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Vergleich der präoperativen Planung mit dem postoperativen Ergebnis bei computergestützt geplanten posttraumatischen Rekonstruktionen des Mittelgesichts-

eine retrospektive Erhebung

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Affidavit

Eidesstattliche Versicherung

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Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

Vergleich der präoperativen Planung mit dem postoperativen Ergebnis bei computergestützt geplanten posttraumatischen Rekonstruktionen des Mittelgesichts-

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München, 28.01.2022 Paris Georgios Liokatis

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Inhaltsverzeichnis

Abkürzungsverzeichnis

CAD/CAM	Computer Aided Design/ Computer Aided Manufacturing
VSP	Virtual Surgical Planning
PSI	Patientenspezifisches/-e Implantat/-e
CT	Computertomographie
3D	Dreidimensional/-er/-e/-es

Publikationsliste

Englischsprachige Originalarbeiten

Liokatis P, Malenova Y, Fegg F-N, Haidari S, Probst M, Boskov M, Cornelius C-P, Troeltzsch M, Probst F-A

Digital planning and individual implants for secondary reconstruction of midfacial deformities: A pilot study. Laryngoscope Investigative Otolaryngology. 2022;1-11. doi:10.1002/lio2.753

Probst FA, Cornelius CP, Otto S, Malenova Y, Probst M, **Liokatis P**, Haidari S.
Accuracy of free-hand positioned patient specific implants (PSI) in primary reconstruction after inferior and/or medial orbital wall fractures. Comput Biol Med. 2021 Oct;137:104791. doi: 10.1016/j.compbiomed.2021.104791.

Wissenschaftliche Vorträge

69. Kongress der Deutschen Gesellschaft für Mund-, Kiefer- und Gesichtschirurgie, Frankfurt am Main, Juni 2019: Positionierungsgenauigkeit bei patientenspezifischen Implantaten (PSI) zur Orbitawandrekonstruktion – Vergleich der präoperativen Planung mit der postoperativen Implantatposition
Probst, Florian Andreas; **Liokatis Paris**; Haidari, Selgai; Malenova, Yoana; Müller-Lisse, Ullrich; Hesse, Ronny; Cornelius, Peter; Ehrenfeld, Michael

138. Deutscher Chirurgen Kongress, Mainz, April 2021: Positionierungsgenauigkeit der 3D-Planung mit oder ohne patentienspezifischen Implantaten (PSI) zur sekundären Rekonstruktion des Jochbeins und der Maxilla - Vergleich der präoperativen Planung mit dem postoperativen Outcome
P. Liokatis, F. Fegg, M. Ehrenfeld, C.-P. Cornelius, G. Mast, F. Probst

1. Eigenanteil

1.1 Beitrag zu Paper I

Paris Liokatis und PD Dr. Dr. Florian Andreas Probst trugen zur Konzeption und Gestaltung der Studie, zur Datenerfassung, Datenanalyse und -interpretation sowie zum Verfassen und zur Überarbeitung des Manuskripts bei. Die Grafiken wurden von Paris Liokatis und PD. Dr. Dr. Florian Andreas Probst erstellt. Prof. Dr. Dr. Carl-Peter Cornelius war an der Konzeption der Studie beteiligt und unterstützte durch intellektuellen Rat und Anregungen. Yoana Malenova trug zur Datenanalyse und -interpretation bei. Dr. Florian-Nepomuk Fegg, Dr. Selgai Haidari, Dr. Monika Probst, Dr. Marko Boskov und PD Dr. Dr. Matthias Tröltzsch waren an der Dateninterpretation und Erstellung des Manuskriptes beteiligt.

1.2 Beitrag zu Paper II

PD Dr. Dr. Florian-Andreas Probst und Dr. Selgai Haidari haben zur Konzeption und Gestaltung der Studie, zur Datenerfassung, zur Datenanalyse und -interpretation sowie zum Verfassen und zur Überarbeitung des Manuskripts beigetragen. Prof. Dr. Dr. Carl-Peter Cornelius war an der Konzeption der Studie beteiligt und half bei der finalen Durchsicht des Manuskriptes mit. Paris Liokatis und Yoana Malenova beteiligten sich an der Datenerfassung, an der Datenanalyse und -interpretation sowie an der Überarbeitung des Manuskripts. Prof. Dr. Dr. Sven Otto und Dr. Monika Probst trugen zur Erstellung und Überarbeitung des Manuskripts bei.

2. Einleitung

2.1 Klassifikation der Mittelgesichtsfrakturen

Der Prototyp für die Klassifizierung von Mittelgesichtsfrakturen ist die Unterscheidung von drei Le-Fort-Varianten. Die experimentellen Kadaverstudien des französischen Arztes René Le Fort gehen auf den frühen Beginn des 20. Jahrhunderts zurück und führten zu einem besseren Verständnis der typischen Knochenbruchlinien des Mittelgesichtsskeletts [1]. Obwohl die Verläufe der sich daraus ergebenden Bruchlinien nicht immer mit den heutigen, oft komplexen Verletzungsmustern im Mittelgesicht übereinstimmen, ist das Le-Fort-Schema in der medizinischen Fachwelt besonders verbreitet. Allerdings bieten moderne Klassifizierungssysteme eine Standardisierung und Dokumentation einfacher bis komplexer Mittelgesichtsverletzungen an, die durch die traditionelle Le-Fort Klassifikation nicht ausreichend zugeordnet werden können [2].

Das AO CMF-Klassifizierungssystem bietet ein strukturiertes Instrument zur Beurteilung von Mittelgesichtsfrakturen, das zwar einfach genug für die tägliche Routine ist, jedoch die Beschreibung von Mehrfachfrakturen ermöglicht [2].

Gemäß der AO CMF-Klassifikation und in Bezug auf die vertikalen Kompartimente können ein zentraler und ein lateraler Teil des Mittelgesichts unterschieden werden. Der zentrale Teil wird weiter in drei horizontale, übereinander geschichtete Partitionen unterteilt [1-3]:

- Oberes zentrales Mittelgesicht
    - Nasenskelett und nasofrontaler Bereich des Oberkiefers
- Mittleres zentrales Mittelgesicht
    - parapiriformer und infraorbitaler Bereich des Oberkiefers
- Unteres zentrales Mittelgesicht
    - Oberkieferkörper

Der laterale Teil des Mittelgesichts besteht aus dem Jochbein und dem Jochbeinbogen.

Die innere Orbita setzt sich aus vier Wänden und dem Apex zusammen [2, 4]:

- Obere Wand oder Dach
- Laterale Orbitawand
- Mediale Orbitawand
- Inferiore Orbitawand oder Orbitaboden

Der orbitale Apex stellt den hinteren Teil der inneren Augenhöhle dar und beginnt dort, wo der rechteckige koronale Querschnitt in eine dreieckige Form übergeht [4].

Die Grenzlinie zwischen den Orbitarändern und den inneren Orbitawänden wird durch die vordere Öffnung der Orbitalhöhle bestimmt [4]. Alle Strukturen rund um die Orbita, die bei streng frontaler Betrachtung auf der äußeren Knochenoberfläche vorstehen, werden als Orbitarand bezeichnet. Die innere Orbita beginnt unmittelbar hinter diesen Strukturen [4].

2.2 Epidemiologie der Mittelgesichtsfrakturen

Männliche Patienten im Alter zwischen 20 und 29 Jahren mit niedrigem Bildungsniveau stellen die Kategorie mit dem höchsten Risiko dar [5]. Neuere europäische Studien bestätigen, dass sich die Hauptursache für Kiefer- und Gesichtsfrakturen von Verkehrs- und Sportunfällen auf zwischenmenschliche Gewalt verlagert hat. Weitere Ursachen wie Arbeitsunfälle, häusliche Unfälle oder Tierangriffe treten seltener auf [6, 7].

Der Schweregrad eines Kiefer- und Gesichtstraumas variiert je nach Art der Ätiologie, der kinetischen Energie des verletzenden Agens und der Dynamik zwischen dem verletzenden Agens und dem Empfänger [8]. Verletzungen können sowohl isoliert als auch als Teil eines Polytraumas auftreten und mit intrakraniellen, zerebralen, okulären, spinalen, thorakalen oder abdominalen Läsionen koexistieren, die die Komplexität und Morbidität des Falles erheblich erhöhen können.

Im Mittelgesicht sind die am häufigsten gebrochenen Knochen das Jochbein und das Nasenbein [9, 10]. Das Jochbein ist die seitliche Stütze des Mittelgesichts und fängt den Großteil der traumatischen Kräfte in diesem Bereich auf. Zu berücksichtigen ist auch die Tatsache, dass der Mensch zum Zeitpunkt des Aufpralls dazu neigt, den Kopf zu drehen, um einen frontalen oder okulären Kontakt zu vermeiden [11]. Die sagittale Prominenz und die geringere Verletzungsresistenz der Nasenbeine im Gesicht erklären die hohe Inzidenz von Nasenfrakturen. Auch die Orbitafrakturen weisen eine hohe Inzidenz von Frakturen auf [7]. Frakturen des zentralen Mittelgesichts in den Le-Fort-Linien treten seltener auf [2].

