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New protocol for in-house management of computer assisted orthognathic surgery

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Abstract

The aim of this study was to evaluate retrospectively the accuracy of a protocol for completely in-house, computer-assisted, orthognathic surgery, generating resin printed intermediate surgical guides. A retrospective, observational study was made on a cohort of 15 patients treated consecutively from September 2017 to May 2019, who underwent bimaxillary orthognathic surgery planned with the same 3-dimensional program and whose surgical intermediate splints were obtained with the same all-in-house protocol. Virtual planned surgical movements were compared with the real surgical outcome. The differences were not significant for eight of the 12 variables considered. The p values, calculated with the Wilcoxon signed rank test, were evenly distributed and ranged from $p = 0.001$ to $p = 0.820$. Significant differences were reported in four measurements: angle between sella-nasion plane and a line connecting the incisal edge and the apex of the root of the most prominent incisor (U1-SN) ($p = 0.001$), angle between Frankfort plane and a line connecting the incisal edge and the root apex of the most prominent upper incisor ($p = 0.008$), dental midline discrepancies ($p = 0.006$), and occlusal plane tilt (U1-FH) ($p = 0.001$), basically due to intraoperative settings. The 3-dimensional resin printed surgical guides were shown to be a reliable alternative to the commercial ones and showed high rate of accuracy for most of the variables assessed. Four out of 12 of these showed significant errors, but two of them were only minimal discrepancies with no clinical implications.

Keywords: Orthognathic surgery; Virtual surgical planning; Computer-assisted orthognathic surgery; Virtual planning accuracy

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Introduction

Intraoperative surgical guides are crucial to achieve predictable results in orthognathic surgery, especially when bimaxillary complex movements are made in the three planes.[1] Classic orthognathic surgical planning requires the combinations of the data obtained from different sources, such as aesthetic examination of the face, frontal and lateral cephalometric analysis, and plaster casts mounted on a semi-adjustable articulator with facebow registration.[2] This allows the surgeon to plan and simulate the movements that the bony segments will undergo during surgery. Unfortunately, the outcome of orthognathic surgery may differ significantly from the planning.[3–7]

In the last decade, advances in imaging technology and 3-dimensional computerised planning have improved the precision of surgical corrections of complex dentofacial deformities. These advances in 3-dimensional technology have resulted in new computerised tools for use in preopera-

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tive planning and the manufacture of surgical splints.[8–12] In these protocols, computerised composite skull models of the patient are generated to accurately represent the skeleton, the dentition, and the facial soft tissue,[10,11,13,14] The move from 2-dimensional to 3-dimensional imaging provides surgeons and patients with extra information that cannot be obtained from cephalograms alone. The software programs enable the surgeon to interact with the 3-dimensional images: it is possible to simulate several different surgical plans, including Le Fort I osteotomy, mandibular ramus osteotomies, and genioplasties. It is also possible to virtually reposition osteotomised bony structures, controlling intercuspation and the interferences among osteotomised bony structures and regions at the base of the skull, therefore simulating the postoperative results on hard and soft tissue in three dimensions on a computer screen. Also, these programs make it possible to obtain intermediate surgical splints using CAD/CAM technology to perform computer-assisted orthognathic surgery, which has proved to be a reliable, innovative, and precise method to transfer the orthognathic plan to the actual surgery. Using digital planning, there is slight chance of incorporating errors, and the few that persist are generally due to improper acquisition of computed tomographic (CT) scans, often linked to poor patient compliance.

The accuracy of the CAD/CAM surgical guides to perform orthognathic surgery rapidly gained widespread popularity and many studies confirmed the ease and accuracy of this method.[8,13,15–19]

On the other hand, most of the software currently available on the market still requires web conference collaboration with bioengineers, often in different countries, to help in the planning phases, and need for assistance of outer companies to finalise the planning process and manufacture the surgical splints. These inconveniences are time-consuming, expensive, and limit the autonomy of the operators.

