UNIVERSITÀ POLITECNICA DELLE MARCHE

FACULTY OF ENGINEERING

Master degree in Biomedical Engineering

Augmented Reality App Development for maxillofacial surgeries

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IV. Abstract

Surgical guides for maxillofacial surgery are usually expensive since they need to be CAD developed and 3D printed for each different patient.

To overcome the cost's problem regarding these surgical guides, augmented reality (AR) technique is taking place in this field.

AR technology allows to merge virtual data with the real environment by augmenting 3D object in specific positions or displaying information about the patient.

The aim of this work is to develop and test in laboratory an AR application appliable to maxillofacial surgeries.

The application consists in overlaying the surgical guides on the mandible of the patient. The surgical guides have been developed on the basis of the surgeon indications, starting from a CT scan of a jaw.

The application has been realized in Unity to be available with HoloLens2.

A 3D model of a mandible has been printed to validate the application.

Five participants tested the application by over tracing the surgical lines on the 3D printed mandible following the projected holograms through HoloLens2.

The participants performed 2 consecutive trials.

The obtained mandible with the surgical lines has been scanned after each trial to digitally reconstruct (through CAD) the traced lines and compare them with the surgical guides previously designed.

The results allow analyzing the accuracy and precision of the developed application.

The mean distances for the two trial are 2,58 mm and 2,43 mm. Pareto analysis has been performed, indicating that among these trials the 75% of position's samples stayed under 4,22 mm in the first trial and under 3,74 mm for the second trial.

Even if the results are comparable with the literature and the use of AR could reduce costs and time of the surgical procedures, the work needs further developments to improve the application.

V. Abstract

Le guide chirurgiche per la chirurgia maxillofacciale sono solitamente costose poiché richiedono di essere progettate in CAD e poi stampate in 3D per ogni paziente.

Al fine di superare il problema del costo di queste guide, una soluzione potrebbe essere data dall'utilizzo della realtà aumentata.

La tecnologia di realtà aumentata permette di far coesistere mondo virtuale e mondo reale grazie all'utilizzo di ologrammi proiettati in posizioni specifiche atte al loro utilizzo, usati anche per aumentare informazioni cliniche sul paziente.

L'obiettivo di questo studio consiste nello sviluppare un'applicazione in realtà aumentata applicabile nella chirurgia maxillofacciale.

L'applicazione consiste nel sovrapporre le guide chirurgiche sulla mandibola del paziente. Le guide vengono sviluppate sotto indicazione del chirurgo partendo da una TAC della mandibola.

L'applicazione è stata realizzata in Unity per essere utilizzata con gli HoloLens2.

Il modello 3D della mandibola è stato stampato per validare l'applicazione.

Cinque partecipanti hanno testato l'applicazione tracciando le linee chirurgiche sopra la mandibola 3D seguendo gli ologrammi proiettati attraverso gli HoloLens2.

I partecipanti hanno effettuato 2 test consecutivi.

La mandibola ottenuta con le linee tracciate è stata scannerizzata dopo ogni test per ricostruire digitalmente (attraverso un CAD) le linee tracciate e compararle con quelle precedentemente pianificate.

I risultati hanno permesso di analizzare l'accuratezza e la precisione dell'applicazione sviluppata.

Le distanze medie per i due test sono state di 2,58 mm e 2,43 mm.

Attraverso l'analisi di Pareto è stato possibile individuare che per i due test, il 75% dei campioni di posizione è rimasto al disotto dei 4,22 mm per il primo test e di 3,74 mm per il secondo.

Anche se i risultati son comparabili con la letteratura e l'uso della tecnologia di realtà aumentata può aiutare a ridurre costi e tempi delle operazioni chirurgiche, il presente lavoro necessita di ulteriori sviluppi per migliorare l'applicazione.

1 Introduction

Maxillofacial surgery is the medical field that treats defects of the jawbone, maxillary bone, teeth, and face. Before such surgeries, the patient undergoes to CT scans to allow the surgeon to prepare a surgical plan by performing simulations based on the acquired patient's data [1].

The gold standard in maxillofacial surgery are the surgical guides, 3D printed guides that are developed custom-made for patient on a CAD software.

These guides are precise and accurate, but they are also expensive, it is necessary to 3D print them in suitable biomaterials that can go directly attached to the bone of the patient.

To overcome the cost's problem regarding these surgical guides, augmented reality (AR) technique is taking place in this field.

AR technology allows to merge virtual data with the real environment by augmenting 3D object in specific positions or displaying information about the patient.

In maxillofacial field, in image-guided surgery's context, AR could represent the next step of this medical area, since AR approach allows the surgeon to directly perceive where and how the holograms are placed into the scene.

By using AR technology, the surgeon could also interact with the projected object maintaining, however, the perception of the real environment.

Since maxillofacial surgeries are long and sophisticated procedures, the widespread implementation of these AR devices is not yet so present in real operating room [2].

In addition, the technology is relatively new, HoloLens2 are available in Italy since 2020, it needs tests and validations, it is important to verify if holograms and real-world alignment is compatible for the specific use in medicine. For these reasons the AR technology is still under development and improvement for medical field application.

The aim of this work is to develop and test in laboratory an AR application appliable to maxillofacial surgeries.

The application consists in augment the surgical guides developed starting from a CT scan of a jaw with the indication of a surgeon regarding where the cuts in the jaw are usually made during the surgery.

The surgical guides placements with respect to the real mandible is made in CAD software by align them to the target support, developed in the same software too.

By using the target support, image targets are attached to it and used by the HMD to recognize and augment the guides where it has been preplanned.

The HMD device used is Microsoft's HoloLens2, released in 2019. Nowadays, none, or very few scientific papers exist about the use of this new device in medical field.

This thesis research is one of the first works that develops AR application for maxillofacial surgery with HoloLens2.

The overall goal of this elaborate is to assess if this first approach to maxillofacial surgery under augmented surgical guides using HoloLens2 can be effectively applied during a real surgery, and if not, which could be the improvements to be done to make it usable in real procedures.

2 State of the art

In this section a review of the literature related to the concepts of augmented reality (AR) applied to the medical field, in particular to maxilla-facial surgery is provided.

Here the findings that other researchers have made regarding the use of AR in the medical field are summarized.

The state-of-the-art review provides a good background about AR topic in order to start developing this thesis with a deep and updated knowledge of the matter about the most recent developments in the AR field.

Extended reality technologies can be divided into augmented reality, virtual reality (VR) and mixed reality (MR) and they are relatively recent developments (Figure 2.1).

Virtual reality concerns all the technologies used in order to create an artificial digital environment which completely replaces the real world providing the user a visual sensation of immersion in such simulated place [3].

Augmented reality regards the display technologies able to overlay a digital content on the real-world.

Mixed reality is a more immersive technology because of its capability to blend digital and real world as AR but letting the user to interact with the digital object projected onto the real world in real time.

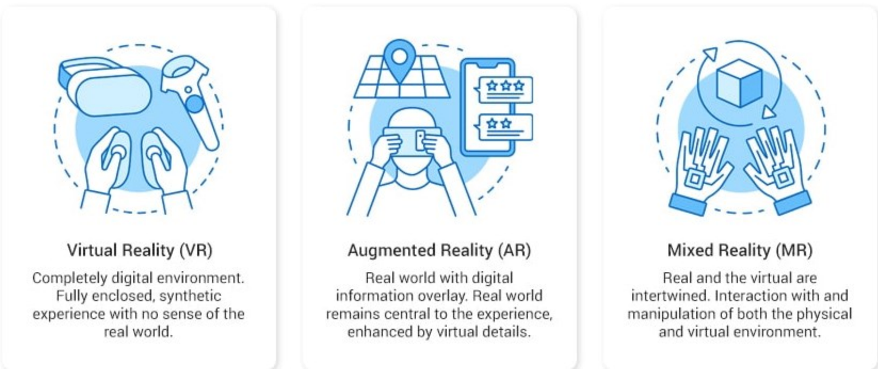


Figure 2.1 Virtual, Augmented and Mixed reality

2.1 History

The first AR technology has been developed by a Harvard professor I. Sutherland in 1968, who invented ''The Sword of Damocles'' device (Figure 2.2). It was a sort of featured head-mounted display hanging from the ceiling over the head of the user who was able to experiment virtual reality content overlayed onto the real world [4].

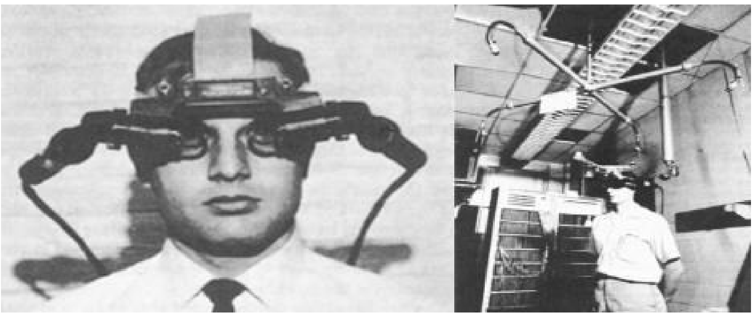


Figure 2.2 The sword of Damocles device

In 1983 M. Callahan developed the first optical see-through HMD by using half-silvered mirrors and monochrome CRT [5].

