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Systematic Review
Computer Assisted Surgery

Systematic review of the software used for virtual surgical planning in craniomaxillofacial surgery over the last decade

A. Tel[a,1], L. Arboit[b,1], M. De Martino[c], M. Isola[c], S. Sembronio[a], M. Robiony[a]

[a]Maxillofacial Surgery Department, Academic Hospital of Udine, Department of Medicine, University of Udine, Italy; [b]Sant'Anna School of Advanced Studies, Pisa, Italy; [c]Institute of Statistics, University of Udine, Italy

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Abstract. Craniomaxillofacial surgery has been experiencing a deep conceptual change in surgical planning over the last decade, with virtual reality technologies becoming widely adopted. The high demand has led to an exponential increase in available software. The aim of this review was to outline the current literature and provide evidence on the most used software for virtual surgical planning (VSP), and also to define contemporary knowledge on which procedures are more ready candidates for VSP. A search was performed in the major databases, and screening of the results according to the PRISMA statement identified 535 articles reporting the implementation of preoperative VSP during the years 2010–2020. A total of 77 different software programs were identified. The surgical procedures were assigned a standardized nomenclature and further simplified into 10 categories for analysis: temporomandibular joint (TMJ), implants (IMPL), malformations (MALF), reconstruction (REC), oncology (ONCO), oral surgery (ORAL), orthognathic surgery (ORTH), cranial surgery (CRANIO), trauma (TRAUMA), miscellaneous (OTHER). The journals they were reported in and the sample size of each study were also investigated. The results showed that the Materialise suite was the most widespread tool for VSP, with a prevalence of 36.3%, followed by the Geomagic family. Several packages were found to be associated with a specific type of surgical procedure. This review offers a synopsis of the array of VSP software reported in the literature and sets the basis for an informed, evidence-based use of this software in craniomaxillofacial surgery.

Keywords: Three-dimensional imaging; Computer-assisted surgery; Neuronavigation; Computer-aided design; Reconstructive surgical procedures; Orthognathic surgical procedures; Maxillofacial surgery; Cranium; Software; Digital image processing; Systematic review.

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[1] Alessandro Tel and Lorenzo Arboit are co-first authors.

Over the last decade, virtual reality technologies have been adopted extensively in craniomaxillofacial (CMF) surgery to create computerized scenarios where surgical procedures are simulated. In the first attempts, computer graphics software was used to import geometrical files reconstructed from volumetric imaging of the patient, including computed tomography (CT) and magnetic resonance imaging (MRI). Since then, more advanced and dedicated software packages have been released almost constantly, with specific features suitable for sophisticated image segmentation, orthognathic surgical planning, and anatomical computer-assisted design (CAD) modules. In current clinical practice, software is a fundamental part of the diagnostic and therapeutic management of the patient, and its role is similar to any medical or surgical device. Therefore, in the USA, software for clinical application must be approved by the US Food and Drug Administration (FDA).

In Europe, the introduction in 2020 of the novel Medical Device Regulation (MDR), formally known as regulation 745/2017,[1] involved substantial modifications not only to reclassify medical devices in terms of safety and health implications, but also to reconsider all processes that have an influence on the health outcome.[2] Software plays a major role among these processes and is considered a medical device in all effects. The literature provides robust evidence that computer-guided surgery has had a considerable impact on the accuracy of bone cutting, allowing the craniofacial skeleton to be taken apart and reconstructed while ensuring compatibility and a good fit of the anatomical parts, and has also allowed the design of customized implants tailored to the individual morphological variations of each patient.[3–5] As software plays a central role, any error occurring in these processes can have detrimental effects on the final clinical outcome.

In CMF surgery, software is used in several steps of the digital workflow, including segmentation of the anatomy and the construction of three-dimensional (3D) models suitable for printing,[6] surgical planning of osteotomies and soft tissue simulation,[7] the design of surgical guides and moulds,[8] creation of implantable prostheses,[9] and the evaluation of distance/angle measurements and assessment of accuracy.[10] Software packages can vary significantly in terms of tools, quality of the 3D reconstruction, and specificity for a type of surgery, for instance orthognathic surgery. Most importantly, only some packages are certified for clinical use and can be adopted legitimately to plan real surgical procedures.

Due to the variety of software used in CMF surgery and in consideration of the hazards related to potentially inaccurate surgical planning, the risk category classification of software used for surgical applications might vary between classes IIb and III; therefore the most suitable choice of software could determine possible subsequent adverse events and related legal issues.

Owing to the extensive adoption of surgical planning in CMF surgery, which has steadily increased over the last decade, and in consideration of the variety of new software programs released by companies over the years, there is no clear consensus on which software is the most appropriate for a specific type of surgical procedure, nor has it been attempted previously to identify common threads that might guide the surgeon into choosing a validated methodology for virtual surgical planning (VSP). A systematic review to catalogue and classify the various applications of medical software in CMF surgery has not yet been performed owing to the enormous quantity of papers published in the last 10 years in this field, and the multitude of software programs both released by companies and tested by universities, in the majority of cases as single experiences.

This systematic review was performed to fill this knowledge gap by defining the state-of-the-art in software used in VSP for CMF surgery, choosing a time range of 10 years to provide a dynamic overview of the evolving trends in VSP and software use. The overall aim of this review was to provide scientific evidence on the most appropriate and validated software used for all of the procedures of CMF surgery, outlining the literature background and providing clinicians with a solid base on which to address the choice of the most appropriate software to plan their surgical procedures, while taking into consideration the safety implications addressed by the MDR.