We present a completely in-house and low-budget protocol for surgical planning and splint manufacturing. It is possible with commercially available programs that allow the surgeon to complete by himself all the steps of the virtual planning up to the generation of a surgical guide that is directly printed with an in-office 3-dimensional resin printer, already adopted in prosthetic dentistry and jewellery. Such kind of protocol, which provides homemade manufacturing of the surgical splint, has not yet been widely published.[20]

The aim of this study was to retrospectively evaluate the accuracy of 3-dimensional software for computer-assisted orthognathic surgery generating in-house resin printed intermediate surgical guides in a sample of 15 subjects who had undergone bimaxillary orthognathic surgery.

Material and methods

A retrospective, observational study was performed on a group of patients treated consecutively from September 2017 to May 2019, who underwent orthognathic surgery, planned with the same 3-dimensional program, and whose surgical splints were obtained with the same all-in-house protocol. For inclusion, the patients had to have undergone bimaxillary orthognathic surgery for abnormal growth of the jaws. The patients had previously had orthodontic removal of dental compensations and were retained with passive arch wires.

Patients were excluded from the study if they were diagnosed with a temporomandibular joint disorder or presented a history of facial bone trauma, tumours, cleft lip or palate, or previous orthognathic surgery.

All participants provided written informed consent before enrollment, and the study has been conducted in accordance with the Helsinki Declaration of 1973 as revised in 1983. As a retrospective study it did not required institutional review board approval.

All the surgeries were planned with the same software (Dolphin 3D, Version 11.95 Dolphin). This program was selected after different experiences because, in addition to great versatility and abundance of diagnostic tools, it has the peculiarity to provide digital surgical guides in .stl format, that can be printed by standard 3-dimensional printers.

A faithful representation of the facial skeleton and the soft tissues was obtained using Digital Imaging and Communications in Medicine (DICOM) data from cone-beam computed tomography (CT). The following settings, were attended to obtain the scans: field of view 20 cm × 20 cm, 110 kV, radiation exposure 59 mSV, and resolution 0.4 mm.

High resolution virtual dental casts in .stl. format, both in preoperative and postoperative occlusion, were needed as well. In our cases, they were achieved starting from a cone-beam CT scan of the plaster models at 0.25 mm. The DICOM data were then processed with open source software (Invesalius version 33.1.1, Centro de Tecnologia da Informação Renato Archer) to process the dental models and save them in .stl format.

According to the Dolphin 3-dimensisonal protocol, the DICOM data of the skull and the .stl data of the dental models were then acquired to build the augmented model, ready for planning and virtual surgery.

The same operator planned all the orthognathic surgeries, guided by real-time 3-dimensional cephalometric and clinical measurements, moving the virtual bony segments until the desired outcome was achieved (Fig. 1). Thereafter, the intermediate splint was generated as .stl file format, then it was processed with a specific program (Creation Workshop, Wanhao) to obtain a proper model to be printed in .cws format. This file was then printed on a desktop 3-dimensional digital light processing resin printer (DLP). DLP resin print technology is a type of vat polymerisation 3-dimensional printing technology that uses a liquid photopolymer resin which is able to solidify under a light source. We adopted the Wanhao Duplicator 7 plus (Wanhao 3D Printer, Jinhua). The intermediate wafer was printed with clear resin (Wanaho, Zhejiang). The settings were: thickness (resolution): 50 microns, 5 bottom layers, cure time: 40,000 ms.