2.3 Symptomatik bei dislozierten Mittelgesichtsfrakturen

Dislozierte Frakturen des Mittelgesichts sind von großer klinischer Bedeutung, da sie schwerwiegende Komplikationen verursachen und zu ästhetischen und funktionellen Problemen führen können [12]. Die Symptomatik dislozierter und/oder nicht adäquat repositionierter Fragmente hängt von dem Bereich des Mittelgesichts, der in Fehlstellung liegt, ab. Im Bereich des lateralen Mittelgesichts können sowohl ästhetische Probleme wie Gesichtsasymmetrie, Verlust der Gesichtsprojektion/Breite als auch funktionelle Störungen wie Mundöffnungsbehinderung und craniomandibuläre Dysfunktion auftreten [13]. Eine nicht ausreichend reponierte Fraktur des zentralen Mittelgesichts kann überwiegend zu kaufunktionellen Problemen wie Okklusionsstörungen, craniomandibuläre Dysfunktion und Kieferöffnungseinschränkung führen [13]. Bei einer Mitbeteiligung der Orbita kommen ein Enopthalmus, ein Hypoglobus, eine Diplopie und Bulbusmotilitätsstörungen häufiger vor [14].

2.4 Operative Versorgung der Mittelgesichtsfrakturen

2.4.1 Primäre chirurgische Versorgung

Der Goldstandard für die Behandlung von Mittelgesichtsfrakturen ist die offene Reposition der Fragmente und die rigide innere Fixierung mit geeignetem Osteosynthesematerial, um die knöcherne Kontur des Skeletts zu rekonstruieren [3]. Grundsätzlich wird empfohlen die endgültige chirurgische Behandlung von Frakturen im Bereich des Gesichtsschädels spätestens 7 bis 10 Tage nach dem Unfall durchzuführen, wenn keine Notfallsituation vorliegt (z. B. Einklemmung der extraokulären Muskeln, Obstruktion der Atemwege) [15, 16]. Dieser Zeitraum dient der Verminderung der Ödembildung, der besseren Ausprägung der klinischen Symptome und der Verschärfung der Operationsindikation. Außerdem ist die Bildung von Adhäsionen und Fibrosen nicht fortgeschritten, was die Reposition der Fragmente erschweren und die Komplikationsrate erhöhen würde [3, 17].

2.4.2 Sekundäre chirurgische Versorgung

Das primäre Ziel bei der Behandlung von in Fehlstellung geheilten Mittelgesichtsfrakturen ist die Wiederherstellung der knöchernen Strukturen. Eine leichte Asymmetrie der Gesichtskontur, wenn es keine funktionellen Störungen gibt, kann mit Knochenersatzstoffen oder mit dem Einbringen von weiteren Implantaten korrigiert werden [18]. Die sekundäre Osteotomie wird aber bei hochgradiger Dislokation der Fragmente sowie bei Vorliegen von funktionellen Einschränkungen als notwendig erachtet [18]. Gleichfalls verlangt die Behandlung von in Fehlstellung geheilten Orbitawandfrakturen eine Rekonstruktion des Orbitarahmens. Eine Reosteotomie ist bei solchen Operationen nur selten erforderlich. In der Regel sollten die betroffenen Orbitawände durch autologe Transplantate oder typischerweise durch alloplastische Implantate rekonstruiert werden [19].

2.5 Digitale Planung und CAD/CAM Instrumente

2.5.1 Primäre Frakturversorgung

Die virtuelle chirurgische Planung und die 3D-Drucktechnologie entwickeln sich auf dem Gebiet der Traumatologie rasant, was die Anwendung dieser Methode im Rahmen der zeitlich begrenzten primären Frakturversorgung durchführbar und zugänglich macht [14]. Die VSP und die PSI können die Diagnose erleichtern und die Ergebnisse der operativen Versorgung verbessern [14]. Allerdings werden die Indikationen sowie die Genauigkeit dieser Technologien umfassend erforscht, um die höheren Kosten zu rechtfertigen, die sie mit sich bringen [14].

2.5.2 Sekundäre Korrektur in Fehlstellung geheilter Frakturen

Sekundäre Rekonstruktionen bei komplexen posttraumatischen Deformitäten des Mittelgesichts erfordern oft individualisierte chirurgische Techniken. Bei solchen komplexen und nicht standardisierten Eingriffen scheint eine individualisierte virtuelle chirurgische Planung von besonderem Nutzen zu sein, denn sie führt zu besser vorhersagbaren Ergebnissen als Freihandtechniken [18, 20]. Ein Vorteil bei sekundären Rekonstruktionen ist, dass ausreichend Zeit für eine gründliche Planung und Vorbereitung bzw. Anfertigung der PSI zur Verfügung steht. Darüber hinaus erlaubt die VSP eine genauere Diagnose, optimiert die Operationsplanung und verkürzt die Operationszeit [18].

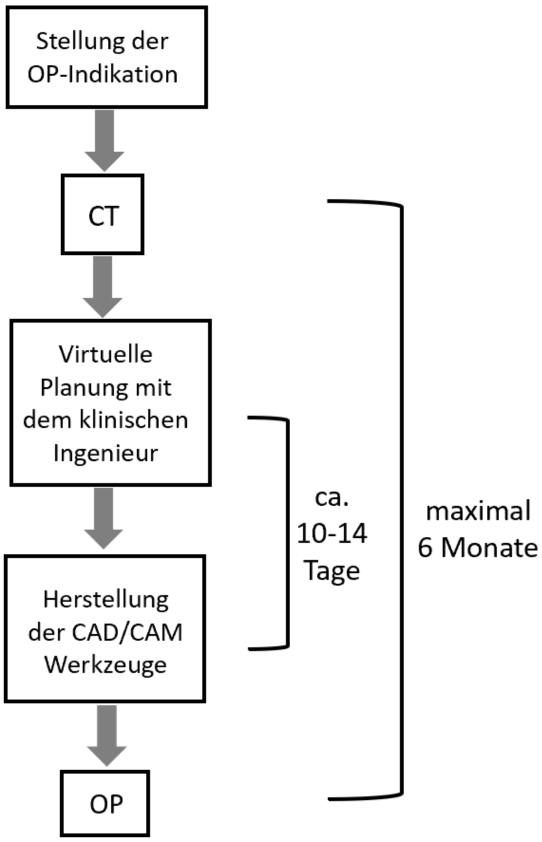

Figure 1. Klinischer Ablauf bei computergestützt geplanten primären und sekundären Rekonstruktionen des Mittelgesichts. Es wird empfohlen, dass der Zeitraum zwischen CT und Operation bei sekundären Rekonstruktionen 6 Monate nicht überschreitet, um Ungenauigkeiten aufgrund von Knochenveränderungen zu vermeiden.

Nach der Entscheidung für die Durchführung der Operation mit der Hilfe von virtueller Planung und CAD/CAM-gefertigten patientenspezifischen Implantaten und Positionierungsschablonen wird eine hochauflösende Computertomographie (Auflösung: 0,625 mm) durchgeführt. Die daraus resultierenden DICOM-Daten werden an den Industriepartner (KLS Martin, Tuttlingen, Deutschland oder Materialise, Leuven, Belgium) zur anschließenden virtuellen chirurgischen Planung in einer webbasierten interaktiven Sitzung übertragen. Nach der endgültigen Genehmigung der Entwürfe der patientenspezifischen Werkzeuge durch den behandelnden Chirurgen werden die PSI durch selektives Laserschmelzen angefertigt.

2.5.3 Übertragung der digitalen Planung auf den Patienten

Die VSP ermöglicht eine sehr genaue Simulation von Osteotomien zur Repositionierung des Skeletts sowie die Herstellung von individualisierten Implantaten zur Rekonstruktion von knöchernen Defekten. Die Herausforderung ist nach einer präzisen Planung die genaue chirurgische Reproduktion des Ergebnisses und aus diesem Grund werden intraoperative Navigationssysteme implementiert [21]. Die Einführung von intraoperativen Navigationssystemen in solche Eingriffe hat die Ergebnisse der Rekonstruktionen insbesondere im Bereich des Jochbeins und des Mittelgesichts deutlich verbessert, deswegen wird diese Technik als der Goldstandard betrachtet [22, 23].

Die Navigationssysteme bringen aber auch Nachteile mit sich: Die Verwendung und die Ausstattung sind kostenintensiv, die Anwendung ist kompliziert und aus diesem Grund steht diese Technik nur in bestimmten Zentren zur Verfügung .

