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Comparison of feasibility, workflow, and costs of two virtual surgical planning systems for orthognathic surgery in patients with cleft lip and palate

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Comparison of feasibility, workflow, and costs of two virtual surgical planning systems for orthognathic surgery in patients with cleft lip and palate

Running title: Precision on virtual surgical planning

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The present scientific article strictly follows the guidelines established by the 1964 Declaration of Helsinki for research involving human subjects. All stages of the study were conducted in accordance with the ethical principles outlined in this important international declaration, ensuring respect for the rights, well-being and dignity of the participants.

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SUMMARY

Introduction: Patients with cleft lip and palate (CLP) present complex skeletal discrepancies which require orthognathic surgery (OS) for functional and aesthetic rehabilitation. In these cases, virtual surgical planning (VSP) is essential. Yet software-related factors such as efficacy, time requirements, and cost can influence treatment accessibility and accuracy. Considering the unique anatomical challenges of CLP, an optimized virtual workflow is essential to improve surgical predictability and reduce intraoperative risks. **Objective**: This study aims to evaluate the feasibility of two VSP software programs, comparing their efficacy, time requirements, and costs in a standardized OS workflow for CLP patients. **Materials and Methods**: Forty-five cone beam computed tomography (CBCT) scans of nonsyndromic patients with CLP who had undergone bimaxillary surgery (Le Fort I and bilateral sagittal split osteotomy) with or without genioplasty between 2013 and 2023 were analyzed. VSP was performed using NemoStudio and OrtogOnBlender (OOB), evaluating feasibility, processing time (from STL file import to surgical guide fabrication), and associated costs, including software acquisition. **Results**: A statistically significant difference ($p<0.05$) was found in software processing time: NemoStudio (8 min 22 s ± 2 min) was faster than OOB (24 min 17 s ± 3 min). Although NemoStudio required fewer steps to complete planning, it presented more interruptions (“bugs”) than OOB. Analysis revealed that NemoStudio costs approximately $8,000.00, including annual STL file export fees, while OOB is free, with extra costs limited to an optional training course. **Conclusion**: Both software programs proved viable for patients with anteroposterior discrepancies up to 10 mm. While NemoStudio demonstrated advantages in time efficiency and workflow simplicity, its high cost may restrict usage. In contrast, OOB, despite requiring longer processing time, offers a cost-effective alternative. The choice of software should align with case needs, especially for larger advancements requiring high accuracy due to anatomical complexity, such as extension and cleft type.

Keywords: Orthognathic Surgery, Virtual Surgical Planning, Cleft Palate

INTRODUCTION

Skeletal dentofacial deformities associated with cleft lip and palate (CLP) represent a complex challenge for oral and maxillofacial surgeons, and require a precise and personalized approach to restore function and aesthetics. Maxillary hypoplasia is common in these patients, a result of multifactorial conditions, previous surgical interventions, often associated with scar tissue formation, and which can compromise the three-dimensional growth of the maxilla and mandible.[1] Orthognathic surgery (OS) has emerged as the gold standard for correcting skeletal discrepancies, especially in cases of class III malocclusion, often associated with CLP.[2] The orthognathic surgeon recommends a Le Fort I osteotomy for maxillary movement and a bilateral sagittal split osteotomy (BSSO) for mandibular movement. In cases of bilateral CLP, complexity increases due to asymmetry and the need for prior alveolar reconstruction with bone grafts (bone block grafting).