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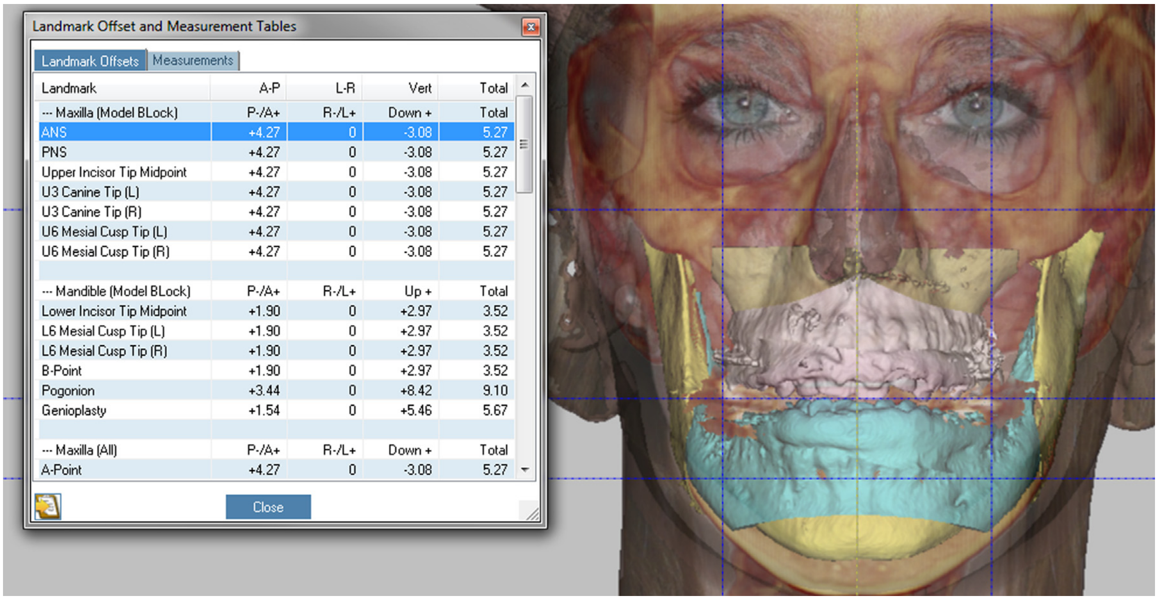

Landmark	A-P	L-R	Vert	Total
--- Maxilla (Model BLock)	P-/A+	R-/L+	Down +	Total
ANS	+4.27	0	-3.08	5.27
PNS	+4.27	0	-3.08	5.27
Upper Incisor Tip Midpoint	+4.27	0	-3.08	5.27
U3 Canine Tip (L)	+4.27	0	-3.08	5.27
U3 Canine Tip (R)	+4.27	0	-3.08	5.27
U6 Mesial Cusp Tip (L)	+4.27	0	-3.08	5.27
U6 Mesial Cusp Tip (R)	+4.27	0	-3.08	5.27
--- Mandible (Model BLock)	P-/A+	R-/L+	Up +	Total
Lower Incisor Tip Midpoint	+1.90	0	+2.97	3.52
L6 Mesial Cusp Tip (L)	+1.90	0	+2.97	3.52
L6 Mesial Cusp Tip (R)	+1.90	0	+2.97	3.52
B-Point	+1.90	0	+2.97	3.52
Pogonion	+3.44	0	+8.42	9.10
Genioplasty	+1.54	0	+5.46	5.67
--- Maxilla (All)	P-/A+	R-/L+	Down +	Total
A-Point	+4.27	0	-3.08	5.27

Fig. 1. Virtual surgical planning (published with the patient's consent).

Fig. 2. Three-dimensional printed surgical splint.

In this way, the surgical planning and simulation were transferred to the patient at the time of surgery using that computer-generated intermediate surgical splint (Fig. 2). The same surgeon who planned the surgeries also did all the bimaxillary orthognathic procedures, according to the authors' standard osteotomy protocol (LeFort I osteotomy and Epker's bilateral sagittal split ramus osteotomy).[21–23] The chin segment was repositioned with simple intraoperative clinical measurements and evaluation of the appropriate lower third vertical dimension and symmetry. The maxillary osteosynthesis was done with four L-shaped 2.0 titanium miniplates and, the mandibular rami sagittal splits were fixed using one or two, four hole, thickened, straight, 2.0 titanium miniplates, bilaterally.