Eine Alternative zu Navigationssystemen ist die Verwendung des CAD/CAM-gefertigten Armamentariums als Mittel, um die VSP auf den Patienten zu übertragen [24, 25]. Konventionelle Osteosyntheseplatten, die präoperativ an stereolithographische Modelle gebogen werden oder CAD/CAM-gefertigte patientenspezifische Implantate und Schablonen sind Instrumente, die nicht nur die Fixierung der Knochensegmente, sondern auch eine präzise Übertragung der digitalen Planung gewährleisten könnten [26].

2.6 Segmentierung

Die postoperativen CT-Aufnahmen wurden mit der Software Mimics (Materialise, Leuven, Belgien) segmentiert, wobei anhand der unterschiedlichen Werte der einzelnen Gewebe auf der Hounsfield-Skala zwischen Weichgewebe, Knochengewebe und Titan unterschieden wurde (Hounsfield-Skala: Weichgewebe: <300, Knochen: 300-1000, Titan: >1500). Anschließend wurden die durch das Osteosynthesematerial verursachten Artefakte für jedes Segment manuell entfernt. Die Segmente wurden dann als STL-Dateien (.stl) in die Software 3-matic (Materialise, Leuven, Belgien) exportiert.

2.7 Auswertung der Abweichung

Die Abweichung zwischen der virtuell geplanten und der postoperativen PSI- und Knochenposition wurde anhand der folgenden Parameter ermittelt:

1. Medianer Oberflächenabstand: Er stellt die geometrische 3D-Abweichung zwischen zwei Oberflächen dar. Zur Berechnung des Wertes wurde der Algorithmus „Part Comparison Analysis“ in der 3-matic-Software verwendet. Der entsprechende Algorithmus ist punktbasiert. Dabei wurde jeder Oberflächenpunkt des Planungsmodells dem nächstgelegenen Punkt des postoperativen Modells zugeordnet, und die jeweiligen 3D-Abstände wurden berechnet. Da der 3D-Abstand zwischen zwei nächstgelegenen Punkten berechnet wird, die nicht immer anatomisch korrespondieren, führt diese Methode zu einer Unterschätzung der Abweichung [27].
2. Lineare Abweichungen in den x-, y- und z-Achsen. Die Abweichungen wurden zwischen fünf Referenzpunkten auf dem Planungsmodell und den anatomisch korrespondierenden Punkten auf dem postoperativen Modell gemessen. Die Referenzpunkte wurden von zwei Prüfern zu zwei verschiedenen Zeitpunkten bestimmt. Die x-Achse entsprach der transversalen (lateral/medial), die y-Achse der sagittalen (anterior/posterior) und die z-Achse der axialen (kranial/kaudal) Ausrichtung. Diese Methode führt zu einer Überschätzung der Abweichung, aufgrund von Ungenauigkeiten bei der manuellen Festlegung der Punkte durch die Prüfer [28].

2.8 Ziel dieser Arbeit

In den bisherigen Studien zur Sekundärrekonstruktion posttraumatischer Mittelgesichtsdeformitäten werden überwiegend Navigationssysteme eingesetzt. Die Implementierung modernster computergestützter Planung und PSI für denselben Zweck wird nur spärlich diskutiert. Aus diesem Grund bestand der Zweck dieser Studie darin, die Durchführbarkeit und Genauigkeit der Implementierung dreidimensionaler VSP und deren Übertragung auf die Chirurgie durch additiv gefertigte Werkzeuge bei der sekundären Rekonstruktion posttraumatischer Deformitäten im Mittelgesicht, einschließlich der Jochbein-, Orbita- und Oberkieferregion, zu bewerten.

3. Zusammenfassung

Das Ziel der Arbeit ist die postoperative Implantat- und Knochensegmentposition mit der präoperativ geplanten virtuellen Position bei sekundären Rekonstruktionen des Mittelgesichtsskeletts und primären Rekonstruktionen der Orbitawände ohne Verwendung von Navigationssystemen zu vergleichen.

Die erste Studie wertet die Implementierung der VSP zur sekundären Korrektur von posttraumatischen Deformitäten im Bereich des lateralen und zentralen Mittelgesichts (des Jochbeines, Jochbogens und Oberkiefers) aus. Die zweite Studie untersucht die Implementierung der VSP zur primären Rekonstruktion der inferioren und medialen Orbitawände.

Die Patientenkohorte in der ersten Studie besteht aus Patienten, die von 2013 bis 2019 in der Klinik für Mund-, Kiefer- und Gesichtschirurgie der LMU München wegen zuvor nicht adäquat versorgter Frakturen im zentralen und lateralen Mittelgesichtsbereich operativ behandelt wurden. Patienten mit isolierten Orbitawand- oder Le Fort I-Frakturen wurden von der Studie ausgeschlossen. In der zweiten Studie wurden Patienten retrospektiv eingeschlossen, die von 2015 bis 2019 in der Klinik für Mund-, Kiefer- und Gesichtschirurgie der LMU München aufgrund von isolierten Orbitawandfrakturen operiert wurden.

8 Patienten wurden in die erste Studie und 27 Patienten in die zweite Studie aufgenommen. Die mediane Abweichung zwischen geplanter und definitiver Position für die PSI und die Knochensegmente wurde erstens zwischen den gesamten Modelloberflächen mittels einem geeigneten Algorithmus der Software 3-Matic und zweitens an anatomisch korrespondierenden Referenzpunkten ausgemessen, analysiert und ausgewertet.

In der ersten Studie betrugen die medianen Abstände zwischen der virtuell geplanten und der postoperativen Position der PSI 2,01 mm (n = 18) gegenüber einem medianen Abstand bezüglich der Knochensegmente von 3,05 mm (n = 12). Bei Patienten, bei denen PSI verwendet wurden, war die mediane Verschiebung der

Knochensegmente geringer als in der Gruppe mit vorgebogenen Platten. Darüber hinaus konnte der Jochbeinbereich mit geringerer Abweichung als der Oberkieferbereich positioniert werden. Ferner zeigte sich die Zahnbogenregion im Vergleich zur kranialen Oberkieferregion eine höhere Positionierungsgenauigkeit.

In der zweiten Studie zeigten die Medianwerte für die Referenzpunktabmessungen eine größere Abweichung bei den Implantaten zur Versorgung der medialen Orbitawand, nämlich 0,79mm. Der Wert für die Gruppe der Orbitabodenimplantate lag bei 0,45 mm. Es konnte keine Korrelation zwischen der postoperativen Diplopie und der Passgenauigkeit der Implantatposition nachgewiesen werden.

Die vorliegende Arbeit zeigt erstens die Machbarkeit der Übertragung der VSP durch CAD/CAM Werkzeuge für die sekundäre Rekonstruktion komplexer posttraumatischer Restdeformitäten im Mittelgesicht, jedoch mit relativ erhöhter Ungenauigkeit, und zweitens die Möglichkeit einer genauen Umsetzung der Planungsposition bei der Rekonstruktion der inferioren und/oder medialen Orbitawand.

Die in der ersten Studie beobachteten höheren Abweichungen lassen sich durch Unterschiede in der Bewertungsmethode sowie durch die Komplexität der Deformitäten, Osteotomien und chirurgischen Verfahren erklären, so dass der Einsatz von Navigationssystemen die Genauigkeit der Repositionierung weiter verbessern könnte.

4. Abstract (English)

The aim of this work is to compare the postoperative implant and bone segment position with the preoperatively planned virtual position in secondary reconstructions of the midface skeleton including the orbital region without using navigation systems.

The first study evaluates the implementation of VSP for the correction of posttraumatic deformities in the lateral and central midface (zygomatic bone and arch, maxilla). Eight patients were included in the study. The metric deviation between the virtually planned and postoperative positions of patient-specific implants (PSI) and bone segments was measured separately by two examiners at corresponding reference points.

The median distances between the virtually planned and postoperative positions of PSI were 2.01 mm (n = 18) versus a median distance of the bone segments of 3.05 mm (n = 12). In patients in whom PSI were used, the median displacement of bone segments was lower (n = 7, median 2.77 mm) than in the group with pre-bent plates (n = 5, 3.28 mm). According to our findings, this study demonstrates the feasibility of transferring the VSP by CAD/CAM tools for secondary reconstruction of complex posttraumatic residual deformities in the midface. However, the higher deviations observed in this case series can be explained by differences in the evaluation method as well as by the complexity of the deformities, osteotomies, and surgical procedures.

The second study investigated the implementation of VSP for reconstruction of the inferior and medial orbital walls. Twenty-seven patients with a total of 33 patient-specific implants were included in the study. Positional deviations were determined using the mean values of the geometric three-dimensional distances between the planned and postoperative positions of the implants. The linear deviations were measured, analyzed, and evaluated at corresponding reference points of the two implant surfaces.

The mean values for the reference point dimensions showed a larger deviation in the implants for restoration of the medial orbital wall, namely 0.79 mm. The value for the

group of orbital floor implants was 0.45 mm. No correlation between the postoperative diplopia and the accuracy of fit of the implant position could be demonstrated. According to our results, CAD/CAM patient-specific implants allow accurate implementation of the planning position when reconstructing the inferior and/or medial orbital wall.