In 1990 T. Caudell uses for the first time the AR in an industrial application while working at Boeing Company. AR was used to assist workers for military and space applications.

In 1993 the first major project on AR has been developed, the KARMA (Knowledge-based AR for Maintenance Assistance). A see-through HMD was used to give instruction for the use of a laser printer [7].

In 1994 Milgram and Kishino proposed the continuous scale ''reality-virtuality continuum'' (Figure 2.3) which ranges between a complete virtual and a complete real environment. In the middle between the extremities there is the mixed reality (MR) where both virtual and real are co-present.

Figure 2.3 Reality-virtuality continuum

In 1999 AR technology has been used to improve navigation during test flights at NASA.

But only in 2000 an important advancement occurred. H. Kato invented the software ARToolKit, which is able to capture real actions allowing also the interaction with virtual objects. Since then, many improvements have been made in AR field until nowadays, where AR is applied to a huge variety of fields: advertising, gaming, industry, training and education and medicine.

2.2 AR technology

AR application development requires both software and hardware including computing devices such as a laptop, a smart phone or a tablet, a monitor or a display as output device, a camera, one or more markers and a tracking system.

The markers, as will be deeply explained in a deeper way later, are objects or even places used by the AR device to combine the real and the virtual environments.

Both mobile and fixed AR technology forms exist, they differ in the places where they can be used, the mobile AR systems are found in smartphones and tablets while the fixed ones require to be used in the specific place where they have been set. The major advantage of the mobile technology is the possibility to use AR everywhere without any limitation, however the fixed systems can realize more accurate and advanced augmentations.

2.2.1 AR Tracking

The tracking is the technique used to augment the objects at specific locations. It is defined as the dynamic process of scanning, recognizing, segmenting and analyzing the spatial properties of either the HMD or augmented objects' targets.

The tracking influences the accuracy of the AR application, it considers the position and orientation of the user whose most important part is the head because usually he wears an HMD in order to display the AR content.

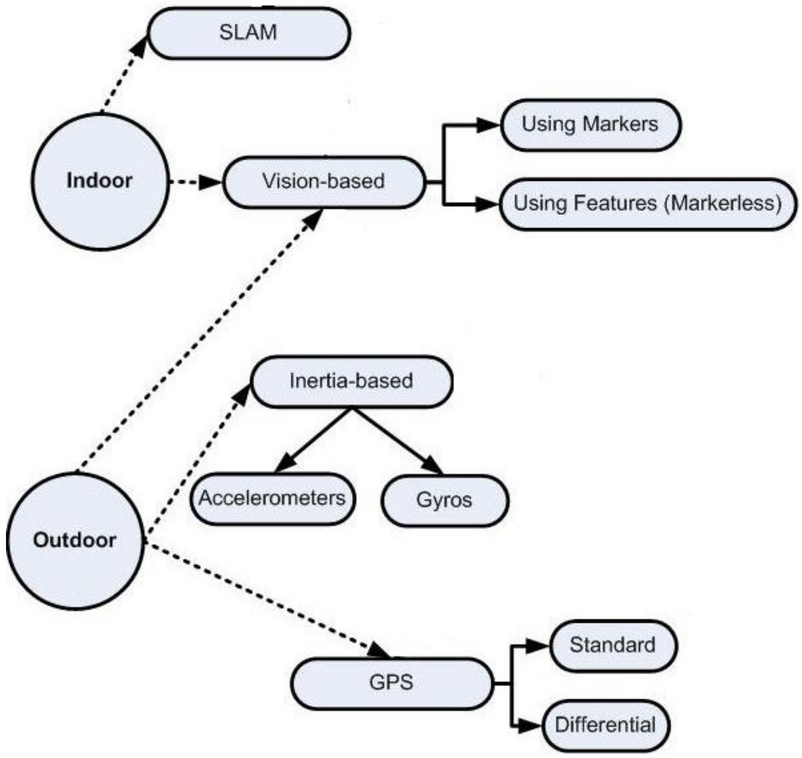


Figure 2.4 AR tracking methods [AR : tracking methods]

As shown in Figure 2.4 the most common tracking method can be divided into 2 main categories [7]:

1. Indoor methods used when AR application and user's movements concern a limited region. As indoor environment it is meant a space with unchanging dimensions where the user's movements are predictable.
2. Outdoor methods are used when the environment is limitless and user's movements are less predictable.

Indoors-methods are accomplished by either outside-in method or inside-out method. In outside-in the sensor is fixed at known position in the environment. The markers are placed on the user HMD. As a result, the sensor is located outside the user but it senses the markers on the user.

Inside-out methods include system where the markers are located around the environment or the environment itself is a marker and the user carries the sensor.

Indoors-system are categorized into 2 other methods: SLAM (Simultaneous Localization And Mapping) and Vision-based techniques.

SLAM method is mostly applied to robotic engineering. The device is able to sense the surroundings understanding the environment and providing an instant tracking.

Vision-based techniques need a computer vision image processing algorithm and could be subdivided into marker-based and marker-less methods [7].

Marker-based techniques require markers, e.g., distinct elements placed in the environment in order to be detected separately from other objects present in the same environment.

Marker could be divided into active and passive.

Active markers are detected by sensor since they produce a signal such as magnetic light.

Passive markers have patterns with a lot of features as it can be seen in Figure 2.5 in order to be detected by the vision algorithm, as will be better explain in next chapters.

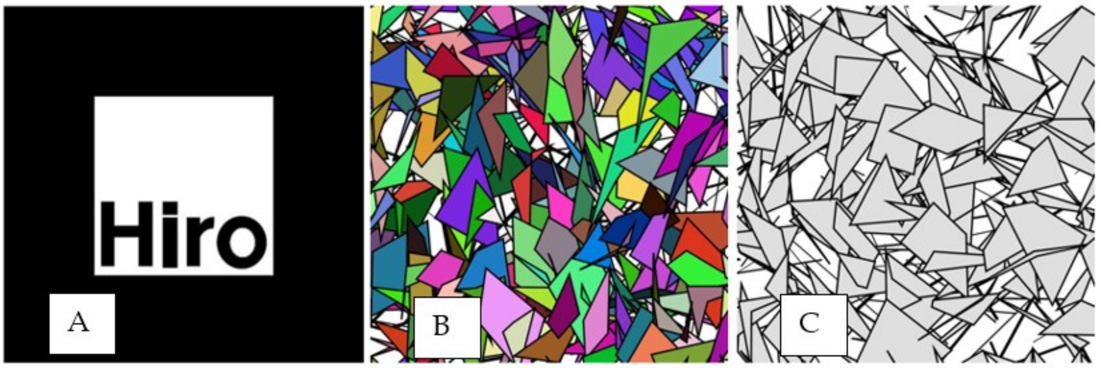


Figure 2.5 Markers examples. A) Hiro marker, B-C) markers generated through the website www.brosvision.com

The most important requisites for a good marker are features' size and pattern.

Different websites exist that create AR markers with different feature numbers, specific size, colored or not.

After the AR system found the image target (marker), the algorithm calculates the relationship between the marker and the camera, and can visualize the digital object in the right position.

Marker-less techniques recognize geometric features in the environment without the need of markers.

In order to create the target, websites and applications able to configure our model to be detected exist such as Vuforia Model Target Generator application (Figure 2.6).

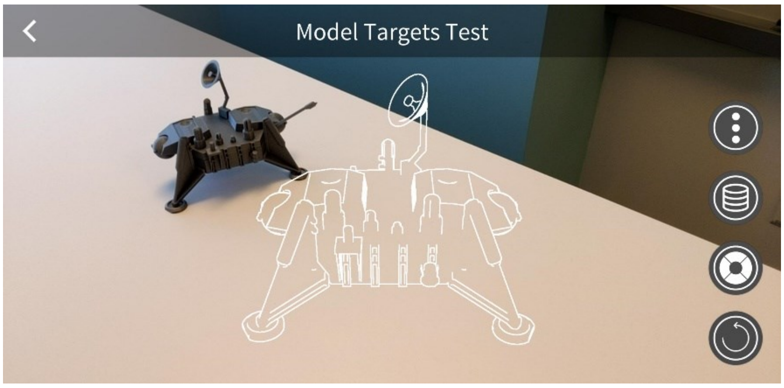


Figure 2.6 Model Target Generator example

Outdoors techniques could be subcategorized into inertia-based methods and GPS methods, although even vision-based method could be used as outdoor AR tracking techniques.