Conventional surgical planning (CSP), based on plaster models and two-dimensional radiographs, although accessible, has significant limitations in accuracy and reproducibility.[3] In contrast, virtual surgical planning (VSP), facilitated by specialized software, allows for accurate three-dimensional simulations, reduced operative time, and accurate predictability of results. However, choosing the ideal software (considering financial cost, time of use, and feasibility) remains a critical issue, especially in institutions or settings where there is a need to perform orthognathic surgery on patients with cleft lip and palate but resources are limited.[4] The feasibility of using software such as NemoStudio 3D-OS for complex cases, such as craniofacial microsomia, is effectively guaranteed,[4] highlighting precision in generating CAD/CAM surgical splints, and the integration of cone beam computed tomography (CBCT) images with digital models. However, although these advances increase the accuracy and efficiency of surgery, challenges persist in soft tissue simulation, where discrepancies between predicted and actual results continue.[5]

In patients with cleft lip and palate (CLP), the complexity of VSP is amplified by unique anatomical alterations such as maxillofacial asymmetries, alveolar defects, and postsurgical scars.[1-3] Maxillary hypoplasia in patients with CLP is a key point in current surgical planning: maxillomandibular discrepancies greater than 10 mm are routinely diagnosed and led to surgical intervention by bimaxillary orthognathic surgery, which must be accurately and calibrated predictable by software. This makes this type of VSP complex and questions the effectiveness of available software. A comparison of the accuracy of software such as Dolphin 3D, Materialize, IPS, NemoStudio, and Blender3D with the OrtogOnBlender[7] add-on shows that open-

source tools are frequently viable (and affordable) alternatives, with performance similar to commercial software. However, the lack of specific algorithms to simulate soft tissue responses in FLP limits predictability, especially in regions such as the lower lip and nose, where scars significantly influence the aesthetic outcome [7].

OBJECTIVE

The aim of this study was to compare feasibility, costs, and usage time for two software programs in virtual surgical planning for patients with type II and III skeletal deformities with CLP.

MATERIALS & METHODS

This is was a retrospective, interventional, cross-sectional study **(clinical trial number: not applicable)** which upon submission and approval by the Research Ethics Committee of the Hospital de Anomalias Craniofaciais (HRAC-USP **CAAE: 77999624.0.0000.5441)** was carried out in the Orthognathic Surgery Sector of the same institution with a sample of 45 individuals divided into 3 groups: **Group 01**: 15 patients with unilateral transforamen cleft having undergone alveolar bone grafting, **Group 02**: 15 patients with unilateral transforamen cleft without having undergone alveolar bone grafting, and **Group 03**: 15 patients with bilateral transforamen cleft undergoing alveolar bone grafting. Individuals with non-syndromic CLP underwent orthognathic surgery (Le Fort I and bilateral sagittal split osteotomy of the mandible) with or without mentoplasty for correction of skeletal class III malocclusion **(Table 1)**, performed from 2017 to 2023 at HRAC-USP using the virtual planning software NemoStudio and OrtogOnBlender, with the aim of comparing the software generated surgical guides, and all patients signed the informed consent form to participate in the research. The inclusion criteria were: adult patients with unilateral or bilateral transforamen CLP with or without alveolar osteoplasty, aged ≥18 years, who had skeletal deformities (class III) with or without indication for genioplasty, and who had documentation and preoperative CBCT scans acquired with VSP performed by the same surgeon using NemoStudio 3D-OS® and OrtogOnBlender software. The exclusion criteria were: CT scans of patients who had undergone additional surgical procedures, such as rhinoplasty; with syndromes or other related craniofacial anomalies and/or incomplete data. The present scientific article strictly follows the guidelines established by the 1964 Declaration of Helsinki for research involving human subjects. All stages of the study were conducted in accordance with the ethical principles outlined in this important international declaration,

ensuring respect for the rights, well-being and dignity of the participants.

3D Image Data Acquisition Protocol:

- CBCTs acquired using i-CAT Next Generation® equipment (FOV 17x23 cm, voxel 0.3 mm;
- Digital models of the arches obtained by intraoral scanning (STL format).

Software Processing:

- NemoStudio 3D-OS:
  Import of DICOM and STLs;
  Creation of the composite skull by automatic segmentation;
  Simulation of osteotomies and bone movements;
  Generation of CAD/CAM surgical guides. ICP (Iterative Closest Point);
- OrtogOnBlender:
  Import of DICOM and STLs;
  Creation of the composite skull by ICP (Iterative Closest Point);
  Simulation of osteotomies and bone movements;
  Generation of CAD/CAM surgical guides.