The use of navigation systems could further improve the accuracy of repositioning, especially in complex midface reconstructions, where the inaccuracy observed in the initial study was relatively high.

5. Paper I

Digital planning and individual implants for secondary reconstruction of midfacial deformities: A pilot study

Laryngoscope Investigative Otolaryngology

2022

Paris Liokatis, Yoana Malenova, Florian-Nepomuk Fegg, Selgai Haidari, Monika Probst, Marko Boskov, Carl-Peter Cornelius, Matthias Tröltzsch, Florian-Andreas Probst

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Abstract

Objective: To evaluate the feasibility and accuracy of implementing three-dimensional virtual surgical planning (VSP) and subsequent transfer by additive manufactured tools in the secondary reconstruction of residual post-traumaticdeformities in the midface.

Methods: Patients after secondary reconstruction of post-traumatic midfacial deformities were included in this case series. The metrical deviation between the virtually planned and postoperative position of patient-specific implants (PSI) and bone segments was measured at corresponding reference points. Further information collected included demographic data, post-traumatic symptoms, and type of transfer tools.

Results: Eight consecutive patients were enrolled in the study. In five patients, VSP with subsequent manufacturing of combined predrilling/osteotomy guides and PSI was performed. In three patients, osteotomy guides, repositioning guides, and individually prebent plates were used following VSP. The median distances between the virtually planned and the postoperative position of the PSI were 2.01 mm (n = 18) compared to a median distance concerning the bone segments of 3.05 mm (n = 12). In patients where PSI were used, the median displacement of the bone segments was lower (n = 7, median 2.77 mm) than in the group with prebent plates (n = 5, 3.28 mm).

Conclusion: This study demonstrated the feasibility of VSP and transfer by additive manufactured tools for the secondary reconstruction of complex residual posttraumatic deformities in the midface. However, the median deviations observed in this case series were unexpectedly high. The use of navigational systems may further improve the level of accuracy.

Introduction

Secondary reconstruction of residual skeletal deformities is required on occasions after severe facial trauma when no treatment has been provided, or primary surgical treatment has resulted in unacceptable outcomes. Inaccurate reduction or remaining defects of the midface, especially of the zygomatic bone, the orbital walls and the maxilla, can have functional and aesthetic consequences of varying degrees. Pronounced post-traumatic deformities may be associated with loss of sagittal projection, changes in vertical facial height, widening of the face and facial asymmetry. In addition, impaired visual function, masticatory dysfunction, malocclusion ortemporomandibular joint disorders can occur [1].

Reconstructive surgery appears to benefit substantially from individualized virtual surgical planning (VSP), yielding more predictable outcomes than freehand techniques [1]. The advantages of computer-assisted planning, especially in complex surgery, are well documented in the literature [2-6]. The application of surgical navigation systems supplementarily to these procedures is proposed to further improve outcomes [7-9]. Intraoperative navigation, however, is a costly and sophisticated procedure due to the fact that it requires specialised technical equipment and trained personnel. Because of the aforementioned reasons the use of such equipment remains reserved to a few centres.

Many solutions have been proposed as alternatives to navigation systems [10-12]. The use of patient-specific implants (PSI) appears to be a promising option and has become increasingly important in recent years [13-16]. Another practical approach is the use of conventional osteosynthesis plates, which are prebent on individual three-dimensional (3D) printed models [17,18].

So far, studies regarding secondary reconstruction of posttraumatic midfacial deformities use predominantly navigational systems [19,20]. Implementing state-of-the-art computer-assisted planning, repositioning guides, and PSI for the same purpose is only sparsely discussed in case reports, with postoperative outcomes analysed not thoroughly in metric dimensions [21]. An exception is a study by Schouman and colleagues (2015), reporting on computer-assisted planning and application of PSI for the reduction and fixation of isolated zygoma fractures.

This is why the purpose of this study was to evaluate the feasibility and accuracy of implementing three-dimensional VSP and transferring it to surgery by additively manufactured tools in the secondary reconstruction of residual posttraumatic deformities in the midface, including the zygomatic, orbital, and maxillary region. The virtual planning technology is transferred into surgery either by means of repositioning guides together with preoperatively individually prebent conventional plates or by use of CAD/CAM fabricated osteotomy guides and PSI. Intraocclusal wafers were implemented in all cases with mobilization of edentulous parts.

Material and methods

Study design

The study sample was obtained from a consecutive cohort of patients who underwent surgical treatment for formerly inadequately addressed fractures in the central and lateral midfacial region from 2013 to 2019 at the Department of Oral and Maxillofacial Surgery and Facial Plastic Surgery, University Hospital of LMU Munich, Germany. All subjects eligible for study inclusion were required to have undergone secondary osteotomies and osteosynthesis in the midface after virtual surgical planning (VSP) and transfer into surgery by CAD/CAM manufactured tools. The use of intraoperative navigation was a criterion for exclusion. Patients after isolated orbital wall or isolated Le Fort I fractures were also excluded from the study. Standards for reporting observational studies (STROBE guidelines) were followed [22]. The institutional ethics committee approved the study protocol (approval number 19-783).

Virtual surgical planning (VSP) and additive manufacturing

High-resolution computed tomography scans of the facial skeleton with a slice thickness of 0.625 mm were performed. The DICOM data of the CT scan were imported into the ProPlan CMF software (DePuy Synthes Maxillofacial, Paoli, USA/ Materialise, Leuven, Belgium). Image-processing with conversion of DICOM datasets into 3D surface models was carried out. The soft tissues were removed with appropriate segmentation, and a 3D model of the craniofacial skeleton was generated. In case of repositioning of tooth-bearing maxillary segments, dental casts in occlusion were scanned and the 3D object generated was imported into the planning software and aligned with the rest of the skeleton.

VSP was performed in an interactive online meeting with the clinical engineers of the industrial partner. If the initial fracture lines could be identified, the 3D model was cut at these areas generating segments corresponding to the original posttraumatic fragments. However, due to the complexity of the fractures in our study, identifying the fracture lines was not always possible. In that case, the main osteotomy lines were defined concerning the existing deformity and aimed to mobilize the midface's related areas. For unilateral injury after setting a midsagittal symmetry plane, the unchanged shape of the contralateral midface was mirrored and superimposed on the side with the posttraumatic deformity. For bilateral injury, symmetry in the three standard planes (axial, sagittal, coronal) was pursued. If the achieved symmetry or occlusion result after the reposition of the initial segments was inadequate, further osteotomy lines were planned in order to mobilize the specific parts of the segments leading to the disturbances. This resulted in many cases in a multi-segmentation as the deformity correction necessitated the separate mobilization of adjacent regions to different directions. Especially regarding the repositioning of the maxilla, for the patients with an intact and not deformed lower jaw, the aim was to restore the pre-traumatic occlusal pattern. If the mandible cannot be used as a reference, initially, the upper dental midline is corrected. After that, the maxilla's occlusal plane inclination (pitch) is adjusted to the desired angle. If the dental arch is asymmetric, further segmentation of the maxilla is performed, as described above. Followingly, the maxilla is rotated (yaw/roll) to a balanced position [23]. After the asymmetry and the orientation of the maxilla have been corrected, the maxilla is moved anteroposteriorly and superoinferiorly to the desired position as determined by the cephalometric analysis and clinical measurements according to Segner/Hasund [24,25]. In case 3, where the mandible was also posttraumatic deformed and a bilateral sagittal split was performed, the upper jaw was repositioned as described above. After that, the distal segment of the mandible is moved into maximal intercuspation. Once the distal segment is in position, the proximal segments of the mandible are aligned.

Following the skeletal rearrangements, computer-aided design (CAD) of different transfer tools was performed, including 3D models, interocclusal wafers, osteotomy and repositioning guides, combined predrilling/osteotomy guides and PSI (Fig.1).

Depending on the case, either

- osteotomy guides and separate repositioning guides, together with individually prebent conventional plates (pre-bending was performed on 3D models) with intraocclusal wafers or

- combined predrilling/osteotomy guides together with PSI and intraocclusal wafers were used.

The plate design was individualized for each segment. Still, two fundamental principles were regarded: At least two screws pro segment were placed to achieve rotation stability. For a three-dimensionally accurate reposition and stable fixation, a three-point fixation of the main segments was pursued.

The CAD/CAM process was finally completed by additive manufacturing of the transfer tools (Fig.1). The PSI and the associated combined predrilling/osteotomy guides were manufactured from selective laser-melted titanium, while the osteotomy and repositioning guides were made from polyamide.

Surgical technique

Individual surgical approaches were used in each case corresponding to the exposure required for the planned osteotomies, including intra-oral, palpebral, transconjunctival, and coronal incisions (Fig.1). Either piezo-surgery instruments or a reciprocating saw were used intraoperatively to carry out the osteotomies and re-osteotomies, respectively.