Methods

The main objective of this systematic review was to provide an overview of the software applications used for VSP in CMF surgery, providing evidence of the most commonly performed procedures and which software packages are the most appropriate for a specific type of procedure.

This study was conducted according to the guidelines described in the *Cochrane Handbook for Systematic Reviews of Interventions* (second edition, 2019)[11] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[12]

The research question of this review was built according to the PICOS framework (participants, interventions, comparators, outcomes, and study design) and can be summarized as follows: "Which is the most commonly used software for virtual surgical planning in each craniomaxillofacial surgery procedure?".

This review was reviewed and approved for registration in the PROSPERO database (International Prospective Register of Systematic Reviews; approval number CRD42020212119).

Literature search

An extensive, systematic literature search was performed by the authors in accordance with the PICOS framework. The 'participants' and 'interventions' items were specifically used to compose a detailed query to investigate virtual planning techniques in the setting of maxillofacial surgical procedures, as shown in Table 1. The following major medical literature databases were searched using combinations of keywords: MEDLINE, Web of Science, Cochrane Library, Scopus, Embase, Google Scholar, ClinicalTrials.gov, and Science Direct. In MEDLINE and Embase, the search was further refined using medical subject heading (MeSH) terms and Emtree categories, respectively, combining the specific items with Boolean operators. The search was conducted across the titles, abstracts, and keywords of all articles to assess their eligibility. Supplementary Material Table S1 provides an overview of the search terms used.

After the primary search, the data were imported into Mendeley (Elsevier NV, Amsterdam, Netherlands) for duplicate removal. An electronic report was generated in Mendeley as a.CSV file and exported to Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). All saved articles were screened by two investigators independently (A.T. and L.A.) through an evaluation of the titles and abstracts. Any disagreement between the two investigators was resolved through consensus or by a third independent investigator (M.R.). The title screening was done through Mendeley, while the subsequent abstract screening was conducted in EndNote 20 (Clarivate Analytics, Philadelphia, PA, USA).

Following the title and abstract screening, all eligible full-text papers were retrieved. A custom Python code was written to extract the main bibliographic data from these articles, namely the title, journal, and year of publication, into an Excel spreadsheet. All data collected by the algorithm were manually validated by the same investigators (A.T. and L.A.) who performed the selection of full-text articles based on the inclusion and exclusion criteria.

Inclusion and exclusion criteria

The search strategy is described in Supplementary Material Table S1, with the keyword search queries structured according to the PICOS scheme. Basically, all articles reporting studies of software applications for VSP in CMF surgery during the period January 1, 2010 to November 1, 2020 were included in this study.

Selected exclusion criteria were applied to the search output to limit the results exclusively to VSP performed for surgical purposes in humans. Dentistry procedures, including basic implantology, prosthodontics, conservative therapies, and orthodontics, were excluded as they did not involve any surgical procedure. However, advanced implantology procedures, including the placement of zygomatic implants and bone regeneration of severe bone atrophy were included due to the invasiveness and oftentimes the need for surgical planning. Articles in languages other than English were also excluded. In addition, articles describing VSP without any reference to the software used were not considered. Search results were limited to original articles, technical notes, clinical trials, and case reports. Review articles and meta-analyses, as well as letters and congress abstracts, were excluded. Studies exclusively about imaging, cadaver or animal research, training-only articles, and anatomical studies were not considered for the purposes of this review. Other studies excluded were those reporting only volume rendering and not a modifiable geometry, as well as studies about photogrammetry and 3D photography, cephalometric studies, airway flow analyses, and navigation-only studies, without any reference to a computerized surgical plan. Studies concerning biomechanical analyses, such as finite element analysis (FEA) and computational fluid dynamics (CFD) were also excluded. Studies on statistical shape models (SSM) were included, due to their immediate implications in surgical planning. Studies for which the abstract was not provided in the selected databases were also excluded. It was decided to include studies describing the use of software for comparison between the planning and postoperative outcome, as the evaluation of accuracy relates directly to the surgical planning. Concordance between the two investigators was assessed using the Cohen κ coefficient.

A summary of the exclusion criteria is provided in Supplementary Material Table S2.

Data collection

The investigators extracted the following information from the eligible studies: title of the paper, journal of publication, year of publication, location, study design and methodology, number of patients, specific software (one or more) used, purpose (planning or comparison), type of surgery. Data were initially extracted automatically using the Python script and were then checked and approved by the two independent investigators (A.T. and L.A.).

The surgical procedures were assigned a standardized nomenclature and further simplified into 10 categories: temporomandibular joint (TMJ), implants (IMPL), malformations (MALF), reconstruction (REC), oncology (ONCO), oral surgery (ORAL), orthognathic surgery (ORTH), cranial surgery (CRANIO), trauma (TRAUMA), and 'OTHER'; the latter was created for cases not encompassed by the previous categories. The definitions of the categories and the surgical procedures grouped within each category are reported comprehensively in Table 1.

Bias assessment

Two authors (A.T. and L.A.) independently assessed the risk of bias using the robvis tool.[13] Five domains were evaluated to describe the risk of systematic errors that might be included in the selected papers: bias arising from the randomization process, bias due to deviations from the intended intervention, bias due to missing outcome data, bias in measurement of the outcome, bias in the selection of the reported result. Data were imported into Review Manager (RevMan) Web software for further investigation. In the case of discrepancies, an agreement was reached through discussion.