The accuracy of the virtual planning method was determined comparing planned movements of the osteotomised jaws to the actual surgical movements. This was done on the assumption that the simple superimposition [8,13,15] of the simulation and the final cephalometric results does not define any correlation between the positional error and surgical movements. A slight positional error can be irrelevant when doing large movements but would be unacceptable if surgical movements were minor[21] (for example, 0.5 mm difference on a 10 mm maxillary advancement means 5% deviation which would be quite a minor error, while a 0.5 mm difference on a 2 mm impaction means 25% deviation – that is quite a huge error).

Cephalometric analysis in the lateral view was made according to Roth-Jarabak analysis; cephalometric analysis in the frontal view was made according to Ricketts analysis using Dolphin® software. Virtual frontal and lateral cephalometries of the simulated surgery were extracted from the 3-dimensional planning and compared to the postoperative cephalometries, immediately after surgery (3rd–5th postoperative days), before possible positional adaptive relapse, or TMJ resorption or remodelling could be established. The resulting data for the simulated and actual movements of the jaws landmarks were then compared. The same operator analysed the preoperative and postoperative cephalometry.

Twelve angular and linear measures were considered in describing jaw movements (Table 1). The mean difference between planned and actual movements was used as a measure of accuracy.

Statistical analysis

Statistical analysis of the differences was made with IBM SPSS Statistics for Windows (version 24.0, IBM Corp) using the Wilcoxon signed rank test.

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Table 1
Linear and angular measurements considered.

Lateral projection	Abbreviation	Definition
Linear measurement		
Anterior facial height	AntFacH	Distance between anterior nasion and menton
Posterior facial height	PostFacH	Distance between sella and gonion
Ramus height	RamusH	Distance between articular and gonion
Angular measurement		
Gonial angle	GonAng	Angle between articular, gonion, and menton points
SNA	SNA	Angle between sella, nasion, and A points
SNB	SNB	Angle between sella, nasion, and B points
ANB	ANB	Angle between A, N, and B points
First upper incisor – SN	U1-SN	Angle between sella-nasion plane and a line connecting the incisal edge and the root apex of the most prominent upper incisor
First upper incisor – FH	U1-FH	Angle between Frankfort plane and a line connecting the incisal edge and the root apex of the most prominent upper incisor
Linear measurement		
Dental midline discrepancy	DentMid	Discrepancy between upper and lower dental midlines
Maxillo-mandibular midline discrepancy	MxMdMid	Discrepancy between maxillary and mandibular midlines
Occlusal plane tilt	OcclTilt	Difference in height from the occlusal plane to the zygomatico-frontal suture left – zygomatico-frontal suture right

Table 2
Preoperative diagnosis and surgical procedures.

Diagnosis	No.
Class II	2
Class III	10
Facial asymmetry	2
Lateral deviation due to condylar hyperplasia	1
Total	15
Surgical procedure:	
Maxilla	
Maxillary advancement	8
Maxillary advancement + impaction	3
Maxillary setback	1
Maxillary set-back + impaction	1
Maxillary impaction	2
Maxillary segmentalisation	6
Mandible	
Mandibular advancement	2
Mandibular setback	10
Mandibular centration	3
Chin	
Advancement	3
Retrusion	9
Centration	3

Results

The orthognathic patients treated at the Maxillofacial Surgery Unit of the University Hospital of Sassari between September 2017 and May 2019 were in total 47. This study was then performed on a cohort of 15 consecutive bimaxillary patients (9 male and 6 female, mean age 36 years) who respected the inclusion and exclusion criteria. Two presented a class II malocclusion, 10 a class III malocclusion, two facial asymmetry, and one lateral deviation due to hemimandibular elongation for condylar hyperplasia (Table 2). Of the 15 patients that were accepted for this study, all underwent repositional genioplasty and six maxillary segmentalisation in two or three segments (Table 3). No complications occurred during or after surgery.