- In cases where no PSI were used, conventional osteosynthesis plates were individualized preoperatively by pre-bending on patient-specific 3D-printed bone models reflecting the planned segment positions. Osteotomy guides and separate repositioning guides were used for the cutting out and rearrangement of the bone segments. Finally, the prebent plates were employed for the fixation in the corrected new position.

- When PSI were employed, the associated combined predrilling/osteotomy guides were aligned to the bone surface and temporarily fixed with screws. Then, with this single guide, the designated holes for the PSI were predrilled by means of integrated drill sleeves and the planned osteotomies were carried out (Fig.1). Finally, the position of the PSI was transferred via the predrilled screw holes.

Computed tomography (CT) was performed postoperatively as a clinical routine.

Study variables, data acquisition and analysis

The study variables were collected by a retrospective chart review of medical history data, clinical findings, radiological findings, and surgical reports. The following variables were analyzed: demographic data, type of posttraumatic deformity and region of the midface regions involved (lateral midface including the zygomatic complex as well as the central midface including the inferior orbital rim and the maxilla), the delay between the initial trauma and the secondary correction, type and number of osteotomized segments, need for additional surgical procedures, type of surgical approach, type of additive manufactured tools used, type of osteosynthesis (individually prebent on the patient-specific 3D model or PSI), intraoperative need for additional manual bent plates, complications, and time of follow-up. In addition, the treatment plans were reviewed, and any modifications of the virtual plan were recorded.

For a metric assessment of the bone segment repositioning accuracy and the PSI positioning, the virtual surgical plan was compared to the postoperative CT. First, the DICOM data of the postoperative CT were imported into a medical image processing software (Mimics, Materialise, Leuven, Belgium). Image segmentation separated soft tissue (HU <300), bone tissue (HU 300-1000) and titanium (HU > 1500). After image conversion to STL-files, the repositioned bone segments and the PSI were compared to the STL-files representing the predictive virtual planning in a CAD analyzing software (3-Matic, Materialise, Leuven, Belgium). For this purpose, the unaltered skull parts of the pre-and postoperative data sets, which were not affected by the surgery, were superimposed. Initially, a rough alignment of the models was performed using three anatomically corresponding landmarks. The landmarks were not standardized due to the different extent of the post-traumatic deformity in each case; they had to be, though, in the undeformed area of the face. Furthermore, a fine alignment was performed using a semi-automatic algorithm provided by the software using global registration.

The lateral midface and the central midface were each evaluated as separate units, even in the case of multi-segmentation. Five evenly distributed reference points on the lateral surface of each virtual bone segment and each virtually designed PSI were determined. The landmarks were not standardized due to the different segment and PSI shapes but had to be possible to easily match on the corresponding postoperative segment or PSI. Especially for the tooth-bearing segments of the central midface, three of the five landmarks for each segment were assigned on teeth cusps (one anteriorly and one on each side) and two on the bone in the lateral cranial area of the segment. These reference points were selected by two independent examiners. 3D distances (Euclidean distances) between the corresponding reference points of the virtually planned segments and the PSI and the corresponding postoperative CT-based models were measured (3-Matic, Materialise, Leuven, Belgium). Color-coded difference images (heatmaps) visualized the localization of areas with high or low geometric deviations (Fig. 2)

The reposition result was evaluated through reference points placed on the lateral surface of the bone based on the principle that the symmetry of the soft tissues requires a symmetrical underlining skeleton. The outcome regarding the soft tissues is affected by additional parameters such as defects, scar contractures, nerve palsies, etc. and was not evaluated in this study.

Statistical analysis

Statistical analysis was performed by Excel (Microsoft, Redmond, USA) and SPSS 25 (SPSS Inc., Chicago, USA). The data were tested for normal distribution using the Kolmogorov-Smirnov test and Shapiro-Wilk test and were not normally distributed. Therefore, the median and range of the geometric deviations were calculated. Additionally, the reliability of the measurements of the two examiners was tested with the Intraclass Correlation (ICC) analysis separately for the bone segments and the PSI.

Results

Eight consecutive patients (6 men, 2 women) were enrolled between October 2013 and April 2019 in the study. The average age was 35,7 years (range 21 to 67 years). The delay between the initial trauma and surgery was 43 months on average (range: 7 months to 7 years). Three patients (cases 3, 5, and 7) had not undergone any prior surgical treatment in the midface area.

The prominent post-traumatic deformity in the cohort was facial asymmetry resulting from loss of the facial projection. The second most common complaint made was malocclusion, often together with the loss of teeth. Patient 5 also suffered from an ipsilateral ectropion. Other complaints were scars and facial synkinesis.

Five patients received VSP followed by PSI fabrication (n=19), and three patients underwent VSP followed by the use of individually pre-bent plates. At patient 1, a Le Fort I osteotomy and maxillary reconstruction with a fibula-free flap was performed. Patient 2 underwent a multi-segmentation of the zygomatic complex into four segments. Patients 3 and 4 received multi-segmentation of the dislocated zygomatic bone and maxilla. In patient 5, re-osteotomies and repositioning of the inferior orbital rim were performed. Patient 6 was treated with a combined osteotomy of the zygomatic bone and maxilla. Patient 7 received a reposition of the zygomatic complex in one segment.

For the reposition of the maxillary segments, interocclusal wafers with mandibulo-maxillary fixation (MMF) were additionally employed. Major complications were not reported. The treatment plans were reviewed, and all planned procedures were implemented as intended, without major intraoperative modifications. One of the 19 PSI was placed in a different location than planned (case 1), and this PSI was excluded from further statistical analysis. Additional conventional plates were not used in any of the cases. Two out of eight patients wished and had their plates removed (15 and 24 months after the main operation) due to a subjective feeling of pressure in the midface. For these patients, no operation-related complications were reported. Furthermore, no bone sequestration was observed in any cases. The associated procedures and main study variables collected for each patient are summarised in Tables 1 and 2.

General superimposition accuracy between unchanged parts of the pre- and postoperative skull models showed a mean error of 0.026 mm. The intraclass correlation (ICC) value was 0.824 for the bone segments and 0.946 for the PSI, indicating good reliability of the measurements between the two examiners, according to Koo and Li (2016) [26].

The median distances between the virtually planned and the postoperative position of the PSI were 2.01 mm (n=18, range 0.92 – 5.61 mm) compared to a median distance between the planned and postoperative position of all bone segments of 3.05

mm (n=12, range 1.68 – 6.06 mm) (Fig.3). The individual deviations between the planned and postoperative position of each PSI and each bone segment are displayed in table 3.

In the patients where PSI were used, the median displacement of the total number of bone segments was lower (n=7, median 2.77 mm, range 1.68 – 3.74 mm) than in the group with pre-bent plates (n=5, 3.28 mm, range 2.87 – 6.06 mm) (Fig.4).

The median distance between the virtually planned and the postoperative position of the bone segments was 2.90 mm (n=6, range 1.68 – 6.06 mm) for the lateralmidface compared to 3.22 mm (n=6, range 2.35 – 3.74 mm) for the central midface (Fig.5).

For the tooth-bearing segments of the central midface (cases 1, 3, 4, 6, 8), each segment's median displacement was also analyzed separately for the position of the dental arch and the rest of the segment (table 3). The dental arch showed a median displacement of 2.03 mm (n=5, 1.07- 3.28 mm), while the cranial part of the segments was in median 4.04 mm (n=5, 3.79- 5.51 mm) displaced.

Discussion

Secondary correction of craniomaxillofacial post-traumatic deformities is a challenging procedure that requires a good understanding of the three-dimensional anatomy of the facial skeleton. One advantage is that there is a sufficient time frame for thorough planning and preparation in these secondary procedures, which allows for computer-aided planning and additive manufacturing. This time frame makes delays between the planning process and the delivery of the CAD/CAM-manufactured surgical tools a negligible factor. The virtual planning technology combined with PSI or individually prebent plates does not require additional equipment and training and is therefore readily available. However, the cost of using digital planning and custom implants is in the mid to high four figures depending on the complexity of the case. For this reason researching and presenting the performance of these methods is necessary.

Alternatively, the use of conventional plates pre-bent on patient-specific models with or without repositioning aids instead of PSI is an option to reduce costs and still be able to implement plan changes at short notice.

This study aimed to evaluate the feasibility and accuracy of three-dimensional VSP and transfer by additive manufactured tools of secondary reconstruction of residual post-traumatic deformities in the midface. All operations were carried out after prior virtual operation planning, albeit minor adjustments were necessary in some cases.

