the reconstructed area, resulting in a lower revision rate [20, 21].

Concerning the implant itself, there is consensus that a PSI provides the best chance for optimal reconstruction of the orbital anatomy [22]. Patient-specific titanium meshes or printed implants are mostly used to correct large orbital defects. The use of other materials has also been described [23].

The objective of this study was to evaluate the clinical added value of SN in patient-specific orbital fracture reconstruction in terms of technical accuracy, operative time, revision rate, complications, and costs compared with conventional techniques.

2. Material and methods

In this systematic review, SN was compared with conventional surgical methods. The review protocol was prospectively registered with PROSPERO (registration number CRD42022381519), followed by the PRISMA principles. The included studies met the PICOS criteria (patient population, intervention, comparison, outcome, and study design).
The criteria included patients or specimens with a fracture of the bony orbit: orbital blowout and medial, lateral, and combined orbitozygomatic fractures with indications for surgical repair. The intervention was a post-traumatic primary or secondary orbital surgery with SN and was compared to a surgical procedure without SN. The outcomes included technical accuracy, preoperative time, operative time, revision rate, complications, and total cost of the intervention. The conventional method was defined as post-traumatic orbital reconstruction surgery with virtual planning, PSI, intra-or postoperative 3D CT imaging, and without the use of a real-time navigation system.

2.1 Search strategy

A systematic search of digital medical databases was conducted on May 16, 2023. The medical databases included PubMed, Embase, Web of Science, and Cochrane Library. For each database, we constructed a search string to analyze publications, including three concepts: surgical navigation, patient-specific reconstruction, and orbital fractures. The search strategies for all the databases are presented in the Appendix. Only full-text articles were included in this analysis.

2.2 Article selection

All articles were reviewed for duplicates and eligibility. Two authors (M.V. and K.D.) independently examined titles and abstracts for eligibility. If the title and/or abstract did not provide sufficient information, the entire article was read. In cases of disagreement, a third reviewer was consulted.

The inclusion criteria were fractures of the bony orbit: orbital blowout and medial, lateral, and combined orbitozygomatic fractures with indications for primary or secondary surgical repair with SN and PSI. Cadaveric studies that used SN were also included. The exclusion criteria were case reports (<2 cases), animal studies, opinion-based research, pediatric population (<16 years), old research (<1990 years), isolated zygomatic arch fractures, absence of preoperative CT imaging, non-surgical management, and non-English articles. Studies that combined endoscopic repair with SN were also excluded. Therefore, we eliminated the beneficial bias of the combination technique.

2.3 Quality assessment

The quality of the included articles was assessed by two independent authors using the Methodological Index for Non-randomized Studies (MINORS) [24].
Statistical analysis was performed using SPSS version 28.0.1.1 (IBM Corporation, Armonk, NY, USA) and Excel version 16.74 (Microsoft, Redmond, WA, USA). Pearson's chi-square test was used to calculate the difference in revision rates between the navigation and control groups. A meta-analysis (random-effects model) using Cohen's d was used to calculate the differences in orbital volumes between the navigation and conventional groups. To improve the statistical power, we extended the meta-analysis of linear accuracy by comparing navigation with historical controls. A *p*-value of 0.05 was considered statistically significant.

3. Results

3.1 Literature search

In total, 3733 articles were identified by analyzing the medical databases, as mentioned above. Ultimately, 27 articles were included in the qualitative analysis (figure 1).

3.2 Study characteristics

Table 1 presents the demographic characteristics of the included studies. In total, 696 patients with orbital fractures were included in this study. The estimated mean average age weighted by study size was 39.6 (±7.5) years. The male-to-female ratio was 2.15, and the follow-up period was 1–28 months. Most studies had a follow-up period of more than six months (Table 2).

The SN system of Brainlab (Brainlab, Munich, Germany) was used in fifteen studies [3, 5–8, 13, 22, 25–32]. Stryker (Stryker, Freiburg, Germany) was used in six studies [1, 12, 33–36]. Medtronic (Medtronic, Dublin, Ireland) was used in four studies [37–40] and TBNavis (TBNavis, Shanghai, China) was used in two studies [10, 41]. Twelve studies reported their results descriptively [1, 10, 25, 27, 28, 33–38, 41], whereas fifteen studies used statistics [3, 5–8, 12, 13, 22, 26, 29–32, 39, 40]. In all studies, imaging was performed using CT with a slice thickness of 0.6 to 1 mm [6, 32]. The used implant was mainly titanium followed by porous polyethylene and hydroxyapatite [12, 33, 34].

3.3 Technical accuracy

The technical accuracy can be described using various methods. The technical angular accuracy in degrees (°) was discussed in three articles, as shown in table 3.1 [5, 7, 22]. None of the articles described angulation with SN in comparison with the conventional method.

Table 3.2 shows all twenty-two studies that described linear accuracy qualitatively or in mm [1, 3, 5–7, 10, 12, 13, 22, 25–28, 30–33, 36–38, 41, 42]. In thirteen studies, the linear accuracy in mm was determined by comparing and overlapping the preoperative plan with the postoperative CT [3,5–7, 10, 13, 22, 27, 28, 31, 33, 34, 41]. Significant improvements in the linear accuracy were reported when using SN compared to the conventional method [13, 30]. Figure 2 shows a descriptive forest plot, based on the six studies (247 patients) that reported standard deviations and mean values. A linear accuracy (± SD) of 0.99 mm (± 0.54mm) was calculated in the SN group, 1.36 mm (± 0.68mm) in the conventional group. Although navigation seems to provide a better linear accuracy, no statistics could be done due to differences in sample sizes and heterogeneity of the studies.