An exhaustive summary of the measures, both angular and linear, planned and actually obtained for each patient, is shown in Table 3. Measurement of the differences among planned and actual movements was deemed accurate (Table 4). The differences were not significant for eight of 12 variables considered. The p values were evenly distributed and ranged from $p = 0.001$ to $p = 0.820$. Significant differences were reported in four measurements: U1SN ($p = 0.001$), U1FH ($p = 0.008$), dental midline discrepancies ($p = 0.006$), and occlusal plane tilt ($p = 0.001$) (Table 1).

Discussion

The results of this study show good accuracy of computer-assisted orthognathic surgery planned with Dolphin 3-dimensional software and guided by homemade resin-printed intermediate splints. Each step of the protocol has to be executed with precision, because the accuracy of each step is built on the accuracy of the previous one.[13]

Most of the variables analysed turned out to be not significant. This means that the difference between the virtually performed orthognathic surgery and the actual postoperative outcome did not differ that much. This result confirms what is already known from published reports: digital planning is much more accurate than the conventional surgical planning.[3–6]

In the digital surgical planning, all the anatomical structures are faithfully reproduced in an augmented model of the face, whilst in the conventional planning, the only structures reproduced in three dimensions are the plaster cast dental models.[18] Computer-aided surgical simulation represents a paradigm shift in surgical planning for patients with cran-

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Table 3
Simulated and actual movements for each patient.

Case no.	Angular distances (°)														Linear distances (mm)													
	GonAng		SNA		SNB		ANB		U1-SN		U1-FH		OcclTilt		RamusH		AntFacH		PostFacH		DentMid		MxMdMid	
	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real	Plan	Real
1	125.8	123.4	86	84.4	84.5	84	1.5	0.4	97.9	107.8	110.7	116.4	1	0.6	48.3	33.6	113.9	83.8	56.5	55.5	0.1	0.2	1.1	−1.7
2	125.1	138.8	83.6	86.1	76.5	83.3	7.1	2.8	94.3	107.4	106.8	109.9	0.2	0.1	42.3	41.4	120.7	109.6	68.8	66.3	2.1	−2.3	1.9	1.8
3	142.4	142.2	73.8	80	71.4	75.8	2.4	4.2	93.5	101.7	112.9	116.6	0.8	0.6	37.8	41.2	131.2	111.5	61.6	67.8	0.7	0.4	0.2	5.7
4	125.4	139.8	89.2	88.6	84.5	84	4.7	4.5	101.3	101.4	110.7	116.2	−0.3	−0.3	35.2	42.3	97.6	102.3	58.3	63.1	0.4	0.1	0.5	−1.8
5	128.2	132.6	86	86.9	80.5	82	5.5	4.9	86.8	99.6	100.7	104.9	0.5	0.1	48.5	47.8	119.4	126.4	74.4	77.5	0.8	−0.2	0.3	1.8
6	125.9	136.6	91.2	83.7	86	77	5.2	6.7	94.6	97.2	104.9	111.2	0.3	−0.6	48.4	45	117.2	108.1	77.6	67.1	0.1	−0.2	0.2	−1.5
7	126.1	128.4	86.3	87.1	83.2	82.3	3.1	4.8	89.7	100.9	100.4	105.5	1.8	0.8	42	45.1	113	115.5	75	76.6	0.7	0.6	1.1	−1.3
8	126.7	141.2	85.2	93.1	81.3	89.2	3.9	3.9	88.7	105.4	105.6	113.7	0.5	0	51.5	42.3	130.7	110.5	75.7	68.8	0	−0.1	1.8	−3.4
9	133.4	138	92.7	86.5	88.1	83.9	4.6	2.5	95.8	97.2	108.8	111.1	1.8	−0.5	45.8	42.5	102.9	119.4	61.8	64.6	0	0.9	2.6	−2.3
10	129.5	121.1	83.5	90.5	81.7	88.1	1.8	2.4	88	97.1	102.6	106.2	1.7	0.9	42.4	36.9	109	116.2	64.7	68.7	0	−3.3	1.5	5.3
11	137.2	133.2	84.4	80.3	82.3	79.5	2.1	0.9	98	102.8	108.8	118.8	1	0.6	47.9	48.5	122.7	113.5	71.7	70.2	0.6	−0.2	0.2	0.1
12	120.7	130.9	72.1	80.3	67.9	72.4	4.2	8	74.3	84.6	93.8	96.5	0.7	0.7	38.6	38.5	119.9	119.8	74.5	69.1	1.4	−0.9	1.2	−1.4
13	125.2	122.7	93.2	94.9	92.1	89.2	1.1	5.7	101.5	104.7	109.7	110.7	3.6	0	47.2	41.1	97.9	96.3	69.4	65.6	0.3	0.1	0.6	0.4
14	129.9	133.7	90.5	86	87.5	82.1	3	3.9	99.5	98	116.2	107.8	1	−0.7	46.8	44.4	108.8	120.1	62.2	67.5	0.7	−0.7	0.5	−2.5
15	130.7	134.1	88.5	88.9	86.2	86.3	2.3	2.6	90.8	106.2	107.5	112.9	1.8	1.1	39.2	42	116	118	65.7	70.2	0.4	0.2	0.5	−0.4