The present pilot study evaluates the treatment of complex residual midface deformities either by employing PSI together with combined predrilling/osteotomy guides or by using individually pre-bent conventional plates (pre-bending on 3D models) together with osteotomy guides and separate repositioning guides. All surgeries were performed without intraoperative navigation. Both surgical techniques showed practical feasibility. In patients where PSI were used, the median displacement of bone segments was lower than in the group in which osteosynthesis was performed with prebent plates. The metrically assessed accuracy of the bone segment repositioning (median 3.05 mm, range 1.68 – 6.06 mm) and the PSI positioning (median 2.01 mm, range 0.92 – 5.61 mm) was unexpectedly high in our series. Besides, procedures involving the central midface showed a trend to an increased deviation compared to the lateral midface, while within the maxillary segments, the deviation in the region of the dental arch was lower (median 2.03 mm, 1.07- 3.28 mm) than the one in the cranial area of the bone segments (median 4.04 mm, 3.79- 5.51 mm). However, these metrical results must be regarded with caution due to the small group size and heterogeneous fracture patterns.

Schouman and colleagues (2015) first proposed the use of PSI and surgical guides for the accurate execution of re-osteotomies in posttraumatic midface deformities. The subsequent reposition of the zygomatic bone achieved an excellent accuracy of 0.2 mm (range 0.05 - 0.38 mm) [27]. In analogy to five patients in our study, PSI in combination with predrilling/osteotomy guides made from titanium were also used in this study from Schouman et al. The reposition accuracy of the zygomatic bones was based in the study from Schouman et al. (2015) on measuring the distance from each point of the postoperative bone-model to the nearest point in the planning-model using an algorithm provided by the planning software. However, this method can severely underestimate the total geometric displacement, as two points closest to each other do not necessarily match anatomically [28]. In our study, far more complex corrections of the midface with single or multi-segment osteotomies took place in combination with Le Fort I osteotomies and, in one case, combined a Le Fort I osteotomy with a virtually planned free fibula-flap transfer. The comparatively higher deviation between planned and resulting positions in our study compared to Schouman and colleagues (2015) is explainable by differences in the method of evaluation as well as by the complexity of the deformities, osteotomies and surgical procedures.

Although greater skeletal deviations in the midface with maximum outliers of up to 6 mm may not have clinical relevance in terms of aesthetics, occlusal displacement even in a millimeter range could lead to functional problems. To evaluate the repositioning accuracy in the dental arch area, computer-assisted surgical techniques employing PSI and associated surgical guides have also been reported and evaluated in mandibular reconstruction [29] and orthognathic surgery [30-33,6,34] using landmark methods similar to the method implemented in our study. Based on the pre-and postoperative evaluation of five occlusal landmarks, high accuracy in maxillary positioning by CAD/CAM fabricated PSI and surgical guides for predrilling and osteotomies was reported with an average deviation of 0.39 mm and a maximum error of 2.02 mm [6]. Using PSI and surgical guides, lower discrepancies between the planned and the final positions of the maxilla were seen compared to VSP and subsequent transfer with customized interocclusal splints, especially in anterior/posterior positioning (average for the PSI group: 0.39 mm, range 0.04 – 0.83 mm vs. average of the interocclusal splint group: 1.42 mm, range 0.47 – 3.04) [34].

In our case series, the deviation of the central midface segments was analyzed separately for the dental arch and the rest of the bone segment, with the dental arch showing a lower deviation (2.03 mm, 1.07- 3.28 mm) compared to the cranial areas of the bone segments (4.04 mm, 3.79- 5.51 mm). The median deviation of 2.03 mm for the dental arch found in our study is significantly higher than the one previously reported in orthognathic surgery [6,34]. However, in orthognathic patients, the performed osteotomies are standardized without multi segmentation, the patients are adequately toothed, the tissues are not scarred and without defects and the movements of the mobilized segments are more delicate. All these factors could decrease the repositioning inaccuracy of posttraumatic deformities. The increased deviation between planned and final positions in our study can be attributed to the increased complexity of our cases with multi-segmentation of the maxilla. Moreover, in most cases, both the zygoma and maxilla were repositioned in the same procedure, which introduces an additional factor for increased inaccuracy compared to orthognathic studies [6,34]. Furthermore, the landmark-based evaluation method implemented in this study has limitations and may overestimate the measured deviation [34].

The increased inaccuracy of the dental arch reposition found in our study raises considerations about the adequacy of the transfer tools used (PSI and intraocclusal wafers) without intraoperative navigation when a multi-segmentation of the maxilla or a simultaneous mobilization of the zygoma is planned. Moreover, the need for additional orthodontic treatment after such complex repositions should also be discussed with the patient.

The accuracy of computer-assisted surgery depends largely on how accurately the virtual planning is transferred into the operation. For this purpose, different CAD/CAM-manufactured tools such as various surgical guides and PSI plus surgical navigation can be employed. When using surgical templates, they must be positioned as closely as possible as in the virtual planning. To ensure prompt and reproducible positioning of the guides, prominent landmarks should be used to assist in positioning. Temporary fixation screws help to secure the correct guide position. The application of the guides often requires an extended degloving of the facial skeleton. Potential negative consequences are an increased risk for bleeding, swelling, nerve lesions, and soft tissue sagging.

So far, only a qualitative evaluation of the achieved positioning accuracy using the repositioning guides has been reported [11,12]. Other principal sources of error in computer-assisted surgery involve different aspects in imaging and image processing [35].

The accuracy could be improved by using navigational systems. Surgical navigation is considered a helpful method for reproducing digitally planned midface osteotomies, especially for the zygomatic area [36]. Some studies, mainly case reports or case series, have presented the implementations of this technology with or without the additional use of patient-specific plates. Only a few of them examined the achieved accuracy [5,37,38]. Surgical navigation presents additional difficulties due to lack, often, of accurate anatomic landmarks in the midface area [39], mainly due to severe trauma and primary operations. The technology requires trained operators, expensive equipment and most likely more operating time. Since a navigation and calibration error of 1 to 2 mm can commonly be assumed [40-43], a deviation of up to 2 mm may be considered excellent for computer-assisted surgery. Surgical navigation may be employed in two ways. It could be used for the exact positioning of surgical guides for cutting and drilling. The guides must be provided with navigational landmarks for this purpose, as is established, for example, in orbital wall reconstruction [44]. This then enables the correct positioning of the bone segments and the implants. Additionally, navigation-guided positioning of bone segments can be used, either via fiducial-based paired-point transformation or by surface contour matching [36].

There are some limitations to the present study design that need to be discussed. First of all, this is a retrospective study with the associated known drawbacks. Additionally, the sample size is relatively small, and the cohort exhibits quite different types of deformities. Furthermore, since landmark-based evaluation might have limitations in terms of repeatability, reproducibility and overestimation of the inaccuracy of the reposition outcome, an algorithm independent of landmark identification was proposed in the study by Ruckschloss et al. [34]. Moreover, the outcome's evaluation was based mainly on a computer analysis of the achieved repositioning accuracy and not on a long-time clinical assessment of the patients.

Future prospective surveys should consider larger sample sizes and more homogenous subgroups with similar defect types to better estimate the accuracy, cost-benefit ratio, and difficulties of the demonstrated computer-assisted approach. Moreover, different control groups, including conventional surgery and the use of navigational systems, are preferable. Since post-traumatic deformities are not too frequently occurring in everyday clinical practice, even in larger centers, multicentre studies will be required. The data pool obtained in our study might be used as a suitable basis for calculating the sample size.

Conclusion

In conclusion, this study demonstrated the practical feasibility of three-dimensional virtual surgical planning and transfer by additive manufactured tools of secondary reconstruction of complex residual posttraumatic deformities in the midface. However, the repositioning inaccuracy reported in this study is unexpectedly high and the use of navigational systems may further improve the level of accuracy.

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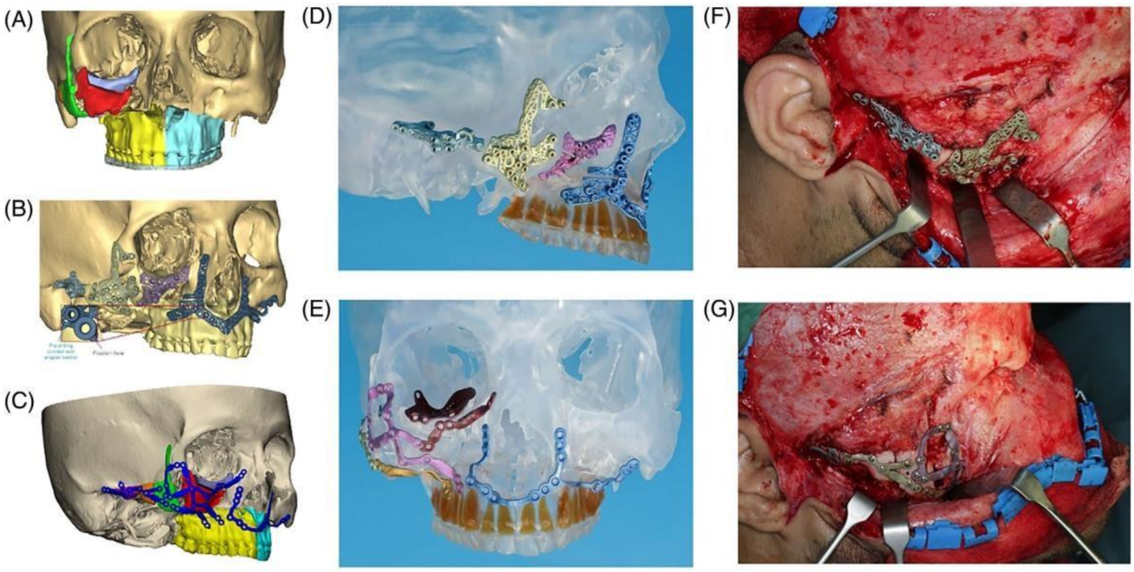