Technical volumetric accuracy was calculated in fifteen studies [3, 6–8, 12, 13, 27–30, 33–35, 39, 40]. Six articles included a control group, resulting in a significant improvement in the volumetric accuracy of SN (table 3.3) [3, 6, 27, 29, 30, 40]. Different methods have been used to calculate orbital volumes. Seven articles compared the reconstructed orbital volume with that of the uninjured orbit [3, 6, 8, 13, 28, 39, 40]. Three articles showed standard deviations; therefore, we formulated a forest plot, as shown in figure 2. A meta-analysis of all three articles found significant differences in volumetric accuracy for the navigation group [3, 6, 40] and a global Cohen's d of -1.45 showed a moderate to large effect size of navigation. Significantly better volumetric accuracy was observed in 42 patients in the navigation group than in 34 patients in the control group. The mean difference (± SD) between the planned orbital volume and postoperative volume was 0.93 cm^3 (± 0.47 cm^3) in the navigation group and 2.17 cm^3 (± 1.35 cm^3) in the control group.

Six articles described the degree of enophthalmos as a technical accuracy parameter (table 3.4) [6, 25, 28, 31, 35, 37]. A significant decrease in enophthalmos was observed when navigation was used compared with the conventional method [6].

3.4 Operative time

Eleven studies reported the operative time qualitatively or in minutes [3, 5–8, 12, 29–31, 35, 39]. Most studies reported increased operative time (table 2). Based on the data available in this study, it was not possible to statistically support the hypothesis that operative time decreases when SN is used.

In ten studies the preoperative time was discussed, as shown in table 2 [3, 6, 7, 12, 13, 28, 30, 31, 35, 39]. Times ranging from 10 to 120 min were described. The "setup time" (time to install the hardware) and "landmarking time" (time to calibrate the hardware with patient-specific soft or hard tissue landmarks) were estimated to be 15–24 min [3, 6, 7, 35].

3.5 Revision rate

In fourteen articles, the necessity for revision was mentioned (table 2) [1, 3, 7, 8, 10, 13, 29–32, 35, 38, 40, 41]. Nine studies reported no need for revision surgery in any of the operated patients, whereas five other articles reported revision rates of 1.2%, 4.1%, 4.6%, 13.3%, and 23.1% [8, 10, 29–31, 35, 38, 40, 41]. The weighted average revision rate was 4.9%, based on a total sample size of 204 patients [1, 3, 7, 13, 32]. The reasons for revision surgery were implant malposition (seven patients) and diplopia (one patient). The revision rate after the conventional orbital fracture repair was 17% [43]. In this study, a statistical difference (p=.002) was found between the revision rates of the navigation and non-navigation groups using the Pearson's chi-square test.

3.6 Complications

Complications were defined as diplopia, inaccurate placement of the PSI, entropion, ectropion, and visible asymmetry of the restored orbit and its contents (table 2). Ten studies reported no complications after SN use, [7, 8, 10, 22, 28, 30, 32, 35, 36, 38] whereas in eight studies diplopia was the most reported complication [1, 3, 6, 13, 29, 31, 39, 44]. Compared with the conventional method, a lower complication rate has been reported [3, 6, 29, 44]. No statistical analysis could be performed because of the heterogeneity in complications and small sample sizes.

3.7 Costs

The cost of the SN procedure was calculated and discussed in eight studies, as shown in table 2. All eight studies showed an increased cost, although the methodology was poorly described [3, 6, 7, 13, 28, 38, 39, 44]. While SN was more expensive, it proved to be cost-effective in the context of revision surgery [3].

3.8 Quality assessment

The studies with the highest MINORS-score were reported by Cai et al. (24/24), Raveggi et al. (16/16), Sukegewa et al. (24/24), Cuyper et al. (22/24), Zeller et al. (22/24), and Zong et al. (22/24) (table 1 and table 2) [3, 13, 32, 40, 44].

4. Discussion

Fracture reconstruction of the bony orbit is important to restore the functional and esthetic role of the bony orbit and its contents [1, 29]. This surgery, however, can be challenging because of their complex anatomy and limited visibility perioperatively [3].

SN has been widely acknowledged for its potential benefits, although it is mainly used in academic centers [3, 5, 9, 14, 17, 45]. Importantly, it is yet to attain the status of a standard of care in current health care practices [14]. Therefore, the objective of this study was to evaluate the added clinical value of SN in the reconstruction of orbital fractures in terms of technical accuracy, complications, operative time, and cost compared with the conventional method.