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Table 4
Comparison of simulated and actual movements. Data are mean (SD).

	Planned movement	Real movement	Difference	Z	p value
Angular distances (°)					
GonAng	128.81 (5.45)	132.21 (6.07)	−4.3 (7.15)	−1.846	NS
SNA	85.74 (6.07)	86.49 (4.41)	−0.75 (5.03)	−0.682	NS
SNB	82.24 (6.32)	82.61 (4.85)	−0.37 (4.89)	−0.227	NS
ANB	3.50 (1.71)	3.88 (2.04)	−0.38 (2.22)	−0.682	NS
U1-SN	92.95 (6.99)	100.80 (5.82)	−7.85 (5.71)	−3.237	0.001
U1-FH	106.67 (5.61)	111.23 (6.26)	−4.55 (4.72)	−2.669	0.008
OcclTilt	1.09 (0.94)	0.22 (0.57)	0.87 (0.98)	−3.182	0.001
Linear distances (mm)					
RamusH	44.13 (4.84)	42.10 (3.91)	1.96 (5.49)	−1.363	NS
AntFacH	114.73 (10.24)	111.40 (10.72)	3.34 (13.01)	−0.682	NS
PostFacH	67.86 (6.84)	67.78 (5.19)	−0.05 (5.05)	−0.284	NS
DentMid	0.55 (0.58)	−0.36 (1.10)	0.91 (1.41)	−2.731	0.006
MxMdMid	0.95 (0.74)	−0.08 (2.70)	1.03 (2.93)	−1.591	NS

iomaxillofacial deformities. All the information needed to perform the surgical simulation are stored virtually in the patient file and will automatically be combined in a single 3-dimensional image. It is possible to have a simultaneous representation in the 3-dimensional space of all the structures that will be affected by the surgery.

In the present paper we compared the planned movements with actual surgical movements in 15 bimaxillary cases operated on with a new protocol of computer-assisted orthognathic surgery with in-house 3-dimensional printed surgical guides. We reported a high rate of accuracy in most of the linear and angular cephalometric measures assessed. Only four of 12 variables were significantly different. For all of the patients, U1-SN and U1-FH angles (Table 1) increased in the postoperative condition compared to the surgical simulation. Interestingly, the postoperative SNA angle remained substantially adherent to the prevision.