FIGURE 1. Computer-assisted workflow. (A) Virtual surgical planning with repositioning of bone segments, (B) CAD of combined predrilling/ osteotomy guides, (C) CAD of PSI, (D) CAD/CAM-manufactured predrilling/osteotomy guides and (E) PSI, (F) intra-operative image showing the predrilling/osteotomy guides and (G) PSI in place

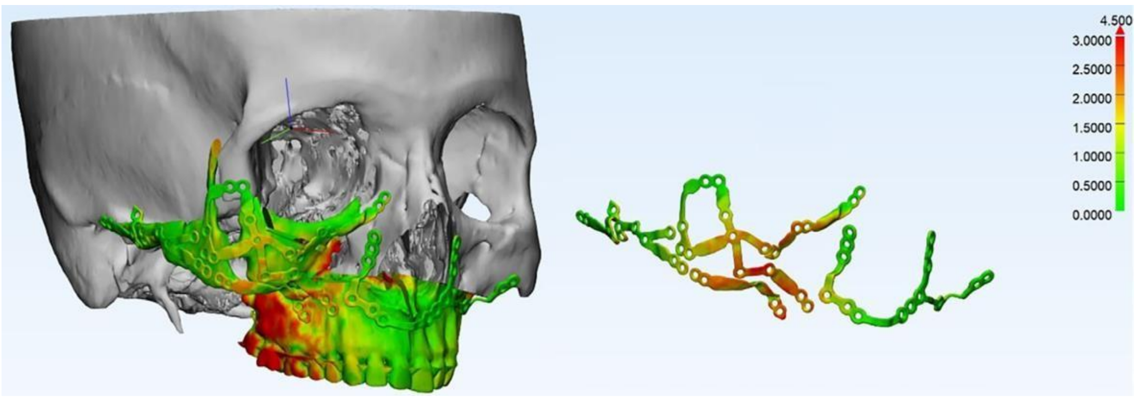


FIGURE 2. Color-coded difference images (heat maps) visualize the degree of geometric deviations for the bone segments and the PSI

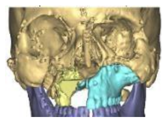
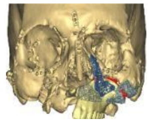
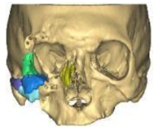
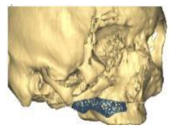
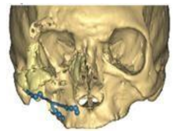
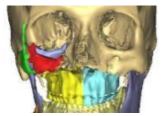
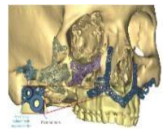
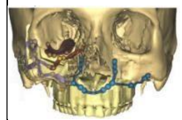
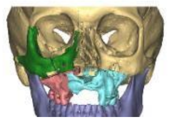
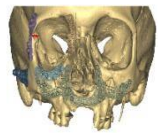
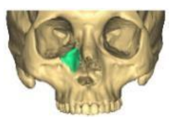
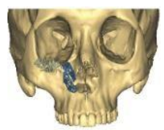
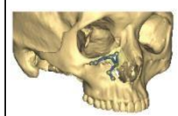
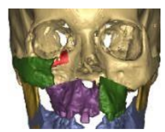
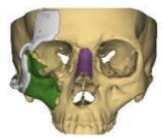
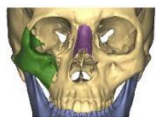
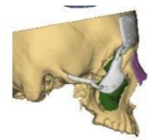
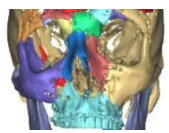
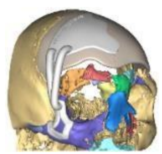
Pt-n.	Age/ Sex	Delay after trauma (months)	Site	Type and number of osteotomized segments	Additional procedures	Osteosyn-thesis	Approach	VSP – bone segments	Surgical guides	PSI
1	21y/ male	15	Maxilla	2	Fibula free graft	PSI	Endo-oral			
2	67y/ male	68	Zygomatic bone	4	Reconstru-ction of orbital floor	PSI	Coronal			
3	29y/ male	48	Zygomatic bone Maxilla	Zygomatic bone: 4 Maxilla: 2	Bilateral sagittal, split of the mandible	PSI	Coronal, endo-oral, palpebral			
4	38y/ female	84	Zygomatic bone Maxilla	Zygomatic bone: 2 Maxilla: 2	Bilateral reconstru-ction of the orbital floor & mandible	PSI	Coronal, endo-oral, palpebral			
5	31y/ male	6	Inferior orbital rim fracture	1		PSI	Transcon-junctival, endo-oral			
6	35y/ male	42	Zygomatic bone Maxilla	Zygomatic bone: 1 Maxilla: 2	Reconstru-ction of the orbital floor & mandible	Prebent plates	Preauricu-lar, palpebral, endo-oral			
7	29y/ female	35	Zygomatic bone	Zygomatic bone: 1	Reposition of the nasal skeleton & mandible	Prebent plates	Coronal, endo-oral, palpebral			
8	36y/ male	36	Zygomatic bone Maxilla	Zygomatic bone: 1 Maxilla: 1		Prebent plates	Coronal, endo-oral, palpebral			

Table 1. Procedures and materials associated with midface repositioning for each patient.

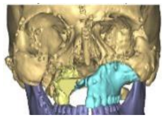
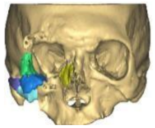
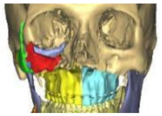
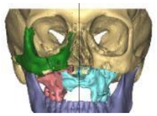
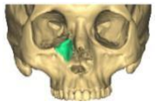
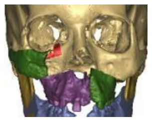
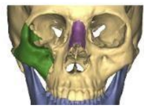
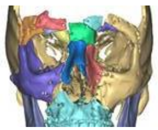
Pt-n.	VSP – bone segments	Post-traumatic deformity	Regions involved	Type of osteosynthesis	Intraoperative need for additional manual bent plates	Time of follow up (months)	Complications	Need for revision/ further procedures
1		Facial asymmetry, malocclusion, bone loss	Central midface	PSI	No	37	-	Plate removal
2		Facial asymmetry, Loss of projection Facial asymmetry, loss of projection, malocclusion	Lateral midface	PSI	No	46	-	-
3		Facial asymmetry, loss of projection, malocclusion	Central and lateral midface	PSI	No	44	-	-
4		Facial asymmetry, malocclusion	Central and lateral midface	PSI	Yes	21	-	Dental implants
5		Ectropion, facial asymmetry	Central midface	PSI	No	13	-	-
6		Loss of projection, malocclusion	Central and lateral midface	Individually prebent plates	Yes	79	-	-
7		Loss of facial projection	Lateral midface	Individually prebent plates	No	63	-	Plate removal
8		loss of projection, malocclusion	Central and lateral midface	Individually prebent plates	No	55	-	-

Table 2. Variables examined for each patient

		Median deviation bone segment (mm)				Median deviation PSI (mm)
Pat	Region of the midface involved	PSI	As a whole	Occlusal part	Non-occlusal part	
1	Central	Yes	3.74	2.03	4.97	2.37/4.86/2.17/3.86
2	Lateral	Yes	2.93			1.12
3	Lateral	Yes	2.22	1.62	4.04	1.72/1.31/2.39/2.36/2.54
	Central	Yes	2.35			1.3
4	Lateral	Yes	1.68	1.07	3.98	1.10/1.84/5.61/2.95
	Central	Yes	2.77			1.59/0.92
5	Central	Yes	3.48			0.95
6	Lateral	No	4.79	2.11	5.51	
	Central	No	3.16			
7	Lateral	No	2.87			
8	Lateral	No	6.06	3.28	3.79	
	Central	No	3.28			

Table 3. Single deviations between the virtually planned and postoperative position of the bone segments and the PSI. Note: In some cases, more than one PSI was placed.