Comparing technical accuracy was difficult because of the large variety of methods used to define the accuracy of the reconstruction. Volumetric accuracy and linear accuracy were most used [3, 5, 6, 8, 10, 12, 13, 22, 27–35, 37–41, 44]. Volumetric accuracy was measured digitally by calculating the preoperative and postoperative volumes or the volumetric difference between the uninjured and injured orbits [3, 6, 8, 13, 28, 39, 40]. Linear accuracy was measured by superimposing the planned situation on the reconstructed implant position or calculating the difference between certain landmarks [5, 10, 12, 22, 26, 27, 29, 37, 38, 41, 44]. Enophthalmos was measured using Hertel exophthalmometry or Cabanis index [6, 28]. Finally, the differences in yaw, roll, and pitch of the implant were also used to calculate the accuracy [5, 32].

The technical accuracy of the procedure depends on the virtually simulated preoperative plan. Preoperative CT, magnetic resonance imaging [MRI] and planning software are necessary [46]. To generate the preoperative virtual plan, virtual (AI-based) mirroring and segmentation of the unaffected side create an ideal virtual template [47]. The natural asymmetry between the left and right sides was estimated to be 0.44 cm^3 and 0.82 mm and is clinically insignificant in the mirroring process [47]. However, the CT slice thickness and the intrinsic measuring error of the software and hardware are factors that could limit the accuracy of matching the mirrored site [48]. In addition, the complexity of orbital fractures and post-traumatic decrease in orbital fat tissue must be considered when comparing orbital volumes and projection of the globe [3].

SN showed significantly accurate results in terms of volumetric measurements. However, a standardized protocol should be developed to measure the accuracy. In combination with a PSI, the SN has an accuracy of approximately 1 cm^3, which is insufficient to provide visible asymmetry.

Two studies quantitatively described the operative time in comparison with the conventional method using quantitative data [3, 6]. In both articles, a non-significant reduction of eight and thirteen minutes was observed with surgical navigation. Other studies only qualitatively described operative times, and the definition of operative time differed. Fifteen to twenty minutes were necessary to install and calibrate the SN equipment, although this time could be compensated by a reduced surgical time [3, 6, 7]. In addition, preoperative virtual planning could familiarize the surgeon with the orbital anatomy and shorten the operative time [4, 6, 29, 50].

The largest study that reported revision rates after conventional orbital fracture repair reported a revision rate of 17% [43]. The main reason for surgical revision was implant malpositioning. Our study showed that SN significantly decreased the revision rate. The study with the highest revision rate was the oldest study (2009). This suggests that patient safety and surgeon familiarity with this technique have improved in recent years [1]. Our results suggest that SN can reduce revision surgery and complication rates [43].

According to literature, complications after orbital reconstruction surgery vary from 3% to 85% [43]. Some studies have also named hypoesthesia of the infraorbital nerve a possible complication. However, this complication is mainly due to the fracture pattern and proximity of the infraorbital nerve to the fracture line and is not necessarily a complication of SN [49].

The cost of the intervention must be seen from the perspective of a lower risk of revision surgery (up to 10000 USD) and the cost of the hardware must be considered in relation to the number of patients treated with this device [26]. This might be considerably higher than expected or reported because of maintenance contracts, licenses, logistical costs, etc. [46].

Meta-analysis was not possible for all outcomes due to the heterogeneity in study design and method of comparing outcomes, such as operative times and complication rates. Additionally, this technique has evolved over the years, indicating that articles written between 2002 and 2010 are not entirely comparable to the most recent literature. The inclusion of unilateral and bilateral fractures might have resulted in a slight bias in accuracy, because the least affected site was reduced and used as a mirror image of the other site. Nevertheless, SN provides immediate feedback to the surgeon to accurately place PSI and contributes to a lower revision rate.

5. Conclusion

This systematic review and meta-analysis represent the first comprehensive assessment of SN in post-traumatic orbital surgery. The objective of this study was to evaluate the added clinical value of SN in orbital fractures compared to conventional methods, focusing on technical accuracy, operative times, revision rates, complications, and costs.
Studies with high MINORS scores showed improved volumetric accuracy when SN was used, highlighting its potential as a safe and precise surgical tool. The mean difference between the planned orbital volume and postoperative volume was 0.93 cm^3 ± 0.47 cm^3 in the navigation group, which differed significantly from that of the control group (2.17 cm^3 ± 1.35 cm^3). Operative times did not show significant differences, which could be attributed to calculation variations across the studies. Furthermore, the implementation of SN resulted in significant reductions in revision rates compared with conventional methods, despite the associated increased costs. The cost-effectiveness of SN can be explained by the reduced need for revision. Hence, utilization of SN is recommended in cases involving large orbital fractures.
In conclusion, post-traumatic orbital reconstruction surgery with SN is accurate within a clinically important precision range of 1 mm and 1 cm^3. Although more expensive, SN provides immediate feedback, resulting in lower revision rates. Therefore, SN has added clinical value for large orbital fractures.