Data analyses

The data were collected in a Microsoft Excel spreadsheet. To produce graphical representations, the Excel file was imported into Scimago Graphica (SCImago LAB, SRG S.L., Granada, Spain), which enhances the visual communication of data by creating a wide array of graphs. A connection plot was generated using the software VOSviewer v1.6.18,[14] an open source package that allows bibliometric networks to be visualized and also includes a mining engine that can be used to define and visualize co-occurrence networks of relevant keywords extracted from a body of scientific literature. Associations between the types of surgical procedure and each software package were investigated using the χ^2 test or Fisher's exact test, as appropriate. The statistical analysis was performed using Stata Statistical Software Release 17 (StataCorp LLC, College Station, TX, USA).

Results

Study selection process

Fig. 1 shows the PRISMA flowchart describing the study selection process. Using a combination of keywords, MeSH, and Emtree terms, the investigators retrieved 17,998 studies,

Table 1. Definitions of the categories for the individual procedures.

Surgical procedures grouped within the predefined classes	Categories
Condylar fractures	TMJ
TMJ replacement	
TMJ arthroplasty (including condylectomy)	
TMJ ankylosis	
TMJ other (ankylosis, minimally invasive)	
Complex implant procedures (implants on microvascular flaps, zygomatic)	IMPL
Syndromic malformations	MALF
Cleft	
Craniosynostoses	
Fibula free flap	REC
Free flaps in trauma sequelae	
Scapula free flap	
Patient-specific implants (PSI)	
Iliac crest free flap	
Soft tissue flaps	
Facial transplant	
Nasal reconstruction	
Orbital mass	ONCO
Bone dysplasia	
Mandible resection	
Midface resection	
Jaw cysts	ORAL
Bone augmentation for atrophy	
Osteonecrosis of the jaw	
Orthognathic surgery	ORTH
Genioplasty	
Distraction	
Cranioplasty	CRANIO
Skull base	
Orbital reconstruction	TRAUMA
ZMC	
Mandibular fractures	
Panfacial	
Midface fractures	
Endoscopy	OTHER
Gender affirming/ethnic plastic surgery	
Orbital decompression	
Foreign body removal	
Aesthetic surgery	

TMJ, temporomandibular joint; ZMC, zygomaticomaxillary complex.

which were saved in a unique BibTeX (.bib) file. This file was then imported into Mendeley to search for duplicates. After the identification of duplicates, 4394 studies were removed. The remaining 13,604 studies were screened by title, and a further 7286 studies were excluded (Cohen's κ coefficient = 0.98). Subsequent screening by abstract led to the exclusion of an additional 4372 reports (Cohen's κ coefficient = 0.96). The full texts of 1946 studies were read, of which 1411 fulfilled the exclusion criteria and were removed (Cohen's κ coefficient = 0.95). Finally, 535 studies meeting the inclusion criteria were included in the review.

Assumptions concerning the collection of data about the software in the selected papers and the journals publishing the papers

As the analysis of the 535 selected papers revealed a total of 77 different software programs, which could have resulted in a complicated and confusing analysis, the following additional criterion was applied to the studies: the prevalence of the software is > 1% of the total usage of software. Overall there were 916 mentions of software reported in the selected 535 papers, therefore all software programs used in at least 10 papers were included.

Concerning the journals, the same cut-off was applied: journals were selected if they published at least 1% of the papers; therefore all journals publishing at least five of the selected papers were included.

In several cases, the software was acquired by another company and changed name: SurgiCase was further developed and became ProPlan, Rapidform was transformed into Geomagic Freeform, Maxilim is no longer available and has been replaced by IPS CaseDesigner from KLS Martin, Geomagic Studio is no longer released and has been replaced by Geomagic Design X, Geomagic Control X, and Geomagic Wrap. In such cases, considering that these software packages were technically different, they were considered as separate entities.

Absolute prevalence of the different software packages

The most used software in the selected studies was Mimics (Materialise NV, Leuven, Belgium), appearing in 194 papers (36.3%), followed by ProPlan CMF (Materialise), which was mentioned in 121 papers (22.6%), and 3-Matic (Materialise), reported in 72 papers (13.5%). After Materialise software, the most reported packages were from the Geomagic family (3D Systems, Rock Hill, SC, USA), with 70 papers mentioning Geomagic Studio and 29 Geomagic Freeform, followed by iPlan from Brainlab (Brainlab, Munich, Germany) appearing in 50 papers. Dolphin (Dolphin Imaging and Management Solutions, Chatsworth, CA, USA) appeared in 38 papers all concerning orthognathic surgery; similarly, Maxilim (Medicim, Mechelen, Belgium), now replaced by IPS CaseDesigner (KLS Martin, Tuttlingen, Germany), appeared in 12 papers. Concerning free software, Meshmixer (Autodesk Inc., San Rafael, CA, USA) was reported in 24 papers, 3D Slicer (Harvard University, Boston, MA, USA) in 17 papers, OsiriX (Pixmeo, Bernex, Switzerland) in 15 papers, and Amira (Thermo Fisher Scientific, Waltham, MA, USA) in 13 papers. A variety of software with fewer than 10 mentions were reported within a single heterogeneous category.