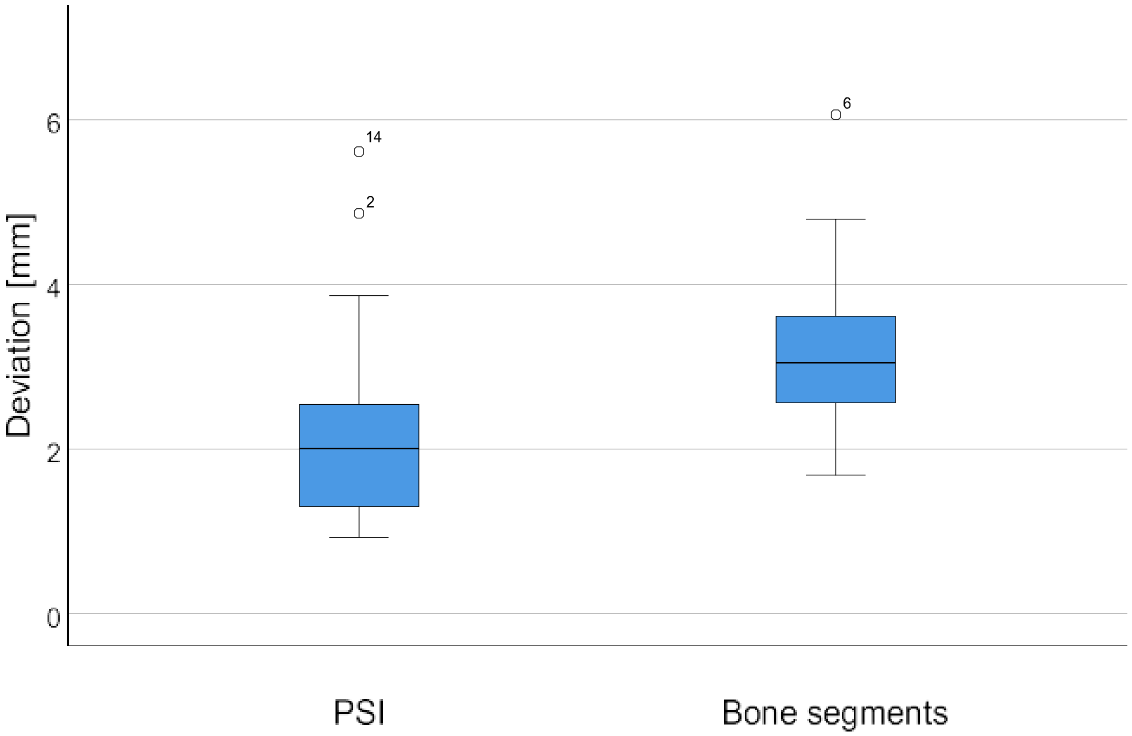


Figure 3. Median distance between the virtually planned and the postoperative position of the PSI themselves (left; n = 18, median 2.01 mm, range 0.92–5.61 mm) and median distance of the bone segments (right; n = 12, median 3.05 mm (n = 12, range 1.68– 6.06 mm)

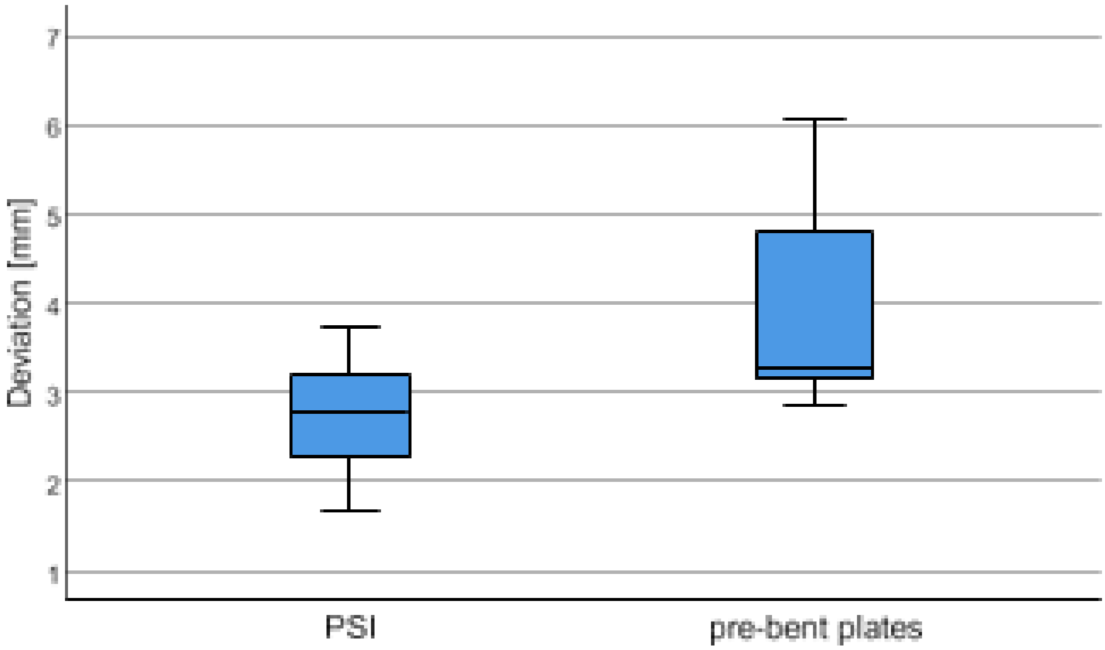


Figure 4. Median distances between the virtually planned and the postoperative position of all bone segments in the group where PSI were applied (left; n = 7, median 2.77 mm, range 1.68–3.74 mm) and in the group without using PSI (right; n = 5, median 3.28 mm, range 2.87–6.06 mm)

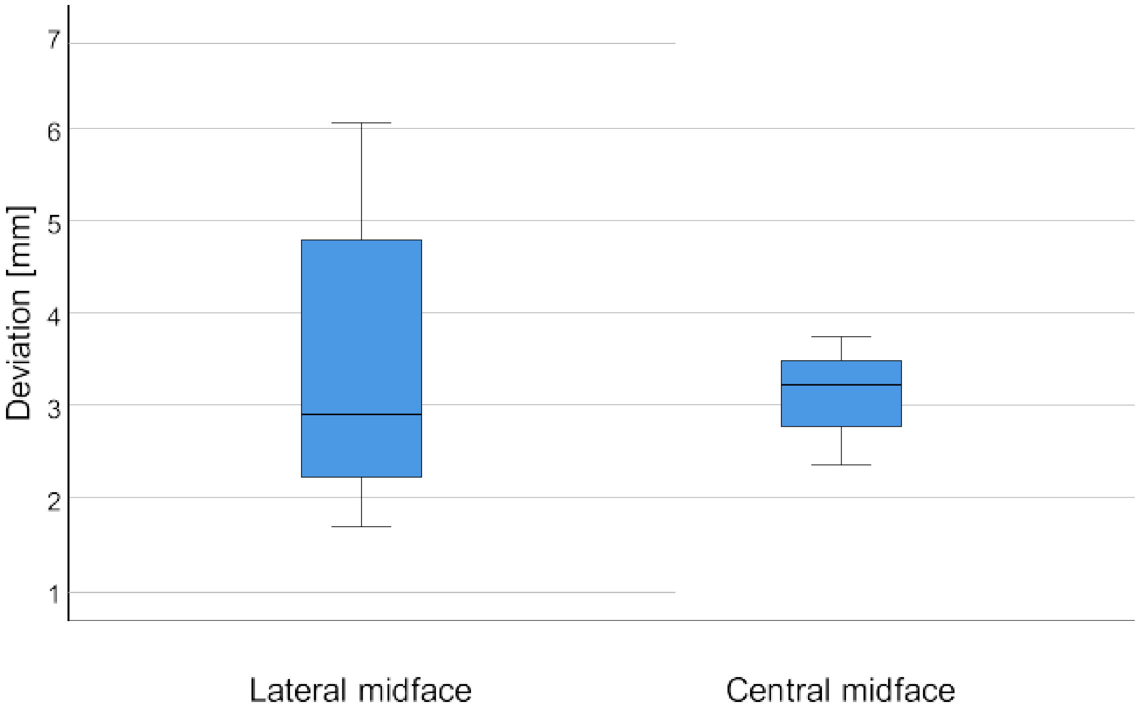


Figure 5. Median distances between the virtually planned and the postoperative position of the lateral midface segments (left: n = 6, median 2.90 mm, range 1.68–6.06 mm) and the central midface segments (right: n = 6, median 3.22 mm, range 2.35–3.74mm)

6. Paper II

Accuracy of free-hand positioned patient specific implants (PSI) in primary reconstruction after inferior and/or medial orbital wall fractures

Computers in Biology and Medicine

2021

Florian Andreas Probst, Carl-Peter Cornelius, Sven Otto, Yoana Malenova, Monika Probst, Paris Liokatis, Selgai Haidari

Comput Biol Med. 2021 Oct;137:104791. doi: 10.1016/j.compbiomed.2021.104791.

Link: https://pubmed.ncbi.nlm.nih.gov/34464850/

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