Appendix

Full Search string:

Database	#Refs	#Refs after duplicates removed
PubMed (Medline)	1885	
Embase	2539	
Web-Of-Science	1471	
Cochrane (Core Collection)	383	
Total	6278	3733

PubMed (Medline)
[tiab] OR orbital-floor [tiab]) AND ("orbital fractures"[Mesh] OR ((“orbit surgery"[tiab] OR orbit*[tiab] OR blow-out*[tiab] OR "orbitozygoma*"[tiab] OR orbital-wall[tiab] OR orbital-floor[tiab]) AND ("Fractures, Bone"[Mesh:NoExp] OR fracture*[tiab]))) AND (“orbital implants"[Mesh] OR orbital-implant*[tiab] OR patient-specific-implant*[tiab] OR "Imaging, Three-Dimensional"[Mesh] OR 3D[tiab] OR three-Dimensional[tiab] OR 3-D[tiab] OR "Reconstructive Surgical Procedures"[Mesh:NoExp] OR reconstructive-surg*[tiab] OR computer-assisted[tiab] OR computer-aided[tiab] OR navigation*[tiab] OR intra-operative navigation[tiab] OR intraoperative navigation[tiab] OR surgical navigation[tiab] OR guided surgery[tiab] OR stereotactic navigation[tiab] OR management[tiab] OR preoperative-plan*[tiab] OR planning*[tiab] OR pre-operative-plan*[tiab] OR pre-surg*[tiab] OR presurg*[tiab] OR pre-plan*[tiab] OR preplan*[tiab] OR preoperative-care[tiab] OR preparation*[tiab])

Embase
(‘orbital fractures’/exp OR ((‘orbit surg*’:ti,ab,kw OR ‘orbit*’:ti,ab,kw OR ‘blow out*’:ti,ab,kw OR ‘orbitozygoma*’:ti,ab,kw OR ‘orbital wall’:ti,ab,kw OR ‘orbital floor’:ti,ab,kw) AND ‘fracture*’:ti,ab,kw)) AND (‘orbital implants’/exp OR ‘orbital implant*’:ti,ab,kw OR ‘patient specific implant’/exp OR 'three-dimensional imaging'/exp OR 'three dimensional':ti,ab,kw OR 'reconstructive surgery'/exp OR 'reconstructive surg*':ti,ab,kw OR 'computer assisted':ti,ab,kw OR 'computer aided':ti,ab,kw OR ‘navigation*’:ti,ab,kw OR ‘intra-operative navigation’:ti,ab,kw OR ‘intraoperative navigation’:ti,ab,kw OR ‘surgical navigation’:ti,ab,kw OR ‘guided surgery’:ti,ab,kw OR ‘stereotactic navigation’:ti,ab,kw OR ‘management’:ti,ab,kw OR 'preoperative plan*':ti,ab,kw OR 'planning*':ti,ab,kw OR 'pre operative plan*':ti,ab,kw OR 'pre surg*':ti,ab,kw OR 'presurg*':ti,ab,kw OR 'pre plan*':ti,ab,kw OR 'preplan*':ti,ab,kw OR 'preoperative care':ti,ab,kw OR 'preparation*':ti,ab,kw)

Web-Of-Science
(TS=(“orbital fractures*” OR ((“orbit surgery” OR “orbit*” OR “orbitozygoma*” OR “blow out” or “orbital wall” or “orbital floor”) NEAR/6 “Fracture*”))) AND (TS=(“orbital implant*" OR “patient specific implant” OR “three dimensional” OR “3D” OR “3 D” OR “reconstructive surg*” OR “computer assisted” OR “computer aided” OR “navigation*” OR “intra-operative navigation” OR “intraoperative navigation” OR “surgical navigation” OR “guided surgery” OR “stereotactic navigation” OR “management” OR “preoperative plan*” OR “planning*” OR “pre operative plan*” OR “pre surg*” OR “presurg*” OR “pre plan*” OR “preplan*” OR “preoperative care” OR “preparation*”))

Cochrane (Core Collection)
((([mh "orbital fractures"] OR ([mh "orbital"] AND [mh ^"Fractures, Bone"])) OR ((“blow-out*” OR “orbital*” OR ((“orbit surgery” OR “orbit*” OR “orbitozygoma*” OR “blow out” OR “orbital wall” OR “orbital floor”) AND “fracture*”)):ti,ab,kw))) AND (((([mh “orbital implants”] OR (“patient specific implant*”) OR [mh "Imaging, Three-Dimensional"] OR [mh ^"Reconstructive Surgical Procedures"])) OR ((“3D” OR “Three Dimensional” OR “3 D” OR (reconstructive NEXT surg*) OR “computer assisted” OR “computer aided” OR “navigation*” OR “intra-operative navigation” OR “intraoperative navigation” OR “surgical navigation” OR “guided surgery” OR “stereotactic navigation” OR “management” OR (preoperative NEXT plan*) OR planning* OR (pre NEXT operative NEXT plan*) OR (pre NEXT surg*) OR presurg* OR (pre NEXT plan*) OR preplan* OR “preoperative care” OR preparation*):ti,ab,kw)))