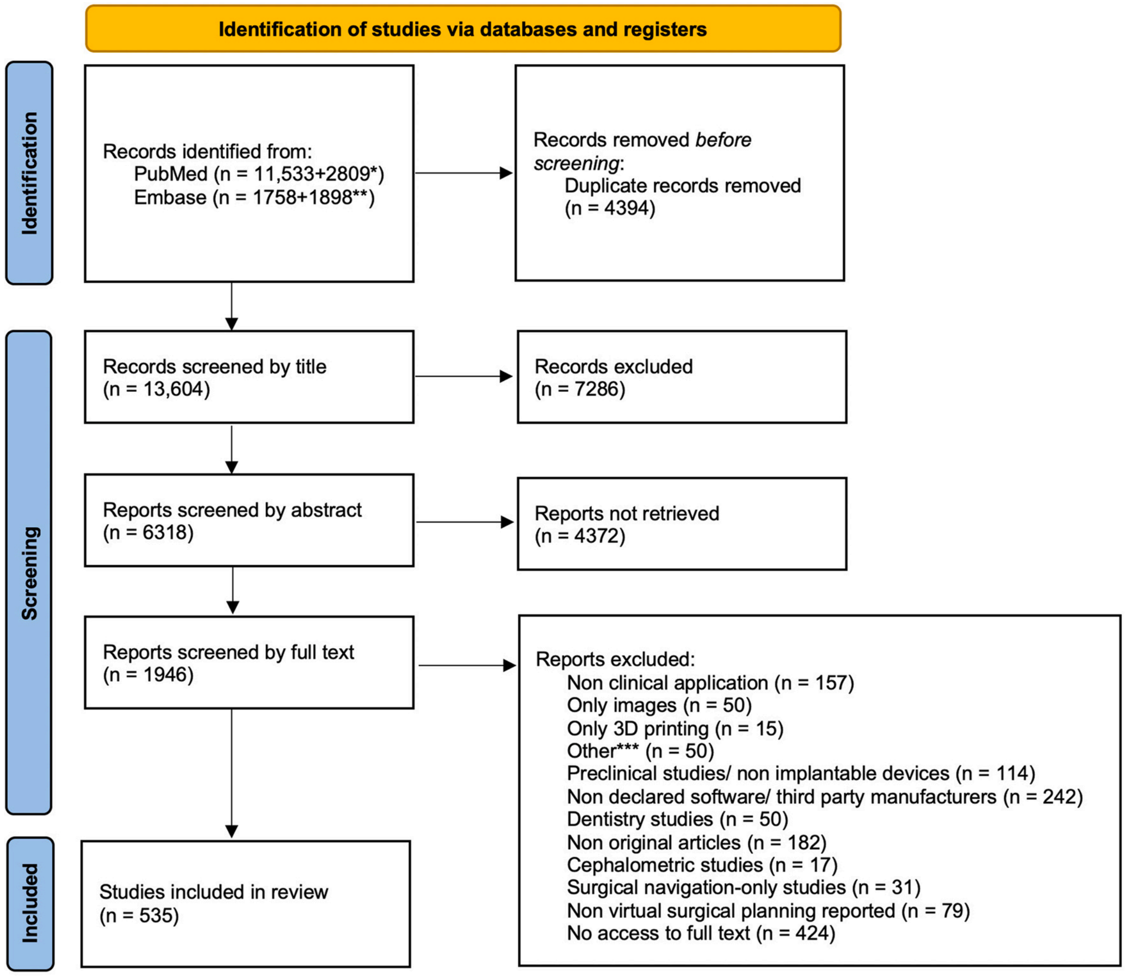

Fig. 1. PRISMA flowchart of the systematic review process. *The first number refers to records identified via keywords, the second refers to records identified via MeSH. **The first number refers to records identified via keywords, the second refers to records identified via Emtree. ***'Other' includes computational analysis/segmentation only; in-house customized software; radiotherapy-based planning; languages other than English; other medical fields; pre-2010.

Fig. 2 reports the absolute prevalence of each software within each of the 535 screened papers.

Distribution of the software according to the journal of publication

Concerning the prevalence of the software mentioned in the selected papers across the journals, the majority of applications were reported in the *Journal of Oral and Maxillofacial Surgery* ($n = 121$), with Mimics the most used software. The next most represented journal in terms of papers citing software for VSP was the *Journal of Craniomaxillofacial Surgery* ($n = 108$), followed by the *International Journal of Oral and Maxillofacial Surgery* ($n = 67$); both journals showed the predominance of Mimics, ProPlan, and 3-Matic, followed by the Geomagic suite. The fourth most cited journal, the *Journal of Craniofacial Surgery*, showed a predominance of the Geomagic suite. Fig. 3A provides a complete overview of the distribution of the software for each journal.

Distribution of the software by type of surgical procedure

The most represented field of application for VSP and software utilization was found to be orthognathic surgery ($n = 243$), followed by reconstructive surgery ($n = 229$) and trauma surgery ($n = 105$). In orthognathic surgery, Mimics was the most widespread software ($n = 58$), followed by ProPlan ($n = 36$), Dolphin ($n = 32$), Simplant ($n = 26$), and 3-Matic ($n = 21$). For reconstruction, ProPlan was reported with a higher frequency compared to Mimics (51 vs 43). Of note, iPlan had a prominent role in trauma surgery ($n = 22$), just after Mimics ($n = 31$), while other software packages were mentioned at a considerably lower frequency. Geomagic Studio and Geomagic Freeform were used mostly in reconstruction. Fig. 3B provides a graphical overview of the software distribution for each surgical procedure.