Inertial systems use gyroscopes and accelerometers as sensors to detect mobile device's position and the objects augmented because their operation is quite similar to human ears' otolith stones.

Gyroscopes detect angular velocities and orientations, e.g., rotational motions while accelerometers detect translational motions. Working together, these two devices are able to track the mobile camera's pose.

GPS methods are mostly used outdoors thanks to their ability to track user position. A database composed by viewpoints longitude and latitudes along with images collected during the years is used for the video tracking. Reference images are obtained and then used as AR references. The most famous examples of GPS based tracking are PokemonGO and HogwartsMistery, two AR games developed for mobile phones.

2.2.1.1 Position tracking algorithm

To correctly show the AR content on the display, the transformation matrix is calculated.

The transformation matrix is formed by a 3D rotation matrix R (|R|=1, $R^TR=I$) and a translation vector t and it is used to convert from world coordinate system to camera coordinate system, then to convert from camera coordinate system to a retinal coordinate system [8].

Eq.1

$$T = \begin{bmatrix} R & t \\ 0\ 0\ 0 & 1 \end{bmatrix}$$

The transformation between the two coordinate systems occurs by pre-multiplying the coordinate of the frame world (W) with the transformation matrix T:

Eq.2

$$\begin{pmatrix} x_C \\ y_C \\ z_C \\ 1 \end{pmatrix} = T_{CW} \begin{pmatrix} x_W \\ y_W \\ z_W \\ 1 \end{pmatrix}$$

It is also possible to chain together transformation matrices to transform from coordinate frame A to a coordinate frame C:

Eq.3

$$T_{CA} = T_{CB} \cdot T_{BA}$$

In camera coordinate system an object point is displayed on a 2D plane where distortion occurs (Figure 2.7)

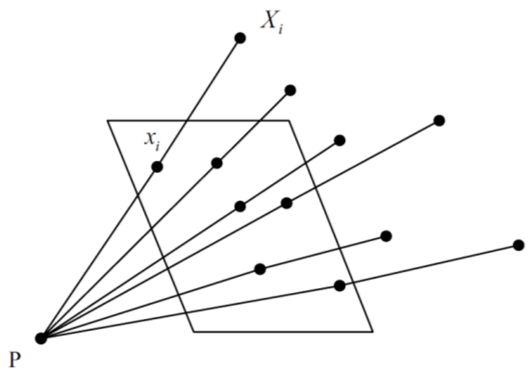


Figure 2.7 Camera diagram: the camera is considered as a pin-hole camera which displays object points on a 2D plane

As it can be seen in Figure 2.8, the O point is the center point of the camera and of the camera reference frame, the O_1 point corresponds to the intersection between the z-axis (main camera axis) and the image plane, O-O_1 distance is the focal length, while retinal and pixel coordinate systems are on the same image plane but with different origins.

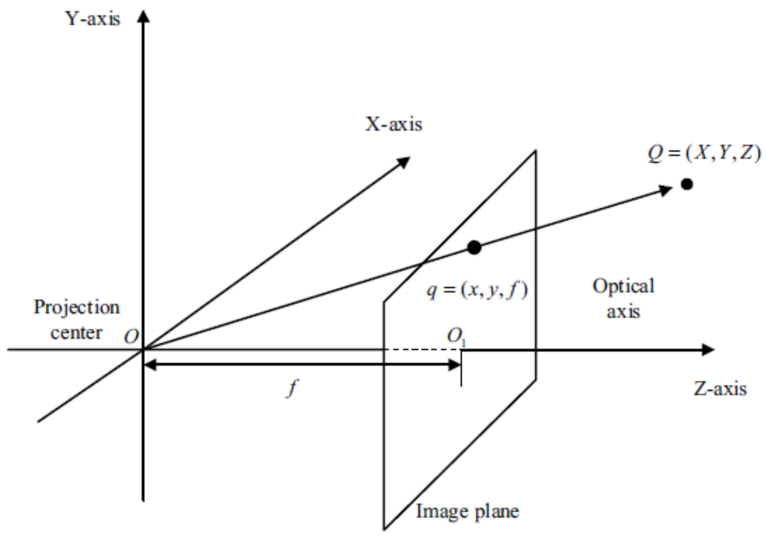


Figure 2.8 Camera model

The transformation from camera to retinal reference frame is a 3D point transformation to 2D point expressed by Eq.4 and Eq.5:

Eq.4

$$Z_C\begin{bmatrix}x\\y\\1\end{bmatrix}=\begin{bmatrix}f000\\0f00\\0010\end{bmatrix}\begin{bmatrix}X_C\\Y_C\\Z_C\\1\end{bmatrix}$$

with [x, y,1] ^{T} represents point coordinate in retinal reference frame

Eq.5

$$\begin{bmatrix}u\\v\\1\end{bmatrix}=\begin{bmatrix}\frac{1}{d_x} & 0 & u_0\\0 & \frac{1}{d_y} & v_0\\0 & 0 & 0\end{bmatrix}\begin{bmatrix}x\\y\\1\end{bmatrix}$$

Where (u,v) are the coordinates of the point and (u_0,v_0) the coordinate of camera main point in the retinal coordinate system, d_x and d_y are the physical dimensions of each pixels along x and y axes in image reference system.

The perspective projection matrix, instead, is calculated by eq.6

Eq.6

$$P = KT_{CW}$$

Where K the camera internal reference matrix expressed in eq.7, and T_{CW} is the transformation matrix. [8].

Eq.7

$$K=\begin{bmatrix}\frac{f}{d_x} & 0 & u_0 & 0\\0 & \frac{f}{d_y} & v_0 & 0\\0 & 0 & 1 & 0\end{bmatrix}$$

2.2.1.2 Tracking problems

From the literature comes out that there are two major types of errors in tracking systems [9]: static errors and dynamic errors.

Static errors affect accuracy even if the viewpoint and the objects are completely still.

Dynamic errors occur just when the viewpoint or the objects move in the environment, they are due to end-to-end system delays, e.g., the time that occurs between the time the user's pose is detected by the tracking system and the time when the images are displayed. These errors are present because in an AR system each single component needs times to fulfill its task [9].

Another problem is the tracking speed, which needs to be at a rate higher than 60 Hz, otherwise the objects would flutter in the scene.

Moreover, latency problem has to be considered, it corresponds to the difference between camera movement and point movement during time. Because of latency the object needs times to compensate the difference between its actual and correct position while the camera is moving. When the camera stops moving the object's offset is corrected.

Both latency and tracking speed can be overcome by changing the frame rate and buffering the camera stream knowing the latency [10].

2.2.2 AR registration

The registration is the technique related to the tracking that takes into account whether the virtual objects are correctly displayed with respect to the targets [11].

Moreover, registration needs to be accurate in medical applications, if, for example, in screw pedicles placement the augmented object is not aligned with the desired position for the placement, all the procedure will fail.

To reach the needed degree of accuracy camera rotation and translation must be accurately taken by using sensors allowing stable registration of camera movements [9].

2.2.3 *AR Visualization*

The overall perception of augmented reality is composed by three main different layers: the real world, the augmented 3D world and the screen space [12].

The real world is the real environment that can be observed through optical or video-see through devices, the AR world is the space where the rendered objects are superimposed and aligned to the real-world, whereas in the screen space the app interface and interaction command appear.

In order to achieve user-computer communication, the interface is used. In AR environment the interface is made by HMD that allow the user to interact and understand what is projected.

Keil et al. reported different techniques for augmented reality visualization that are listed below:

- Annotation and labels
- Highlights
- Assisting visual aids
- Additive elements
- Trans-media material

2.2.4 AR Displays

Two main categories of AR display exist: optical see-through and video see-through.

Both kinds of devices will be explained associated to HMDs (Figure 2.9).

Figure 2.9 HMD devices examples

Through the use of HMDs the user is able to see the surrounding environment realistically. Both AR and VR visualizations are possible using HMDs allowing the immersive experience to the user. The biggest difference is that with AR one or two cameras are needed and attached to the device due to the fact that in AR, visualizations are strictly related to the real user environment; while on the contrary with VR cameras are not necessary because the user is place in an environment that doesn't consider the real surrounding.

Optical see-through displays allow the user to keep track of the real world directly through a semi-silvered mirror, called optical combiners, in front of the user's eyes.

The mirrors are partially transmissive and partially reflective allowing the user to directly see through them and to also perceive virtual content.

Ideally all the light reaching the monitor should be reflected into the eyes and all the real-world light should reach the eyes.

Actually, most existing optical see-through HMDs reduce the amount of light reaching the user's eyes due to the combiners silvered nature which lets in only a part of the real-world light, making the device to act as sunglasses if turned off.

Figure 2.10 shows an optical see-through diagram.