A possible explanation is that both U1-SN and U1-FH values are mostly increased in the patients that underwent segmentalisation of the maxilla: the anterior fragment acquired a more pronounced torque during surgery than it was expected in the simulation, the centre of rotation of the premaxillary fragment in the A landmark. It is easy to understand that the torque of the maxillary fragments differs between simulated and real conditions because of the actual and unpredictable bony contacts along the osteotomies of the palatal vault.

A second, less convincing, explanation for these increased values is that during the 3-dimensional cephalometric analysis phase, the landmarks of the upper incisors' roots have been placed on to the bony surface of the premaxillary bone in a slightly more advanced position than they were placed on the 2-dimensional lateral postoperative cephalograms. This way, there would be some discrepancy between the simulated and the actual postsurgical incisor's proclination: this latter would be greater than expected because the upper incisor's axis was mistakenly placed in a more vertical position during the planning steps. This error can affect the angle among U1 axis and both the lines SN and FH.

The Dental-Midline discrepancy was also found to be a significant variable, although the differences between the virtual (0.55 (0.58)) and the postoperative (−0.36 (1.10)) mean values are so slight that could have been caused by the smallest variation in positioning the landmarks on the cephalometries.

Finally, the occlusal plane tilt comparison gave a *p* value of 0.001, which is considered to be significant in statistics. The difference between the virtual and the postoperative mean tilt is approximately 0.90°, a measure so small to be considered anyway insignificant from a clinical point of view. Facial asymmetry is in fact usually noticed only when occlusal canting is more than 3–4°.[24]

The major limitation of this study is the quite small number of patients undergoing evaluation. For this reason, a subgroup analysis of the case series has not been made. This type of analysis could be useful to establish if there are differences in the accuracy of the procedure according to the type of jaw movements. Further studies on larger cases will be needed.

In our opinion, the most relevant aspect in this study is the reliability of the intermediate digital splint in-house manufacturing. Digital planning software for PC-assisted orthognathic surgery is nowadays quite diffused. The one adopted in this study (Dolphin 3D, Version 11.95) permits in-house prototyping at a cost affordable for any institution (around €14,000 depending on the local market condition). After the surgical guide was virtually processed, the file was suddenly transferred to a 3-dimensional resin printer in the same office. This recent type of low cost 3-dimensional printers adopts Direct UV-light Printing (DUP) technology.

Normal UV light is the source of energy that provides to start the free radical polymerisation needed to change the liquid Imagepac resin into hardened objects.

In our experience, these printers are reliable and accurate, they are easy to use and do not require a dedicated room. The costs of the hardware are quite minimal: 3-dimensional resin printer described in this work (Wanhao Duplicator 7 plus, Wanhao 3D Printer) was sold, at that time, at around €500. We are now testing different models of resin printers, already

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adopted in jewellery and dentistry, that cost even less (around €200–250) and seem to perform well (for example, Photon, Anycubic). Resin consumption is negligible and each splint required less than a € of materials. Ultimately, the upside of 3-dimensional resin printers is that they make it possible to finalise the planning process in complete autonomy, without the need to discuss the cases with non-medical personnel, to upload data to outer companies, waiting long days for manufacturing and shipment, often from foreign companies. In our experience with two different medical companies, in addition to the cost of the software (around €9–10,000), the price of each splint was around €300 to be charged to the patient, that is now the price of a whole LCD-resin printer.

Conclusions

A new protocol for virtual surgical planning and completely in-house surgical guides manufacturing is reported. These 3-dimensional resin printed surgical guides were demonstrated to be a reliable alternative to the commercial ones and showed high rate of accuracy for most of the variables assessed. Four out of 12 of these showed significant errors, but two of them were only minimal discrepancies with no clinical implications.

To confirm this study's results, is necessary to perform other researches on larger and more homogeneous samples.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patients' permission

As a retrospective study it did not required ethics approval. Patients' permission was obtained.

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