Distribution of the software by number of patients enrolled in the studies

Fig. 3C shows a similarity in software adoption between studies including a small number of patients, such as case reports, technical notes, case–control studies, and small cohort studies, and studies including a large number of patients, like clinical trials. For all types of study, the three most represented software packages were Mimics, ProPlan, and 3-Matic. However, the vast majority of studies enrolled small

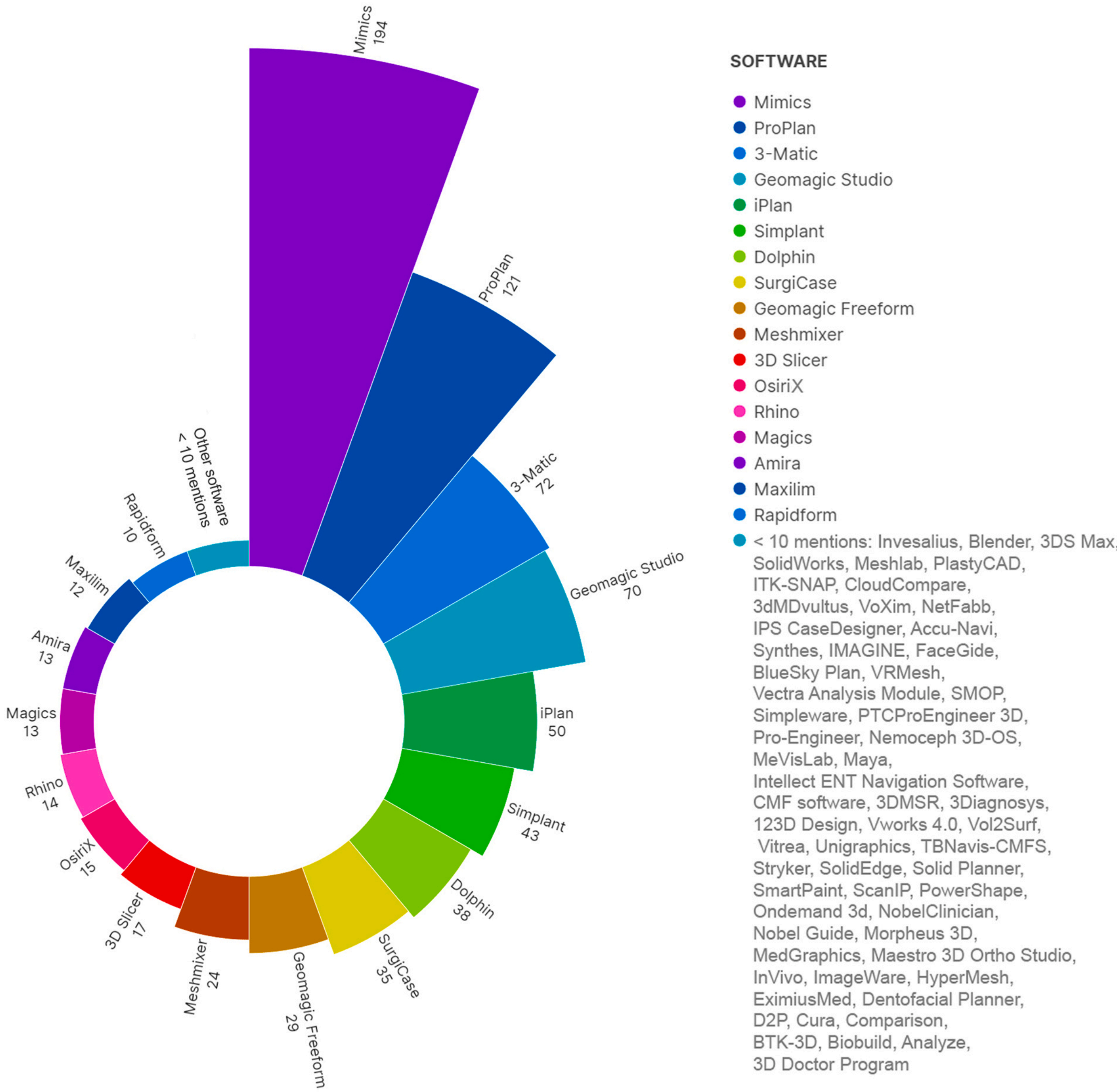

Fig. 2. Graphic diagram showing the prevalence of different software packages within the screened articles. In this spiral plot, the height of each coloured block refers to the absolute prevalence of the software package. The last block includes software packages mentioned in fewer than 10 papers.

numbers of patients, and many studies consisting of case reports and technical notes reported software applications in single cases. Only two studies reported a sample size of 129 or more patients.

Definition of a bibliometric connection graph

The selected papers were imported into Mendeley and a unique BibTeX file (.bib) was generated. The.bib file was read by VOSviewer and 1733 keywords were selected. As reported previously for the assumptions, only keywords with a recurrence rate superior to 1% (17 or more mentions) were selected, and keywords matching the exclusion criteria were deleted. An association network map was generated, as shown in Supplementary Material Fig. S1.