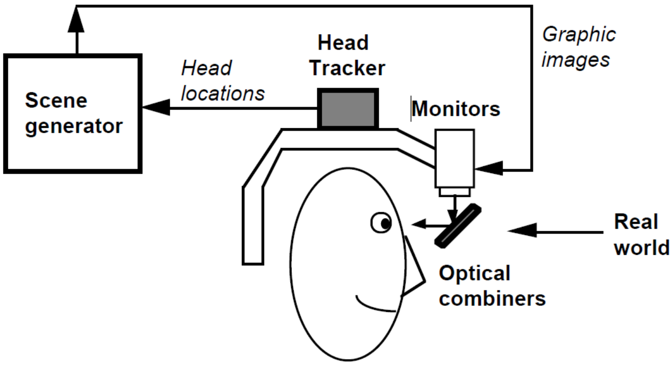


Figure 2.10 Optical see-through diagram

Video see-through HMDs, on the contrary, are equipped with one or two head mounted video cameras and one screen for each eye.

The scene generator component creates the graphic images that are combined with real world view provided from the cameras. As a result, the user is able to see a 3D environment in which real and virtual elements are blended. With video see-through devices if the glasses are switched off the user is blinded, in fact, he/she does not see the real world directly [13]. In Figure 2.11 is possible to observe the diagram of a video see-through device.

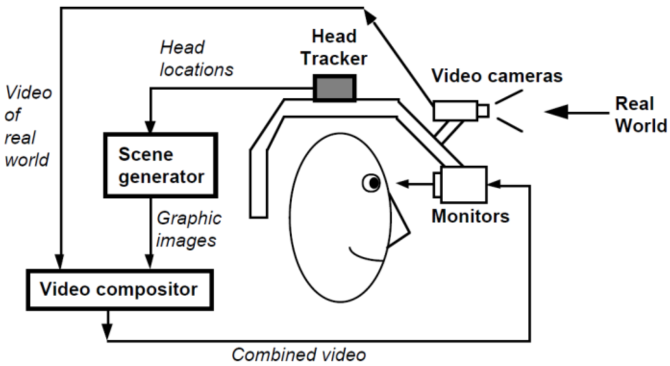


Figure 2.11 Video see-through diagram

2.3 Uses of AR in the medical field

The use of AR in medicine has been adapted to be used both as training tool and as surgical tool. It allows the physician to integrate diagnostic and treatment procedures with data visualization for a better working experience, safety and costs.

AR systems analyzed in this thesis focus on surgical guides to be used during maxilla-facial surgeries and orthopedic surgeries. Many studies pointed out that AR integrated procedure are comparable with traditional ones, however, there are still some limitations that needs to be overcome in future developments [14].

In Table 2-1 are listed the scientific articles related to the AR application in medical field, more specifically in orthopedic and maxillofacial surgery.

Table 2-1 Science papers about the application of AR in medical field. Columns: papers, HMD type, additional used device, application, used markers, AR content, results, pros, cons

PAPERS	HMD TYPE	ADDITIONAL USED DEVICES	APPLICATION	USED MARKERS	AR CONTENT	RESULTS	PRO	CONS
A Novel Dental Implant Guided Surgery Based on Integration of Surgical Template and Augmented Reality	HDM Sony HMZ-T1 personal 3D viewer	CCD	Development of an AR-based dental implant placement system appliable to either partial (PE) or fully (FE) edentolous patients. Accuracy evaluation between virtual planned and in vitro prepared implant site.	Rectangular resin marker (60x60x2 mm)	Planned implants with the adjacent anatomical structures to confirm the template position. Different colors to differentiate nerves and sinuses.	Mean deviation: 0.5±0.33 mm (FE) & 0.46±0.20 mm (PE) Apex: 0.96±0.36 mm (FE) & 1.23±0.42 mm (PE) Angle: 2.70±1.55 ° (FE) & 3.33±1.42 ° (PE) Depth: 0.33±0.27 mm (FE) & 0.48±0.37 mm (PE) Lateral: 0.86±0.34 mm (FE) & 1.1±0.39 mm (PE)	Less complicated approach with respect to other studies, better visual feedback is provided, deviations remain in the safety zone	In vitro study, reduced superstructures fit precision due to the deviations.
Mandibular Angle Split Osteotomy Based on a Novel Augmented Reality Navigation Using Specialized Robot-Assisted Arms -- a feasibility study	nVisor ST60	MicronTracker + Robotic Arm system	Development of an AR navigation in combination with a RAS (robot-assisted surgery) to perform the MASO technique with improved precision and automation	marker complex + custom-made module connector	The mandible and the marker complex are displayed within the drill position in different colours	Position error: 0.95±0.14 mm (experimental group) & 1.64±0.57 mm (control group) Average angle error: 5.34±2.48 ° (experimental group) & 10.46±4.36 ° (control group)	Minimal invasiveness, simplified operation and limited error	Difficult design process of the marker complex

PAPERS	HMD TYPE	ADDITIONAL USED DEVICES	APPLICATION	USED MARKERS	AR CONTENT	RESULTS	PRO	CONS
Augmented Reality as an Aid in Maxillofacial Surgery: Validation of a Wearable System Allowing Maxillary Repositioning	eMagin Z800	2 USB SXGA cameras + 1/3" image sensor + 2 optics	Maxillofacial surgery: LeFort1 osteotomy with AR aid	6 mm-diameter balls drilled into the vestibular cortical bone and brackets on the teeth	Green asterisks are displayed in positions defined during the planning in order to allow to move the maxilla to replicate planning	Average accuracy: 1.70±0.51 mm Lowest error: 0.60±0.20 mm along the frontal axis Greatest error: 1.06±0.40 mm along the vertical axis	Good average accuracy, HDM uses visible light	In vitro study
Precision of a Novel Craniofacial Surgical Navigation System Based on Augmented Reality Using an Occlusal Splint as a Registration Strategy	nVisor ST60	3D camera	Development of an AR based navigation system in order to measure the precision of the system during hole drilling in beagles' mandibles.	Fiducial marker as reference	Virtual 3D model and guidance information are displayed onto the real mandible.	Drilling holes mean time: 208 s Mean error: 1.32±1.77 ° Angular deviation range: 0.97°-2.89° Mean distance deviation: 1.29±0.7 mm	Shorter time to make the holes	Deviation should be less than 1.5 mm
Head-Mounted Display Augmented Reality to Guide Pedicle Screw Placement Utilizing Computed Tomography	HoloLens + Novarad OpenSight app (to integrate CT data with AR)		pedicle screw placement in a lumbar phantom	22-gauge cannulated spinal needles roughly at the pedicles	Virtual trajectories for screws are superimposed over the lumbar phantom to recreate the path that the surgeon has to follow	Placing time: 200 s Circular deviation radius: 2.5 mm 35 out of 36 needles remained within the pedicles	Technique usable for screw placement without the use of real-time fluoroscopy	Manual alignment of the hologram, static CT images, procedure made on a phantom

PAPERS	HMD TYPE	ADDITIONAL USED DEVICES	APPLICATION	USED MARKERS	AR CONTENT	RESULTS	PRO	CONS
Augmented Reality - Guided Lumbar Facet Joint Injections	HoloLens		Facets joint injections	3 ring markers	3D model with only 2 articulated vertebrae and 3 ring markers is displayed over the phantom model	39/40 perfect needle placements under AR guidance 40/40 perfect needle placements under CT guidance	Faster procedure, no unsafe placements, 1 AR guided placement missed the joint space by 2mm	Different needles are used with respect to the usual ones
The Holographic Human for Surgical Navigation Using Microsoft HoloLens	HoloLens		Show a stereoscopic vision of highly precise 3D-CG medical model	no markers - once a 3D-CG medical model is placed in a blended environment it is fixed to the place	Holographic human and 3D-CG surgical instrument are simultaneousl y generated. The human is superimposed on the actual patient	Stereoscopic vision of a precise medical model projected over the real world	High-definition holograms	
Effective Application of Mixed Reality Device HoloLens: Simple Manual Alignment of Surgical Field and Holograms	HoloLens	VEC-TRA H1 hand-held 3D imaging system	Manual alignment	3 points on the body surface near the surgical field marked as references acquired using VEC-TRA H1	Holograms of the considered body part are displayed with the points used as reference	Alignment time: 45.89s Mean error: 2.98 mm	Anatomically accurate alignment	Not suitable to be used as a strict mean of navigation system

PAPERS	HMD TYPE	ADDITIONAL USED DEVICES	APPLICATION	USED MARKERS	AR CONTENT	RESULTS	PRO	CONS
Video See-Through Augmented Reality for an Oral and Maxillofacial Surgery	4K camera		Maxillofacial surgery	no markers but TLD algorithm is used	Nerve canal and teeth are overlayed on the patient to help surgical visualization during the surgery	Target overlay error: 1mm	Simple clinical setting, seamless integration into the current medical procedures, good overlay accuracy	Tools and blood occlusion affect negatively the image registration, depth perception issues
A Novel Evaluation Model for a Mixed Reality Surgical Navigation System: Where Microsoft HoloLens Meet the Operating Room	HoloLens		Development of a new systematic method to evaluate Mixed Reality Navigation system already existing during clinical applications	radio opaque fiducial markers removed from the physical model but their placement is marked on the phantom	3D reconstruction of a patient's angiogram	Minimum static error Maximum walking error	Good precision, recall and FI-measure. Full efficacy of the method	According to this method the HMD has to be used in static conditions limiting the movements
Augmenting Microsoft's HoloLens with Vuforia Tracking for Neuronavigation	HoloLens		Investigation of HoloLens augmentation integrated with Vuforia object tracking to assess improvements in holographic stability	Cylindrical target created through Vuforia	3D model of a skull phantom is projected onto the real skull phantom in order to assess accuracy and errors	Manual registration times: 95 s Mean perceived drift: 4.39 mm Mean standard error: 1.29 mm	Significantly greater hologram stability	Needing to maintain a line of sight between the target and the phantom which is difficult to obtain at arm length distances.