Reference	Year	Study design	Number of patients (n)	Male	Female	Mean age (years ± SD)	Diagnosis	MINORS
Gellrich et al. [12]	2002	Prospective	18	15	3	38	Orbital fracture	08/16
Schmelzeisen et al. [33]	2004	Retrospective case series	5		/	/	Orbital wall and floor fracture	09/16
Pham et al. [37]	2007	Retrospective	2	2	0	41.5	Orbitozygomaticomaxillary complex	06/16
Bell et al. [1]	2009	Retrospective	13	9	4	43.8	Primary and secondary orbital floor fracture	10/16
Yu et al. [41]	2010	Retrospective	6	4	2	27	Orbitozygomaticomaxillary complex	11/16
Markiewicz et al. [34]	2011	Retrospective	23	18	5	41.3 (± 15.6)	Orbital fracture	10/16
He et al. [25]	2012	Retrospective	11	/	/	/	Orbitozygomaticomaxillary complex	9/16
Cai et al. [26]	2012	Prospective	29 * and 29**	56	2	33.5* and 32.4**	Orbital fracture	24/24
Andrews et al. [38]	2013	Retrospective	8	6	2	29.2	Orbital fracture	08/16
Yu et al. [10]	2013	Retrospective	34	/	/	29	Orbitozygomaticomaxillary complex	12/16
Kim et al. [35]	2013	Case series	5	3	2	42	Orbital wall and floor fracture	09/16
Essig et al. [27]	2013	Retrospective	94 (60 navigation)	58	36	38 (± 19)	Orbital wall and floor fracture	08/16
Novelli et al. [28]	2014	Retrospective	11	9	2	32	Unilateral orbital fracture	10/16
Dubois et al. [5]	2015	Prospective	10	/	/	/	Unilateral orbital fracture	14/16
Shin et al. [36]	2015	Prospective	34	/	/	/	Orbital floor fracture	10/16
Cha et al. [39]	2016	Prospective	12	7	5	49 [± 14]	Orbital wall fracture	13/16
Sukegawa et al. [40]	2017	Retrospective	4* and 4**	4	4	45.13	Orbital floor fracture	16/16
Schreurs et al. [22]	2017	Prospective	2	1	1	/	Secondary orbitozygomaticomaxillary complex fractures	08/16
Zavattero et al. [29]	2017	Prospective	30* and 25**	21* and 15**	9* and 10**	38* and 42**	Orbital fracture	20/24
Bao et al. [30]	2019	Retrospective case control	15* and 10**	10* and 7**	5* and 3**	41.1* and 39.4**	Orbitozygomatic fractures	19/24
Dong et al. [8]	2020	Retrospective	10	5	5	57.5	Medial orbital wall fractures	22/24
Cuyper et al. [3]	2020	Retrospective	22	12	10	51	Orbital floor fracture	22/24
Zeller et al. [13]	2020	Retrospective	81	/	/	/	Orbital fracture	22/24
Zong et al. [6]	2020	Retrospective case control	40* and 30**	25* and 24**	15* and 6**	37.4* and 40.6**	Orbital wall and floor fracture	22/24
Chu et al. [7]	2022	Prospective	15	4	11	39.2 (± 16.0)	Orbital/orbitozygomaticomaxillary complex	14/16
Consorti et al. [31]	2022	Prospective	25	/	/	19-85	Combined orbital medial wall and floor and large isolated Orbital floor fractures	12/16
Raveggi et al. [32]	2023	Retrospective case series	73	47	26	46	Isolated orbital floor fractures	16/16
Total			**696 (controls included)**	**362**	**168**	**39.6 (± 7.5)**	Fractures of the bony orbit	

Table 1: *Study characteristics, patient demographics, diagnosis, and follow-up time. *=experimental group: navigation and **= control group: conventional.*

Reference	Year	Mean operation time (min)	Pre-operation time (min)	Revision needed (n)	Complications (n; complication)	Control/follow-up (months)	Cost (descriptive)	MINORS
Gellrich et al. [12]	2002	+30*	+60*	/	/	/	/	08/16
Schmelzeisen et al. [33]	2004	/	/	/	/	/	/	09/16
Pham et al. [37]	2007	/	/	/	/	/	/	06/16
Bell et al. [1]	2009	/	/	3	3; inaccurate placement, entropion, ocular dysmotility	/	/	10/16
Yu et al. [41]	2010	/	/	0	/	1	/	11/16
Markiewicz et al. [34]	2011	/	/	/	/	/	/	10/16
He et al. [25]	2012	/	/	/	/	/		
Cai et al. [26]	2012	/	/	/	less diplopia*	12	Increased	24/24
Andrews et al. [38]	2013	/	/	0	0*	6	Eliminating the cost of scan	08/16
Yu et al. [10]	2013	/	/	0	0*	5-65	/	12/16
Kim et al. [35]	2013	78* and 54**	24*	0	1* and 5	11.7	/	09/16
Essig et al. [27]	2013	/	/	/	/	/	/	08/16
Novelli et al. [28]	2014	/	Increased*	/	0*	/	Increased	10/16
Dubois et al. [5]	2015	extra time, not specified	/	/	/	/	/	14/16
Shin et al. [36]	2015	/	/	/	0*	/	/	10/16
Cha et al. [39]	2016	117.5 (± 25.2)	120*	/	1*; diplopia for 6m	3.5	Cost effective	13/16