Statistical associations between the software and type of surgical procedure

The following associations, either positive or negative, were found to be statistically significant: Mimics and CRANIO (positively associated, $P = 0.003$); ProPlan and REC (positively associated, $P < 0.001$); ProPlan and TRAUMA (negatively associated, $P = 0.010$); ProPlan and CRANIO (negatively associated, $P = 0.005$); iPlan and ORTH (negatively associated, $P < 0.001$); iPlan and TRAUMA (positively associated, $P < 0.001$); Simplant and ORTH (positively associated, $P < 0.001$); Simplant and TRAUMA (negatively associated, $P = 0.004$); Dolphin and ORTH (positively associated, $P < 0.001$); Dolphin and REC (negatively associated, $P < 0.001$); Dolphin and TRAUMA (negatively associated, $P = 0.003$); Magics and CRANIO (positively associated, $P = 0.006$); Maxilim and ORTH (positively associated, $P = 0.023$);

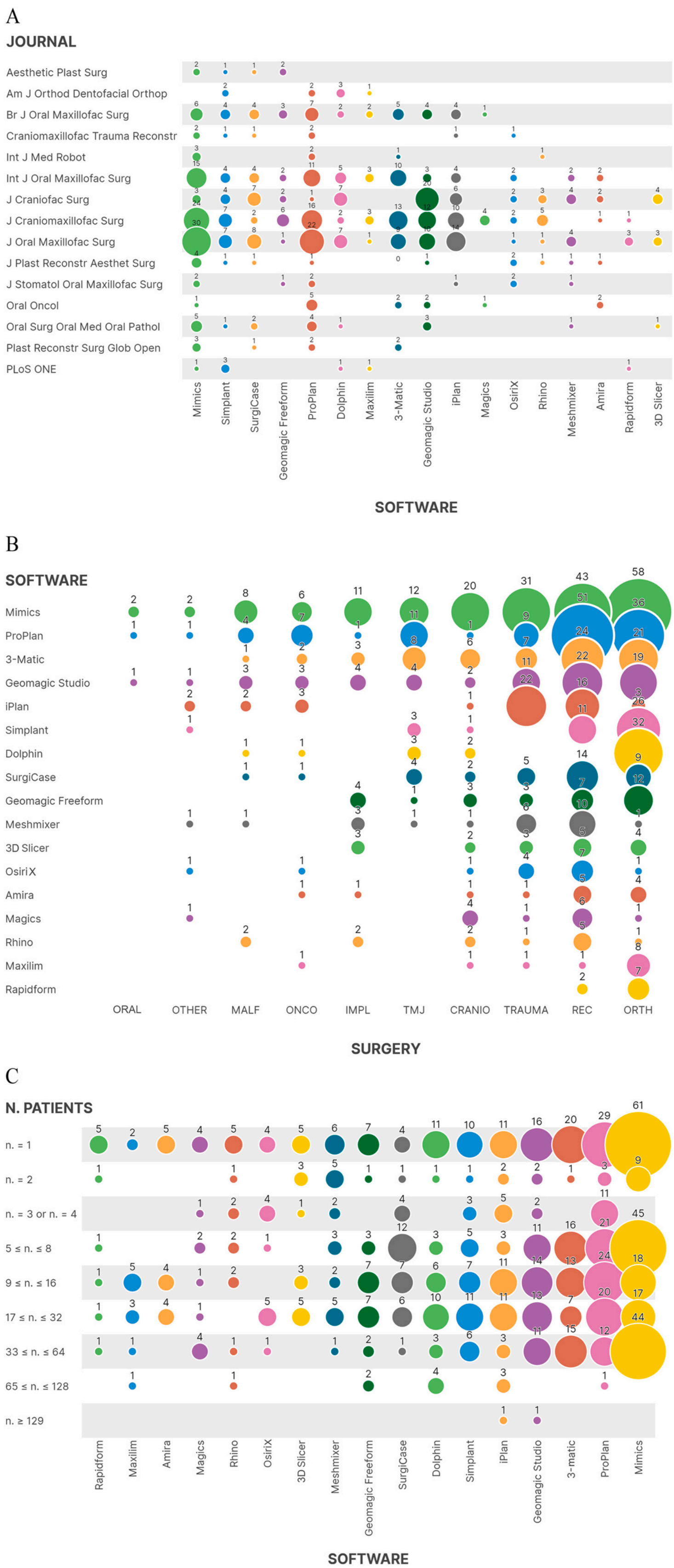

Fig. 3. (A) Bubble plot showing the prevalence of each software within each journal. The size of each bubble accounts for the number of mentions of the individual software within

Rapidform and ORTH (positively associated, $P = 0.015$), Geomagic Freeform and IMPL (positively associated, $P = 0.022$). Supplementary Material Table S3 reports complete outputs of the associations identified using the χ^2 test.

Discussion

The main purpose of this study was to provide an extended overview of the software used in CMF surgery, organizing the considerable body of scientific literature on the use of technologies for VSP produced in recent years. As there has been an exponential growth trend in these technologies over the years, it was decided to include a defined interval period of 10 years, in order to capture both the evolution in applications of VSP and the modifications of the software packages in terms of functionality and nomenclature. In fact, in evaluating the array of software used in CMF planning, it has to be taken into account that over the 10-year period several packages changed their name, either because they were merged with or split into other software, or because other companies incorporated them and changed their names.