PAPERS	HMD TYPE	ADDITIONAL USED DEVICES	APPLICATION	USED MARKERS	AR CONTENT	RESULTS		PRO	CONS
Toward Holographic-Guided Surgery	HoloLens	PST base system for optical tracking	HoloLens device is combined with the optical navigation system, applied to a phantom in order to assess accuracy of the experiment	reflective markers mount for the HoloLens + reflective spheres for the object	Cube hologram which represents the position of the cube on the measuring board	Tight fit experiment: Mean Euclidean distance = 0.6±0.2 mm (IGS) & 0.7±0.2 mm (AR) Maximum error= 1 mm (IGS) & 1.4 mm (AR)	Loose fit experiment: Mean Euclidean distance = 0.7±0.4 mm (IGS) & 2.3±0.5 mm (AR) Maximum error= 2 mm (IGS) & 3.6 mm (AR)	Switching focus problem solved, usable for a wide range of interventions,	Statistically significant difference between the IGS and AR experiment in loose fit experiments.

In orthopedic field AR technology has been used to guide the surgeon during the insertion of screws in the lumbar vertebrae [15] or during the operation of facet joint injections [16].

In both papers HoloLens are used as head mounted device (HMD) on which the STL files of the spine have been loaded with the AR application.

The AR app consisted in recreating the trajectories that the surgeon had to follow in order to put in place the screws or the needle.

Both Agten et al. and Gibby et al. [15-16], in order to assess accuracy, have taken CT images of the phantoms after the AR guided injections allowing them to measure the deviations between the AR injections and the preoperative planned placement.

It is remarkable the fact that in these studies they have used silicone material or opaque agar gel in order to simulate soft tissues present over the real vertebrae which don't allow to see the bone directly.

Great accuracy has come out in both case studies, whilst the drawbacks mostly concern the fact that it was used agar gel in order to replicate the soft tissues consistency which is good to simulate them but not perfect and the different dimensions of the used needles, in fact Agten et al. had to use a larger needle due to the presence of the agar gel that influenced the direction of the injection.

They pointed out, however, how AR is useful for the surgeon whose hands stay free and sterile during the whole procedure allowing a faster surgery.

Oral and maxillofacial surgery treats teeth, jaws, face, head and neck's diseases or defects.

Thanks to the CT scans made on the patient before the surgery it is possible to create the STL file of the maxilla of the patient in order to use it to create an AR application which could let the surgeon to operate without the usual surgical guides.

The MASO (mandibular angle split osteotomy) procedure is the most used to treat prominent mandibular angle. AR application to MASO has been performed by L. Lin et al. [17] assisted by a robotic arm system with limited errors.

Both L. Lin et al. and Y. K. Lin et al. in their papers [17-18] have used the AR in order to superimpose the 3D virtual models on the real environment improving this one thanks to the addition of colored lines indicating the nerves or the sinuses to avoid collateral damages.

Three studies [1-17-18] have used a customized image target as marker use to make the HMD displaying in the right place the holograms.

The marker used by Y.K. Lin et al. is made in acrylic resin and measures 60x60x2 mm. The used pattern is a simple square with the ''CCU'' letters written in the middle.

L. Lin et al. proposed a marker with displayed a black and white squares and rectangles, while T. Jiang et al. used a ''Hiro'' marker, which consists of a white square enclosed into a black one and in the white part appears the Hiro word in black.

These markers have in common the fact that they are rich in features, which are used by the HMD to recognize the marker. The more the feature are, the better the device will identify the marker and the better the holographs will be displayed.

It has to be noticed that the markers, in all these papers, have been attached to the mandible by creating a splint linked to a dental cast or orthodontic bite, in this way the marker stays still in its place.

Jiang et al. have directly drilled the beagle's mandible to attach the marker, whilst for the other cases a custom-made surgical template of the patient's mandible was used.

As it can be seen in Table 2-1 some studies used just HMDs while others integrated them with stereoscopic system or CCD cameras to perform the accuracy tests.

To be noticed is the studied proposed by Badiali et al [2]. in which instead of using the above-mentioned markers, they printed a replica of a cadaveric skull on which 6 mm-diameter balls have been inserted and a virtual skull model cut along the LeFort 1 osteotomy line was superimposed. These balls are used as marker references for the HMD, in addition three holes were drilled over the teeth and used as references to individuate the maxilla position.

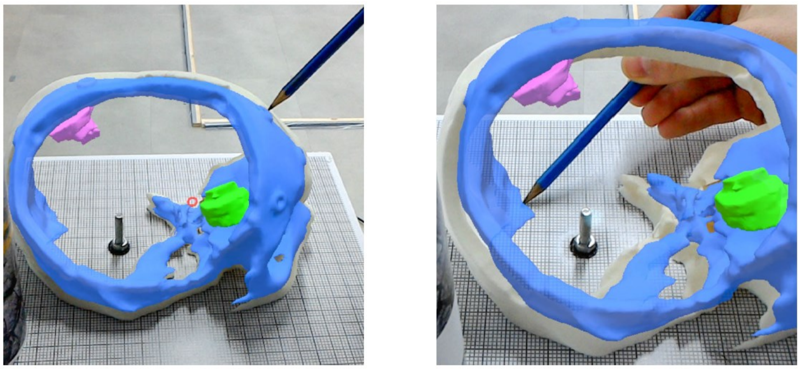
It is also, remarkable the study proposed by J. Wang et al. ''video see-through augmented reality for oral and maxillofacial surgery'' [1] in which they have used a real-time marker-less image registration method by matching the patient's teeth model with the teeth pose uploaded on the device in order to correctly position the phantom for the surgery. Limitations could be due by the occlusive presence of surgical tools which can be overcome by the fact that the image registration is just needed when the surgeon needs visual guidance.

D. Mitsuno et al. [19] presented a method for the manual alignment between holograms and surgical field by using reference points marked on the body surface. The surface with the points is then acquired using a 3D imaging system and superimposed onto the real body surface. They proposed to create an ABC triangle (where ABC are the vertex and correspond to the 3 reference points marked on the real body surface) annotating its pose and matching it with an abc triangle (corresponding to the 3 reference points on the holograms) pose.

The paper ''Toward Holographic-Guided Surgery'' by J.W. Meulstee et al. [20] proposed
two different methods to assess and improve accuracy in image guided surgery (IGS), a tight-fit experiment and a loose-fit experiment, showing also how to pass from the HMD reference system to the IGS reference system using the transformation matrix.

T. Frantz et al. in their research proposed the use of the HMD ''HoloLens'' with the SDK ''Vuforia'' to provide a more spatially stable hologram. The tracking has been made using Vuforia software that allows to create databases with the chosen target. They used a phantom skull and performed different measurements in order to assess the accuracy of the method.

The localization accuracy has been then quantified by the user's ability to place the point of a stylus on the phantom based on holographic points displayed on the HMD. The points on the phantom were not visible and the researcher performed different registration trials at different distances from the phantom (Figure 2.12) [21].



(a) (b)

Figure 2.12 Example of measurement techniques

a) Measuring localization accuracy by placing the tip of the stylus in the center of the holographic fiducial

b) Measuring perceived holographic drift by the difference in similar points

A similar work has been proposed also by T. Itamiya et al., they have used HoloLens and Vuforia SDK as well, but in order to develop a new application software development method to show stereoscopic vision of 3D models [22].

In both works Vuforia has been used to create the database with the AR marker recognizable by the application uploaded on the glasses.

2.4 Advantages and limitations of AR systems in the medical field

The use of augmented reality in medical field is increasing during the last years due to its ability to improve both educational and surgical aspects.