Sukegawa et al. [40]	2017	/	/	0	0*	6 to 28	/	16/16
Schreurs et al. [22]	2017	/	/	/	/	3	/	08/16
Zavattero et al. [29]	2017	More in the early cases* less in the later cases		0* and 2**	1* and 3**	> 6	/	20/24
Bao et al. [30]	2019	+60*	120*	0	0	<18	/	19/24
Dong et al. [8]	2020	<60*	/	0	0	> 6	/	22/24
Cuyper et al. [3]	2020	91 (± 26.7) * and 120 (± 62.5)**	10*	1	2*; persistent diplopia	<1.5	Increased	22/24
Zeller et al. [13]	2020	/	Increased*	1	3*; diplopia	3	Increased	22/24
Zong et al. [6,7]	2020	117.4 (± 36.7)* and 125.3 (± 40.7)** p>0.05	<20*	/	3*; 1 diplopia, 2 asymmetry and 6** (2 diplopia, 4 asymmetry)	>6	Cost effective	22/24
Chu et al. [7]	2022	Increased	Increased*	2	0	>6	Increased	14/16
Consorti et al.[31]	2022	Not increased	15*	0	1; ectropion	<12	/	12/16
Raveggi et al. [32]	2023	/	/	3	0	>6	/	16/16

Table 2*: Mean operation time, pre-operation time, revisions, complications, follow-up time, cost. *=experimental group: navigation and **= control group: conventional*

.Table 3.1

Reference	Year	Technical accuracy angle (°)*	Technical accuracy angle (°)**	*p*-value	Method of calculating outcome
Dubois et al. [5]	2015	<5.6	/	/	Pitch, jaw, roll, measured digitally and with an orbital implant dislocation frame.
Schreurs et al. [22]	2017	<4.5	/	/	Pitch, jaw, roll, measured digitally and with an orbital implant dislocation frame.
Chu et al. [7]	2022	No difference in planned angles and postoperative angles for middle and posterior part	/	<0.016	Presurgical angles in comparison with postoperative angles of the anterior, middle and posterior part of the orbitozygomatic complex

Table 3.2

Reference	Year	Planned position implant (mm)*	Planned position implant (mm)**	*p*-value	Method of calculating outcome
Gellrich et al. [12]	2002	1.3	/	/	Globe projection
Schmelzeisen et al. [33]	2004	1.3	/	/	Preop plan and postop situation
Pham et al. [37]	2007	<1	/	/	Symmetry of landmarks, measured from skull base
Bell et al. [1]	2009	6 good,6: fair, 1 poor: not further specified	/	/	Subjective: patient and surgeons' opinion
Yu et al. [41]	2010	<2	/	/	Preop plan and postop situation (landmarks]
Markiewicz et al. [34]	2011	2.4	/	/	Preop plan and postop situation
He et al. [25]	2012	100% symmetry* and 74.3%	/	/	Preop plan and postop situation
Cai et al. [26]	2012	3.2	/	0.001	Vertical distance at orbital floor boundaries
Andrews et al. [38]	2013	1.0-2.0	/	/	Not specified
Yu et al. [10]	2013	1.6	/	/	Preop plan and postop situation (superposition]
Essig et al. [27]	2013	<0.3	/	/	Preop plan and postop situation (superposition]

Novelli et al. [28]	2014	<2	/	/	Preop plan and postop situation (superposition]
Dubois et al. [5]	2015	0.8	/	/	Preop plan and postop situation (superposition] markers embedded in implant
Shin et al. [36]	2015	Exact correspondence	/	/	Subjective: patients' and surgeons' opinion
Schreurs et al. [22]	2017	1.2-1.5	/	/	Preop plan and postop situation (superposition]
Bao et al. [30]	2019	3.4 (AIO), 4.2 (AIJ), 4.9(AIZ)	4.9 (AIO),4.9 (AIJ) 10 (AIZ)	<0.01	Asymmetry-index
Cuyper et al. [3]	2020	1.8 (NAV) 1.9 (NAV-CBCT)	1.9 (CBCT)	>0.05	Preop plan and postop situation (superposition)
Zeller et al. [13]	2020	0.648, 0.712, 0.636, 0.757	1.132, 1.217, 1.022, 1.288	<0.001	Preop plan and postop situation (superposition landmarks]
Zong et al. [6]	2020	0.9 (± 0.5)	/	/	Preop plan and postop situation (superposition)
Chu et al. [7]	2022	Significant reduction deviation rate	/	/	Preop plan and postop situation (superposition)
Consorti et al. [31]	2022	0.7	/	/	Preop plan and postop situation (superposition)
Raveggi et al. [32]	2023	88% <2mm (MPA)	/	/	Preop plan and postop situation (superposition)

Table 3.3

Reference	**Year**	**Volumetric accuracy (cm^3) ***	**Volumetric accuracy (cm^3) ****	***p*-value**	**Method of calculating outcome**
Gellrich et al. [12]	2002	0.43	/	/	/
Schmelzeisen et al. [33]	2004	4.0	/	/	Vpreop-Vpostop
Markiewicz et al. [34]	2011	5.1	/	/	Vpreop-Vpostop
Kim et al. [35]	2013	2.2	/	/	Vpreop-Vpostop