Materialise Mimics and 3-Matic are part of a single software suite named Mimics Innovation Suite. As indicated by the prevalence data, Mimics was the most widespread and powerful software reported in the literature over the 10-year period and currently represents the gold standard tool to perform medical image segmentation and generate 3D anatomical reconstruction through validated algorithms.[3,15–32] 3-Matic software was specifically conceived as an anatomical CAD software, translating the most powerful features of a classic CAD package over anatomical models, including Boolean operations, sketch generation, geometry creation and editing, and robust alignment features.[4,10,28,29,32–46]

ProPlan CMF software was designed specifically for clinicians and was found to be the second most used package for surgical planning, closely following the Mimics Innovation Suite. The software Simplant was originally developed by Materialise to plan CMF surgeries, but it was then split into a Simplant package specifically for dentistry procedures (Simplant) and a CMF software called SurgiCase CMF to plan surgical each journal. (B) Bubble plot showing the prevalence of each software for each type of surgical procedure. The size of each bubble accounts for the number of mentions of individual software within each class of procedure. (C) Bubble plot showing the prevalence of each software according to the size of the studies considered. The size of each bubble accounts for the number of mentions of individual software within each category of sample size for each study. ORAL, oral surgery; OTHER, all other surgeries; MALF, malformations; ONCO, oncology; IMPL, implants; TMJ, temporomandibular joint; CRANIO, cranial surgery; TRAUMA, trauma; REC, reconstruction; ORTH, orthognathic surgery.

procedures. Thereafter, SurgiCase was rebranded as ProPlan, the most specific software for CMF surgical planning, which includes different modules for orthognathic surgery and reconstruction.[8,10,34,35,47–60,61-80]

In the past, Maxilim software was well acknowledged in the field of orthognathic surgery,[81–92] especially thanks to the works of Swennen,[93] but was subsequently replaced by IPS CaseDesigner, released by KLS Martin. Currently, IPS CaseDesigner is often used for orthognathic surgical planning, although there are relatively few papers considering that this software is relatively new.[94–98]

Geomagic Studio was a complete package developed and branded by 3D Systems with multiple applications in CMF surgery.[15,31,49,70,74,76,79,99–111] Currently available is Geomagic Freeform, a software designed to manage organic surfaces that is widely used across the industry to design and manufacture patient-specific implants. The peculiarity of Geomagic Freeform is that it allows the user to sculpt digital clay, overcoming the limits of tessellated polygonal meshes and facilitating the management of complex anatomical shapes.[4,29,37,66,109,112–125]

Rapidform software contained features more specific to the processing of 3D scan data and reverse engineering[64,126–133]; this software was assimilated within the Geomagic suite and transformed into Design X.

Dolphin suite was developed specifically for orthodontics and has a robust module for orthognathic surgery, resulting in its widespread use in orthognathic surgical planning, especially for its advanced cephalometry features.[38,102,106,134–148]

iPlan CMF, now renamed Elements, was developed by Brainlab with the purpose of integrating planning with navigation systems. This software allows both manual and automatic segmentation, with the latter method based on anatomical atlases for structure recognition.[35,51,66,75,81,103,108,113,115,149–158]

A variety of free packages are reported in the literature: Meshmixer is a freely downloadable software developed by Autodesk that provides a wide array of tools for mesh editing, and is used mostly to design devices, such as surgical guides and moulds.[7,159–177] 3D Slicer, a software developed by the Harvard Medical School, has a modular architecture ranging from segmentation to radiomics.[160,162,165,173,176,178–180] Amira is a research package whose use has been reported in several papers,[9,10,39,130,178,181–183] and OsiriX is a medical image visualization software that can also perform basic segmentation and 3D reconstruction.[77,163,184–186] In its MD version, which is not free, OsiriX is also approved by the FDA. OsiriX has a twin open-source version, Horos, which includes similar basic features. Table 2 provides a summary of the features of the selected software.

It appears that there have been no previous attempts to catalogue the software used for VSP in CMF surgery. This is likely because of the overwhelming amount of literature being published every year in this rapidly growing field and because of the variety of software used, as well as the difficulty extracting the use of a specific software from each article.

Regarding technical applications, VSP and 3D printing, which rely respectively on software packages and 3D printers, are applied in parallel, since medical image processing, segmentation, and 3D mesh creation are the prerequisites of a printable STL file. Nevertheless, the literature on medical 3D printing in CMF surgery is more systematized than that on VSP, and many successful attempts have been made to catalogue various 3D printing technologies and applications.[187–189] The disparity in the organized literature between VSP and 3D printing is due to the high complexity and effort required to define rapidly changing knowledge, in which, however, some common threads deserve scientific evidence.

In fact, as recently promulgated regulations consider software as a medical device, the current authors believe that it is important to provide a scientific background for the choice of the various packages, delineating the precise landscape of software for clinicians and researchers, the evidence behind each of them, and their most successful and documented applications for any kind of surgical procedure.

It is believed that the long time period covered by this review and the considerable number of papers analysed contributed to providing a reliable overview of the software applications for VSP in CMF. However, some factors impairing the data collection process should be highlighted, including the fact that a substantial proportion of papers reporting virtual planning applications did not state the software package used, which represented an exclusion criterion according to the study selection process. This most often happened when the surgical planning was outsourced to an external company that exclusively provided images to the clinicians without specifying the methodology of VSP used.

Notwithstanding the limitations, the results of this systematic review clearly indicate that the Materialise software suite is the leading tool for VSP in CMF surgery (prevalence of 36.3% for Mimics), supported by a considerable body of literature and a high number of applications. The wide toolset for segmentation, FDA/CE approval, and excellent integration with 3-Matic for CAD functionality make Mimics the recommended choice to approach VSP in CMF surgery. ProPlan CMF, with its complete set of tools and a guided workflow, is the preferred choice of many institutions around the world (prevalence of 22.6%) and is a valuable package that suits the clinician's needs. 3-Matic is a powerful software that optimizes the functionalities of engineering CAD tools on complex anatomical models and is approved for the creation of surgical guides and implants; it requires specialist knowledge in virtual planning and 3D modelling (prevalence of 13.5%). After the Materialise suite, the Geomagic suite represents the predominant group. Current applications of Geomagic Freeform span multiple fields, and this software is applied especially for the design of implants and surgical guides; its main drawback is that it is not approved by regulatory entities for medical use.