Variables Evaluated:

Execution time (minutes) for each step Data import
Creation of the composite skull;
Simulation of osteotomies;
Marking of Arnett points;
Generation of the surgical guide.
Costs:

Software license; Technical training; Maintenance/additional resources.

- Feasibility

Frequency of bugs/crashes;
Need to reconnect to the internet (NemoStudio requires continuous connection).

Statistical Analysis

Student's t-test

Chi-square test

Fisher's test

Software used:

R 4.0.0

($p < 0.05$).

Standardizations regarding VSP in both software:

- Patients positioned in the acquisition of CBCT/Facial analysis based on the Natural Head Position (NHP) and replicated in the software;
- CBCT acquired in centric relation;
- True Vertical Line and Frankfurt Plane as reference in lateral normal;
- Bipupillary plane as a reference in frontal norm;
- Maxillomandibular advancements performed in all patients (Class I occlusion was standardized as a result for making the surgical guide);
- Only intermediate surgical guides were performed;
- All VSPs were initiated by mandibular surgery;

Table 1: Patient groups

Group 1	Unilateral CLP **with alveolar bone graft**	15
Group 2	Unilateral CLP **without alveolar bone graft**	15
Group 3	Bilateral FLP **with alveolar bone graft**	15

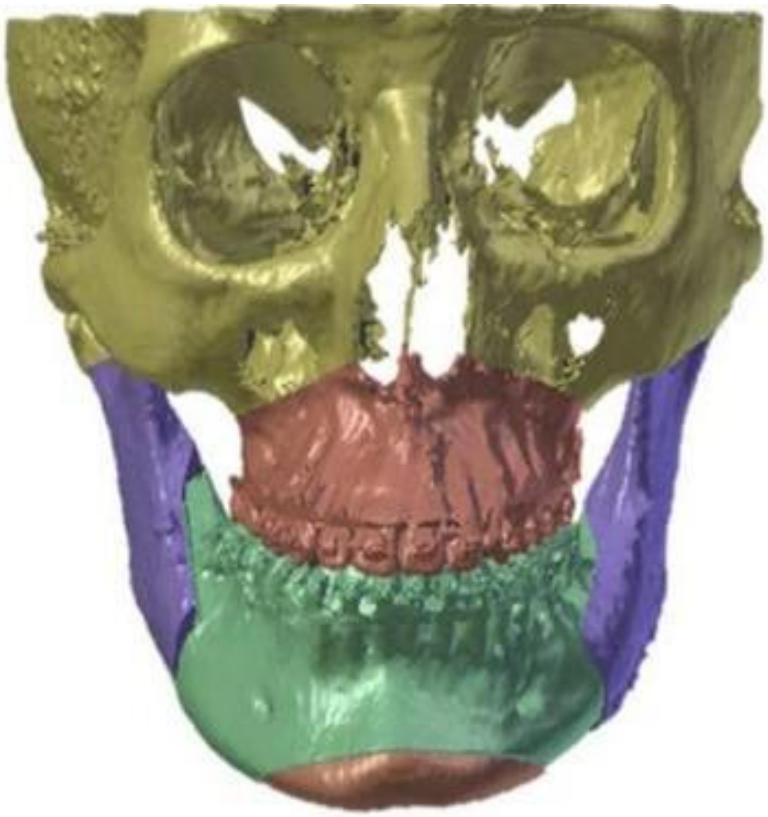


Figure 1: OrtogOnBlender - Composite skull (personal collection)