AR devices allow the optimization of the integration between the surgical plan and the surgery itself [23]: AR applications allow the preoperative 3D reconstructions which could be used for planning a surgery and could also be used during the surgery by means of HMD allowing the user to see medical information from medical values to holographic organs images and better improving the whole operational environment. Using HMD is a great advantage since there is not anymore, the necessity to move the display during a surgery procedure [14].

Moreover, it is well known that practice and training help human performances and this is one of the reasons why AR simulations are more and more used in medical field: specialized training simulators are created to improve medical students, practitioners or surgeons' skills.

One of the most remarkable benefit of using AR simulation is the possibility to create a safe environment for the user in the sense that he could fail without dangerous consequences [3] and redo the same task over and over in order to better learn what he will have to do during the real surgery or even to help memorizing the passages of the surgery itself.

During a surgery, AR is usually used for tailoring preferred incisions and cutting planes or displaying the positions of organ components in order to improve the safety; however, AR systems are really useful for organs with little movement which are easier to be displayed (e.g., bones, skull, brain).

Another major advantage is the possibility to visualize the precise localization of blood vessels, nerves or any other occluding or dangerously damageable part present during the surgery.

Although AR has introduced new perspectives, there are several limitations to be highlighted. The most important is the accuracy of the system which has to be as good as possible.

There is, in addition, the occlusion problem pointed out in different studies, which consists in the loosening of the hologram due to the occlusion by surgical instruments of the marker or reference points. This is, however, easily overcome because the surgeon can point out to the medical equip if they are interfering with the AR application.

Another issue could also be the HMD which could become uncomfortable to be worn for long periods due to its weight and heat production; it has also been demonstrated that AR projections produce nausea, headache and other not so pleasant symptoms for the user [14].

More technical issues could be the battery life of the HMD, in fact a surgery can last several hours and the glasses must have a battery life compliant with the surgery durations.

Also, the difficulty in the creation of an AR application for the medical field must be considered, in fact, it requires programmers, software developers and also physician in order to make the application appliable on real patients.

Moreover, the application, before it can be used on real patients, needs to be tested and validated, so it could take times to be effectively usable in the operating room.

In Table 2-2 all the pros and cons of AR application in the medical field that have been explained above, are summarized.

Table 2-2 Advantages & Disadvantages of AR application in medical field

ADVANTAGES	**DISADVANTAGES**
Visualization of information usually not available allowing to facilitate the surgery	The accuracy of the system needs to be almost perfect and it is difficult to obtain
Improved training for physician and medical students	Occlusion due to surgical tools or blood
Creation of a safe environment for the user: less failing fear	HMD has to be comfortable for the user
Possibility to re-do the task over and over to help the memorization of surgery phases	Symptoms due to AR projections
Visualization of the precise localization of blood vessels, nerves or any other occluding or dangerously damageable part present during the surgery	Battery life of the HMD
Faster procedure	The need of a team of different people specialized in different field
The surgeon hands are more-free to operate	The need of validation tests that takes times before the application can be applied on the real patient

3 Materials and methods

The aim of this work is to design and develop an AR application usable in the maxillofacial surgery to replace the surgical guides during the procedures.

This section presents the area of application of AR in maxillofacial surgery and the tools usually used to develop and validate an AR application. The tools include different kinds of hardware and software, from CT scans or intraoral scans to CAD tools, and specific software for AR development. In this section, even the methods available to align the models and the holograms are illustrated.

3.1 Maxillofacial surgery applications of AR

AR application is a relatively new approach in surgery field. It is most used in maxillofacial, orthopedic and neurosurgical fields since the body parts treated are not moving, they remain quite still during the whole procedure. AR applications already developed are most suitable for being used with stationary body parts.

For this thesis' purpose we will focus on AR application in maxillofacial surgery.

AR applications are involved during osteotomies, orthognathic surgeries, mandibular advancements.

Osteotomy procedure is used to treat both the jaw and the maxilla, the bone is cut and repositioned as decided during the surgical planning (Figure 3.1).

Mandibular advancements are procedures used to reposition the mandible performing an osteotomy on the jaw (Figure 3.1).

Orthognathic procedures are used to improve both the function and appearance of the upper and lower jaws, the teeth and the facial appearance as a whole. The genioplasty is one of the applications of orthognathic surgery, it is the chin surgery (Figure 3.1).

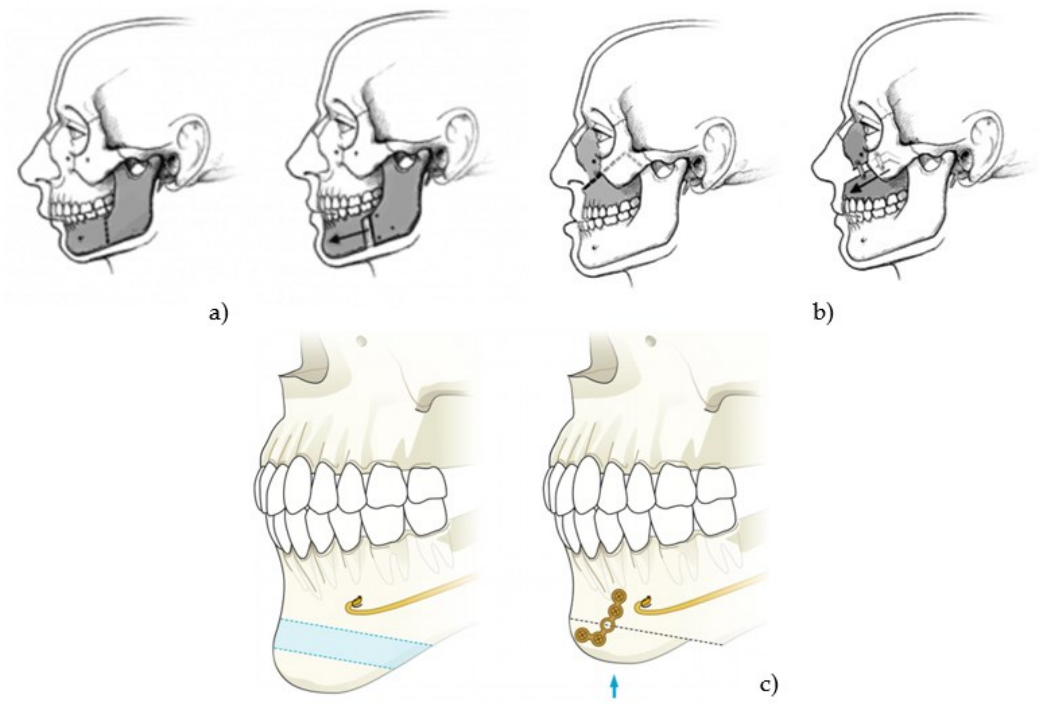


Figure 3.1 Surgery applications. a) mandibular advancement, b) maxillary osteotomy, c) chin surgery

Different studies exist about the application of AR guidance during these kind of surgery as can be seen in 2° chapter.

All these surgeries need a surgery planning before being realized by the surgeon.

The surgery planning is a preoperative phase during which the surgeon and the medical equip define the surgical steps and the bone segment navigation.

Usually, the surgical planning is made starting from a 3D model of the patient using the images provided by a CT scan.

Nowadays this phase is computer-based, it uses CAD software in order to obtain the 3D models which are then printed and used to plan the procedure.

There are several different methods to plan the surgery such as rapid prototyping (RP), computer aided engineering (CAE), computer aided design (CAD) and surgical simulation.

RP includes different techniques used to fabricate a scale model of an object starting from 3D CAD data. The development of the object is done by 3D printing or additive layer manufacturing technology.

RP models allow to test form, functions and design validation onto the patient data before testing them on the actual patient.

CAE tools are used to analyze the robustness and performances of the designs prior the building of the physical model.

CAD, instead, is used to create, modify, analyze or optimize a design. CAD softwares could be either 2D vector-based systems or 3D solid and surface modelers.

Virtual or Augmented reality technologies are also used for surgical planning to facilitate the manipulation of the 3D data.

3.1.1 Bone cutting

In maxillofacial field, orthognathic surgery is usually used to correct the jaw conditions and malocclusion problems.