Essig et al. [27]	2013	27.7	25.7	<0.05	Vpostop* VS Vpostop**
Novelli et al. [28]	2014	0.2	/	/	Vreconstructed-Vuninjured
Cha et al. [39]	2016	99.42 (OVR) and 0.64cm^3	/	0.02	Injured orbital cavity volume/ Uninjured orbital cavity volume
Sukegawa et al. [40]	2017	0.8	1.2	<0.036	Vreconstructed-Vuninjured
Zavaterro et al. [29]	2017	3.1 (significant reduction)*	2.1 (not significant)**	<0.05	Vpreop-Vpostop
Bao et al. [30]	2019	2.2	1.6	<0.01	Vpostop-Vpreop
Dong et al. [8]	2020	0.5	/	<0.001	Vreconstructed-Vuninjured (no difference)
Cuyper et al. [3]	2020	3.1 (NAV), 1.5 (NAV+ CBCT)	3.7 (CBCT)	<0.046	Vreconstructed-Vuninjured
Zeller et al. [13]	2020	No difference in pre-postop		>0.05	Vreconstructed-Vuninjured
Zong et al. [6]	2020	0.6 (± 0.4)	1.6 (± 0.8)	0.022	Vreconstructed-Vuninjured
Chu et al. [7]	2022	No difference in pre-postop	/	>0.05	Vpreop-Vpostop

Table 3.4

Reference	**Year**	**Enophthalmos***	**Enophthalmos****	***p*-value**	**Method of calculating outcome**
Pham et al. [37]	2007	<1mm	/	/	Postreduction CT
He et al. [25]	2012	<2mm (90.9%)	/	/	Postreduction CT
Kim et al. [35]	2013	<2 mm (100%)	/	/	Exophthalmometry
Novelli et al. [28]	2014	1.3	/	/	Cabanis-index
Zong et al. [6]	2020	0.4 (± 0.3)	1.5 (± 0.8)	0.014	Cabanis-index

Consorti et al. [31]	2022	18/20: resolved	/	/	Superposition preop CT-postop CT

Table 3: *Accuracy parameters*
3.1: *Technical accuracy angle (°).*
3.2: *Studies that include the technical accuracy (mm) in the navigation* and control** group. AIO: asymmetry index Orbitale; AIJ: asymmetry index Jugale; AIZ: Asymmetry index Zygion; NAV: navigation; CBCT: Cone-Beam computed tomography; MPA: mean area percentage.*
3.3: *Studies that included the technical volumetric accuracy (cm^3) Navigation*; Conventional**; CBCT: Cone-beam computed tomography; MPA: Mean area percentage.*
V: Volume; preop: preoperative; postop: postoperative.
3.4: *Studies that included the degree of enophthalmos for navigation* and conventional**.*

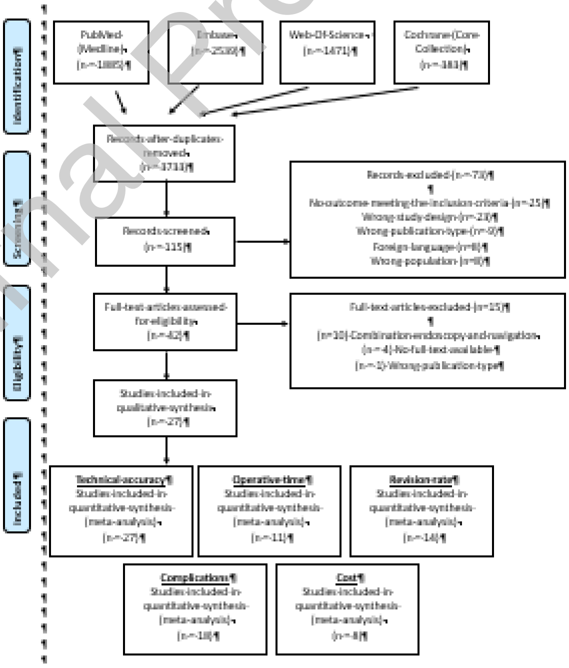
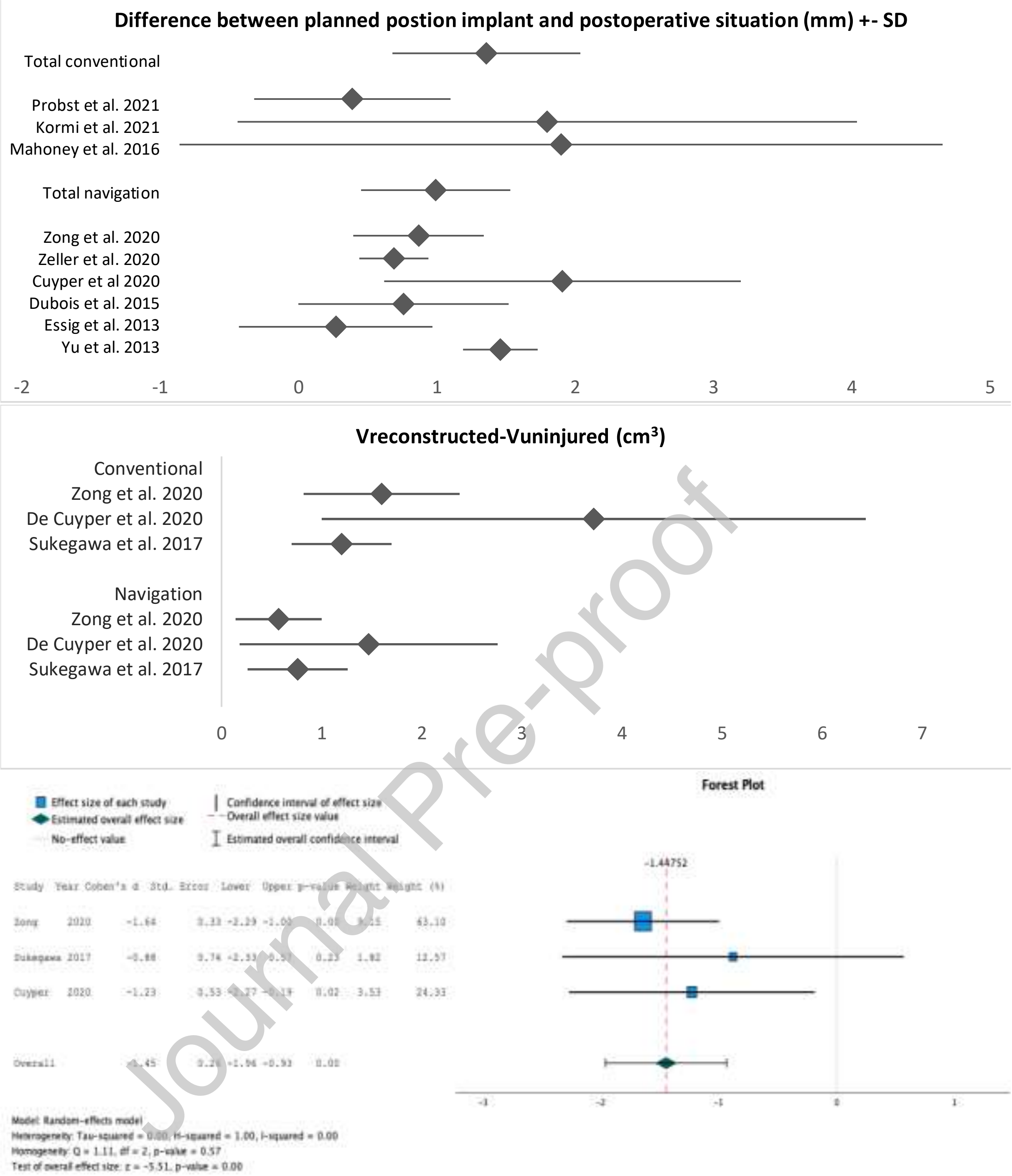