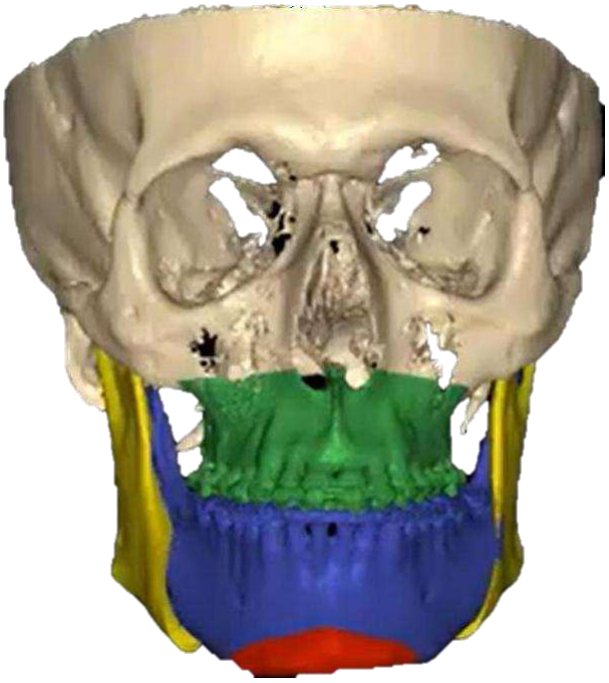


Figure 2: NemoStudio - Composite skull (Prof. Dr. Renato Yaedu Collection)

RESULTS

Table 2: Usage Time Comparison: OrtogonBlender vs. NemoStudio

Stage	Software	Standard deviation
Import	NemoStudio: 07min32s OOB: 04min18s	+/-1.23 +/- 0.58
Compound Skull	NemoStudio: 04min45s OOB: 07min18s	+/- 0.86 +/- 1.47
Osteotomy	NemoStudio: 01min10s OOB: 04min18s	+/- 0.15 +/- 0.22
Cephalometry Identification	NemoStudio: 02min48s OOB: 05min20s	+/- 0.22 +/- 0.19
Guide Creation	NemoStudio: 01min35s OOB: 03min28s	+/- 0.11 +/- 0.04

Comparing usage time - OrtogonBlender / NemoStudio: OOB required less time to import files into the software, but was slower in all other stages.

Table 3: Comparative "bugs" analysis between OrtogonBlender and NemoStudio

Stage	NemoStudio	OrtogonBlender	Difference	Test	p-value
Import	15 (36%)	3 (37.5%)	80%	Chi-square	P < 0.001
Compound skull	22 (55%)	5 (62.5%)	72.2%	Chi-square	P < 0.001
Osteotomies	4 (9%)	0	100%	Fisher	P=0.0002
Cephalometry Identification	0	0	0	-	-
Guide Creation	0	0	0	-	-
TOTAL	41 (100%)	8 (100%)	78.4%	Chi-square	P < 0.001

NemoStudio presented 10.2x higher chance of presenting "bugs". OrtogonBlender presented considerable problems in the segmentation of the skull.

Table 4: OrtogonBlender and NemoStudio comparative feasibility and cost analysis

Software	Acquisition	Training	"Bugs"	Availability	Compound skull	Accuracy
Nemo Studio	≈50,000 + 1,200 Reals annually (+data export fee)	10,000 Reals	Return to top User-dependent project saving	Internet connection	Automatic segmentation	Dedicated software for simple and complex surgical cases
OOB	Free	630.00 Reals	Automatic saving	Offline operation	Semi-automatic segmentation	"Add-on" created for Orthognathic Surgery with questionable accuracy in cases complexes

DISCUSSION

NemoStudio demonstrated greater efficiency in total planning time (8 min 22 s ± 2 min) **(Table 2)** as compared to OOB (24 min 17 s ± 3 min), with a statistically significant difference ($p < 0.05$). This advantage was observed mainly in the composite skull modeling steps (NemoStudio: 4 min 45 s vs. OOB: 7 min 18 s)**(Figure 1 and 2)**. Noting, however, the creation of the composite skull by NemoStudio is automatic and requires considerably less user input for its creation, reducing the possibility of error at this stage. When generating the CAD/CAM surgical guide, NemoStudio required 1 min 35 s, while OOB (being semi-automatic) required 3 min 28 s. The data suggest optimized technical steps (NemoStudio), possibly automated algorithms and more intuitive interface programming.[6]

However, OOB was faster at importing files (4:18 vs. 7:32 for NemoStudio), which is likely related to its independence from a continuous internet connection (a NemoStudio requirement) which according to the results, caused frequent dropouts. This difference highlights the importance of technical stability in environments with limited infrastructure.