There are different procedures included in the definition of orthognathic surgery and osteotomy:

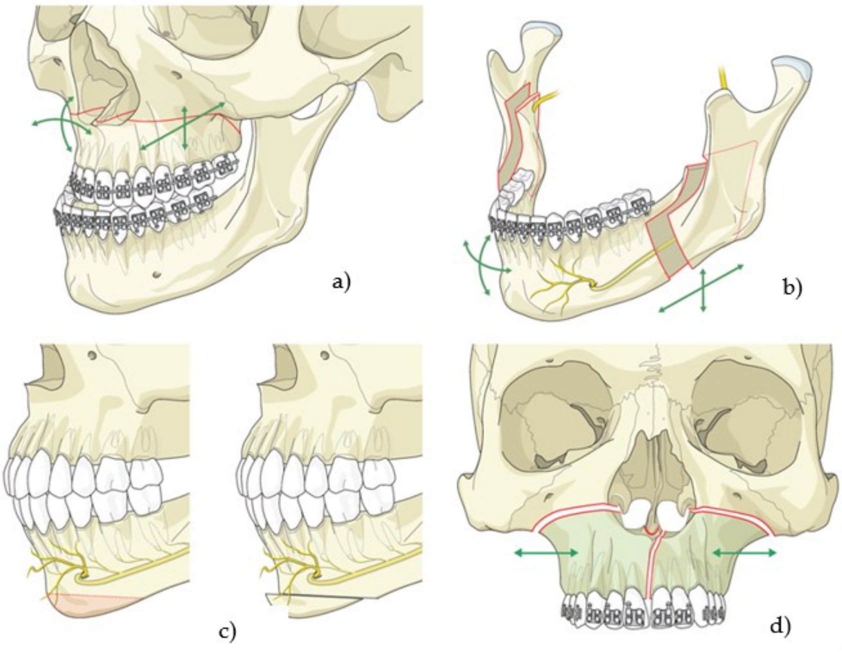


Figure 3.2 Cutting lines. a) Maxillary osteotomy, b) Sagittal split osteotomy, c) Genioplasty, d) Rapid palatal expansion osteotomy

- Maxilla osteotomy, used to correct upper jaw deformities or open bites. Incisions below both eye sockets are made allowing to move the upper jaw, the roof of the mouth and the upper teeth altogether as a single unit (Figure 3.2 a).
- Mandible osteotomy, used to correct receded mandible or open bites. Incisions are made behind the molars and lengthwise.

  Included in mandibular osteotomy procedures there is sagittal split osteotomy (Figure 3.2 b), used to correct mandible retrusion and mandibular prognathism. Horizontal and vertical incisions are made in order to move the mandible forward or backwards.
- Genioplasty osteotomy, used to advance or retract the chin. The incision is made below the premolars bilaterally and it is vertically extended in order to detach the chin from the mandible (Figure 3.2 c).
- Rapid palatal expansion osteotomy used in patients with constricted maxillae (Figure 3.2 d).

3.1.2 Surgical guides (virtual model)

The surgical guides are the lines used by the surgeon during the procedure to correctly cut the bone and/or reposition the bone after the cutting.

Figure 3.3 3D physical surgical guides

Usually, these lines are custom made and 3D printed (Figure 3.3), so they are physical objects, while with the use of AR application it is possible to project the lines without printing them.

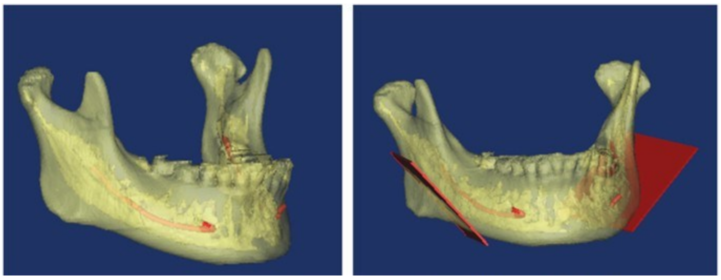


Figure 3.4 AR cutting planes used as surgical guides

To do so, a CAD software is needed in order to precisely make the lines in the right position and with the right measurements. These guide/navigation lines could be made as surface of few millimeters or as volume, then they could be colored and meshed in order to be imported into the software used to make the AR application.

3.1.3 Resin dental splints

The dental splint is a device, usually made in resin, used during procedures such as osteotomy to correctly reposition the cut part of the mandible.

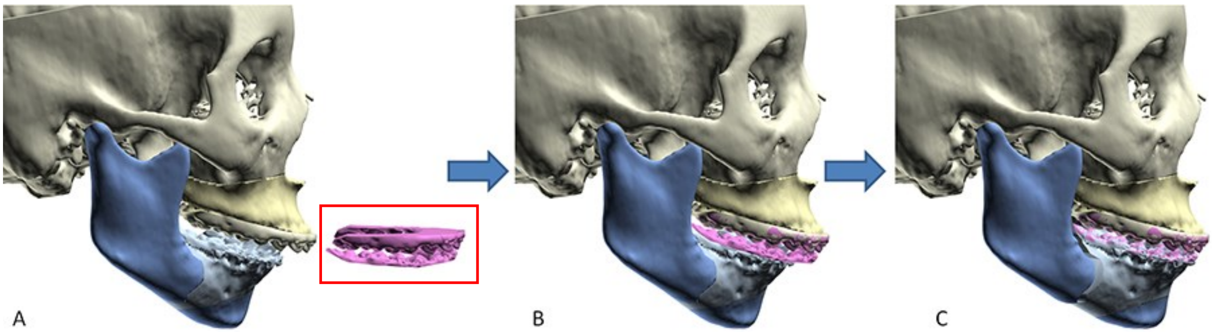


Figure 3.5 Dental splint example

Normally, a dental splint is custom-made by a technician starting from bite registrations and patient's teeth plaster cast or mould (Figure 3.5).

The patient is asked to bite a prefabricated mould made in a thermoplastic material which if heated is adapting to the patient's bite.

Then the cast or the mould are scanned with a laser sensor and the laser lines are projected onto the cast surface, a 3D image is created in the scanner software. After a CAD software is used to design the MAD.

During the procedure, the surgeon places the bite device and then brings forward or backward the mandible portion until the teeth perfectly fit the bite. In this way the user knows that the repositioning has been made correctly.

3.2 Data acquisition and 3D model reconstruction

Usually, the patient before a surgery undergoes a computed tomography (CT) or magnetic resonance image (MRI) to obtain images of the region to be treated, such as the mandible for maxillofacial procedures. The CT images and the related 3D model are used to plan the surgery.

Indeed, using CT images it is possible to create 3D reconstructions of the scanned parts which then provide the surgeon with a better visualization of the anatomical parts.

The 3D reconstructions are realized using different CAD software tools as described in the sections below.

3.2.1 CT scan images

In maxillofacial field the surgeon needs the images of the patient's jawbone that can be obtained by a CT scan.

CT scan is an imaging technique that uses x-rays to obtain a cross-sectional image of a body allowing to see inside it without cutting.

The x-ray beam rotates around the object within the scanner such that multiple x-ray projections pass through the object and are detected by an electronic detector array that records pattern of densities. Through complex reconstruction methods, an image is generated that records internal structure of object (Figure 3.6).

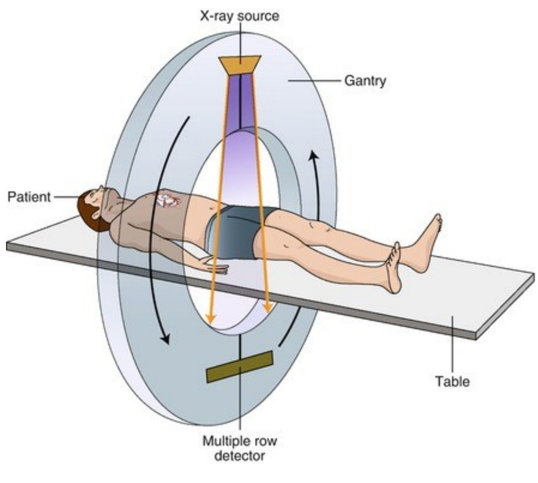


Figure 3.6 CT scan working principle

The tomographic image is a picture of a slice of the patient's body part, it consists of a square matrix of elements (pixel), each of which represents a voxel (volume element) of the tissue.

A measurement made by a CT detector is proportional to the sum of the attenuation coefficients (Figure 3.7). The attenuation coefficient is a measure of how easily a material can be penetrated by an incident energy beam (e.g. x-rays). It quantifies how much the beam is weakened by the material it is passing through.

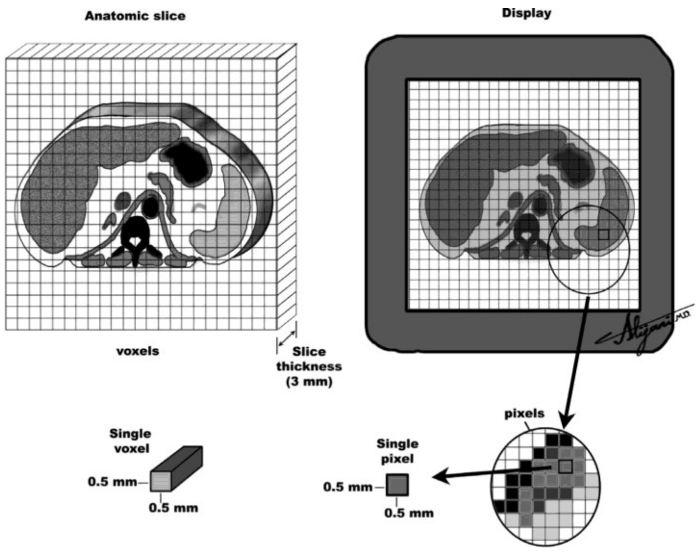


Figure 3.7 CT image

By tomographic reconstruction algorithms the image is then created and displayed in black and white.