Table 2. Overview of the main features and approval for medical application of each software package.

Software package	Approved as a medical device	Manufacturer	Details	Free
Mimics	Yes	Materialise	Medical image segmentation and 3D model reconstruction	No
ProPlan	Yes	Materialise	CMF surgical planning	No
3-Matic	Yes	Materialise	Anatomical-CAD, alignment and analysis, design of PSIs	No
Geomagic Studio	No	3D Systems	Reverse engineering and polysurface editing	No
iPlan	Yes	Brainlab	Implemented by navigation systems with virtual planning capabilities	No
Simplant	Yes	Materialise, now Dentsply Sirona	Used once for orthognathic planning, now exclusively for dentistry procedures	No
Dolphin	Yes	Patterson Companies	Orthognathic surgical planning	No
SurgiCase	Yes	Materialise	It was once a module for CMF surgical planning, now it has become an online platform for case discussion	No
Geomagic Freeform	No	3D Systems	Sculpting of organic surfaces (clays), design of PSIs	No
Meshmixer	No	Autodesk	Polysculpt and modelling, design of guides	Yes
3D Slicer	No	Harvard University, NIH	Research software for segmentation, radiomics studies	Yes
OsiriX	Yes (only MD version)	Pixmeo	Medical image visualization software with simple segmentation	Yes/No[a]
Amira-Avizo	No	Thermo Fisher Scientific	Research for industrial and scientific data visualization	No
Magics	No	Materialise	3D printing pre-processing	No
Rhino	No	Robert McNeel & Associates	Software for NURBS modelling in industrial design	No
Maxilim	Yes	Medicim (now IPS CaseDesigner, distributed by KLS Martin)	Orthognathic surgical planning, now called IPS	No
Rapidform XOR	No	Rapidform Inc.	Scanning and reverse engineering	No

3D, three-dimensional; CAD, computer-assisted design; CMF, craniomaxillofacial; NIH, National Institutes of Health; NURBS, non-uniform rational basis spline; PSI, patient-specific implant.
[a]OsiriX MD version with FDA clearance is not free.

Regarding the citing journals, specialist journals have reported the majority of applications of software in CMF surgery, as expected, with the *Journal of Oral and Maxillofacial Surgery*, the *Journal of Craniomaxillofacial Surgery*, and the *International Journal of Oral and Maxillofacial Surgery* representing more than half of the citing journals (55.3%).

Concerning the statistical associations between the type of procedure and software packages, the results of the χ^2 test showed that Mimics is used widely across all surgical fields and therefore no specific association was found with any particular type of procedure, although the *P*-value showed statistical significance for the CRANIO group. Statistically significant associations were found between TRAUMA, CRANIO, and REC and ProPlan, with the association being remarkable for REC procedures ($P < 0.001$), owing to the predefined module for reconstruction in ProPlan, which makes it the ideal choice. iPlan/Elements was found to play a key role in TRAUMA procedures, where it represents an important tool for navigation planning, while Dolphin was found to have a strong association with ORTH ($P < 0.001$), but not with other procedures such as REC and TRAUMA, owing to its almost exclusive application in orthognathic surgery. Maxilim/IPS CaseDesigner was found to be associated with ORTH with statistical significance as well.

The long timespan of 10 years considered by this systematic review has captured much of the evolution in this field, although some transformations are still occurring at present and should be mentioned to provide an accurate depiction of the software used in CMF surgical planning. For instance, there is a growing trend in the use of IPS CaseDesigner from KLS Martin in orthognathic surgery, similarly to data concerning Maxilim. However, to catalogue and order the knowledge in this highly complex field, more efforts will be required in the future and a systematization of knowledge will become essential to include further updates in technology and software packages. For instance, it is expected that before 2030 there will be a steep increase in mixed and augmented reality applications, and the surgical planning itself will be performed by virtual interaction with the physical space, manipulating objects and repositioning bones.

Moreover, as demonstrated in Fig. 3C, the level of evidence for VSP and 3D printing applications in CMF surgery is low, due to the multitude of research studies performed on single cases or small cohorts of patients, the paucity of studies with a larger sample size, and an almost complete lack of randomized clinical trials. Many more efforts by researchers around the world will be needed to pool their experience and provide experimental, blinded trials to raise the level of scientific evidence for a technology that has already proved its usefulness for more than 10 years.

This systematic review is novel in providing an updated overview of the software used for virtual surgical planning in craniomaxillofacial surgery over a long time span of 10 years. As software is considered a medical device, it is important to provide clinicians with the conceptual bases for an evidence-based choice according to their specific needs, expertise, and objectives. Repeated efforts will be needed to systematize knowledge and build evidence in this rapidly evolving field of craniomaxillofacial surgery as technology progresses both in software and in hardware.

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Competing interests

None.

Ethical approval

Not required.

Patient consent

Not applicable.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ijom.2022.11.011.

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Correspondence to: Maxillofacial Surgery Unit
Academic Hospital of Udine
Department of Medicine
University of Udine
P.le S. Maria della Misericordia 1
33100 Udine
Italy.
E-mail: massimo.robiony@uniud.it