Figure 1. *Flowchart (Prisma 2009) of article selection*



Study	Year	Cohen's d	Std. Error	Lower	Upper	p-value	Weight	Weight (%)
Zong	2020	-1.64	0.33	-2.29	-1.00	0.00	9.15	63.10
Sukegawa	2017	-0.88	0.74	-2.33	0.57	0.23	1.82	12.57
Cuyper	2020	-1.23	0.53	-2.27	-0.19	0.02	3.53	24.33
Overall		-1.45	0.26	-1.96	-0.93	0.00		

Model: Random-effects model
Heterogeneity: Tau-squared = 0.00, H-squared = 1.00, I-squared = 0.00
Homogeneity: Q = 1.11, df = 2, p-value = 0.57
Test of overall effect size: z = -5.51, p-value = 0.00

Figure 2: *Technical accuracy (mm and cm^3)*

A. Forest plot of the mean linear accuracy in millimeters for conventional surgery and SN

B. Forest plot of the technical volumetric accuracy in cm^3, comparing conventional surgery with SN.

C. Cohen's d for overall effect on volumetric accuracy of SN.

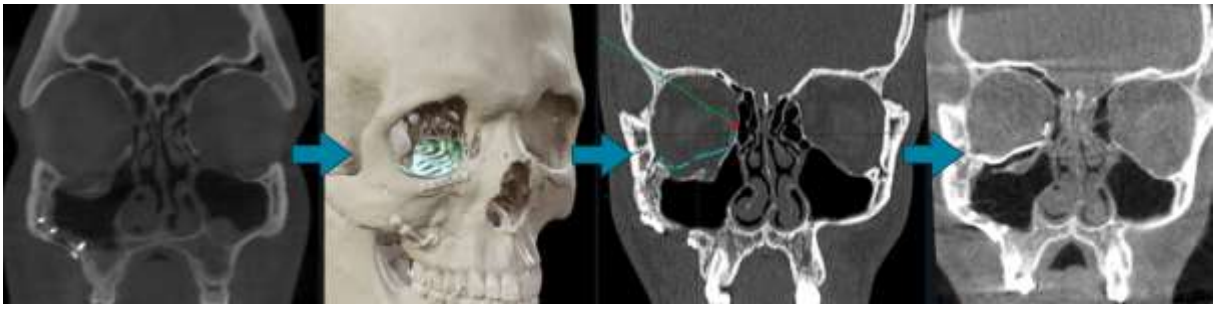


Figure 3: *Clinical workflow at the department of Oral and Maxillofacial Surgery, University Hospitals, Leuven, Belgium*
Step 1*: Radiographic data obtained by 3DCT imaging is transformed to a digital imaging and communication in medicine (DICOM) format.*
Step 2: *Digital segmentation and virtual planning of the PSI. The digital model is imported into navigation software and the PSI is manufactured.*
Step 3: *Surgical navigation using the preoperative digital planning and real-time feedback of the navigation probe during surgery. This step is not used in the conventional method.*
Step 4: *Intraoperative or postoperative 3D CT imaging for final check of the position of the PSI.*

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Declaration of interests

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