BUG OCCURRENCE

NemoStudio had a significantly higher crash rate (41 total bugs) **(Table 3)**, especially during data import (15 bugs) and composite skull modeling (22 bugs). In contrast, OOB presented only 8 bugs, all concentrated in skull segmentation (5 bugs). Statistical analysis (chi-square, $p < 0.001$) confirmed this discrepancy, indicating that NemoStudio was 10.2 times more likely to crash. Software bugs increase total planning time. However, in complex cases (such as bilateral transforamen FLPs)[7-9] they do not compromise the software's reliability

The high occurrence of bugs in NemoStudio is likely linked to its reliance on remote servers and the complexity of its automated tools, which often fail in atypical anatomical scenarios common in complex cases, such as dentofacial deformities with severe anteroposterior discrepancies (>10mm).Although it requires more time for manual segmentation (as observed in the composite skull stage), OOB proved to be more stable, possibly because its software is both local and modular.

COSTS AND ACCESSIBILITY

NemoStudio requires a high initial investment (R$50,000.00 + an annual R$1,200.00 file export fee), plus additional training costs (R$10,000.00)**(Table 4)**.[5] In contrast, OOB is free, with costs limited to optional courses (R$630.00). This difference is crucial for institutions with limited resources such as public hospitals or clinics in developing regions. Despite its cost, NemoStudio offers advantages in accuracy for complex cases (discrepancies > 10 mm), while OOB is still consolidating its accuracy in larger and more robust maxillomandibular movements. This limitation of OOB may be related to its lack of specific algorithms for FLP, as highlighted by Balan (2020). Any choice of software should consider not only the budget but also the complexity of the case [10.]

CLINICAL IMPLICATIONS

Simple vs. complex cases:

For patients with unilateral FLPs, with or without prior grafting with moderate discrepancies (<10 mm), OOB may be a viable alternative, combining low cost and planning stability

For patients with bilateral or unilateral trans-foramen FLPs, with or without graft, in any type of discrepancy, NemoStudio, despite its bugs, offers greater accuracy in

maxillofacial simulation and generation of CAD/CAM guides.

TRAINING AND LEARNING CURVE:

NemoStudio required fewer manual steps, but its dependence on a high-quality internet connection and its higher bug rate required greater technical support compared to OOB, which, although more complex, slower, and semi-automatic, allowed greater user control over the process. This can be advantageous for teams with experience in 3D software.[10-13]

CAD/CAM INTEGRATION:

Both software programs allowed the fabrication of surgical guides. However, NemoStudio stood out for its direct integration with commercial 3D printers. OOB required adaptations and preparations to export files with satisfactory quality for printing.[14,15]

STUDY LIMITATIONS

Specific Sample: Data were collected at a single center (HRAC-USP), which may limit the generalization of the results.

Experience Bias: Even if an operator has been previously calibrated, processing time may vary depending on user familiarity with each software.

Standardization of anteroposterior discrepancies: Although maxillomandibular advancements were performed in all patients, there was no standardization regarding the size of the discrepancies, advancements of less than 5 mm, or advancements of up to 12 mm.

CONCLUSION

Our study demonstrated that although NemoStudio is faster and more accurate for complex cases, its high cost and technical instability may limit its widespread use. Yet OOB is an economical and stable alternative, this, though it requires more planning time and may not be ideal for extensive maxillary advancements. Any software choice should be individualized, considering costs, case complexity, and available infrastructure. Future studies should explore integration of FLP-specific algorithms

into the open-source software, as well as improving NemoStudio's stability in real-world clinical scenarios.

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