A CT image provides structural information of the scanned body part, so it is useful for the surgeon to visualize the position of the jawbone and to reconstruct the 3D model of the bone to plan the surgery.

3.2.2 Intraoral scans

An intraoral scanner (IOS) is a medical device that allows to take impressions of the dental tissues in a digital way allowing to save time and cost [24]. IOS use light sources to detect teeth and soft tissues of the mouth from different angulations, then a 3D model of the patient is created.

No invasive substances are required to take the impressions and the scanned data saved in the STL format are sent to a CAD/CAM (computer-aided design and manufacturing) software that allows to manipulate and create the 3D model to be printed.

The light sources used can be distinguished for their use:

- Ambient lighting is used in passive techniques to illuminate intraoral tissues.
- White, red, or blue lights are used in active techniques where the object is illuminated from a single luminous point and through the triangulation process the distance between the object and the light is calculated.

Once operative the scanner emits the light bundle which is deformed by the teeth, detecting their pose [25].

The currently leading IOS available are four (Table 3-1)[intraoral digital impression technique]:

a)TRIOS (Figure 3.8)

b)CEREC (Figure 3.8)

c)iTero (Figure 3.8)

d)Planmeca Planscan (Figure 3.8)

Figure 3.8 IOS types. a)TRIOS, b) CEREC Primescan, c) iTero, d)Planmeca Planscan

Table 3-1 IOS types

Ios type	Company	Working principle	Light source	Powder coat spraying	Output file format
TRIOS	3-Shape, Copenaghen, DNK	Confocal microscopy and ultrafast optical scanning	LED	No	STL
CEREC primescan	Sirona, Bensheim, DEU	Smart Pixel Sensor captures the data at an extremely high resolution and assesses the contrast in each pixel	Blu light at a specific wavelength	No	STL
iTero	Cadent, Carlstadt, NJ, USA	Parallel confocal imaging	Red light laser beams	No	STL
Planmeca Planscan	E4D, LLC, Richardson, TX, USA	Optical coehernce tomography and confocal miscroscopy	Blue light laser	No	STL

IOS is a useful technique because the impressions are taken in shorter time and it is possible to immediately work on the impression. They show great accuracy and precision, along with less discomfort for the patient and a simplified procedure for the clinician.

The dental impression is then used in maxillofacial surgeries to recreate the model of the teeth used to create the orthodontic bite used during the procedure, to find the right position of the jawbone in surgeries like osteotomy.

3.2.3 CAD tools

The 3D model is obtained using CAD software that are able to render the dataset obtained from the CT scan in the DICOM format.

Software as Rhinoceros, MIMICS or ProPlan (Figure 3.9) allows the engineer or the surgeon to generate the STL model of the patient which can be used in AR app or be printed so that the surgeon can plan the procedure directly visualizing the structures that will be surgically treated and he can also manipulate them.

The CT scanned dataset can be directly imported into one of these softwares which can create a mesh object from it, able to be exported in various format according to the purpose, printing or AR applications.

These CAD software allow to create also navigational surgical guide which will perfectly fit the patient.

The CAD techniques allow a more rapid and accurate way of surgical planning, in fact in the past the procedure depended on the surgeon's experience regarding the anatomical parts involved, using CAD software this limit is now encompassed.

Figure 3.9 CAD tools' logos

3.2.3.1 MIMICS

MIMICS, which stands for Materialise's Interactive Medical Image Control System (Materialise, Belgium), is a medical image-based processing tool for creating 3D models developed to link these images to different applications.

MIMICS models can be applied to RP, CAE, CAD and surgical simulation.

In Figure 3.10 is represented the main screen configuration of MIMICS:

1. *Main toolbar*: contains the menus for the tools available
2. *Icon list*: contains the most used tools.
3. *Screen*: is divided into four panels displaying the four main views, coronal, sagittal, axial and 3D.
4. *Project management toolbar*: is the database of all objects, it contains tabs corresponding to each of the object types.

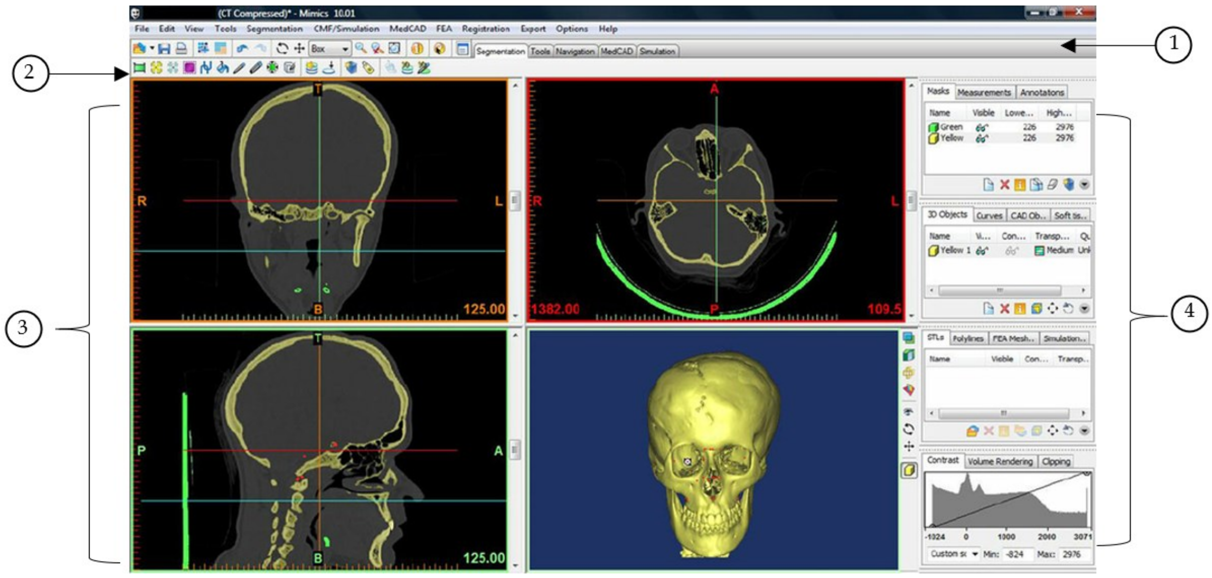


Figure 3.10 MIMICS interface

3.2.3.2 ProPlan

ProPlan (Materialise, Belgium) is a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT or MRI scanner (Figure 3.11). It is also used as pre-operative software for simulating/evaluating implant placement and surgical treatment options.

ProPlan has been intended to be applied to maxillofacial surgeries.

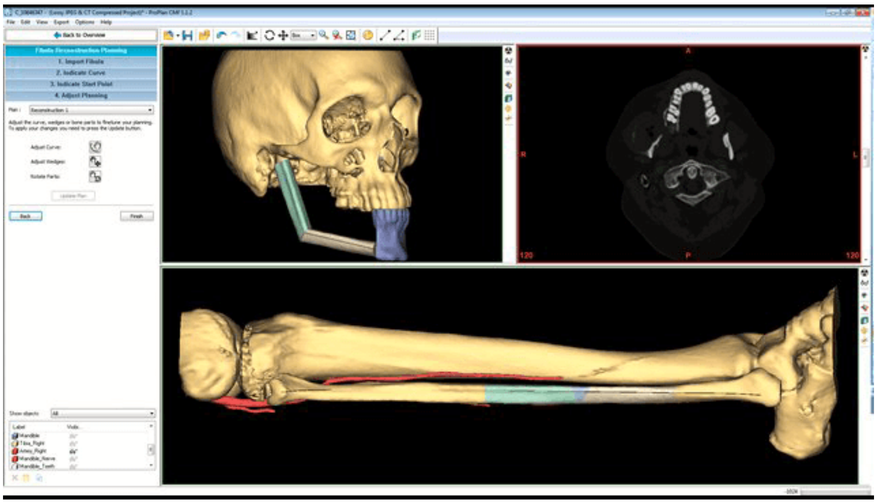


Figure 3.11 ProPlan interface

Starting from a CT scan of a patient it allows to:

- Generate 2D or 3D visualizations of the patient's anatomy
- Plan mandible and midface reconstructions, osteotomies, reposition bone fragments and orthognathic procedures
- Perform accurate 3D cephalometric analyses
- Virtual Splint creation, exportable to your 3D printer

3.2.3.3 Rhinoceros 6

Among the several different CAD tools available on the market, Rhinoceros is explained in a more detailed way because it has been used to create the models.

Rhinoceros 6 is a CAD software for surface modelling developed by Robert McNeel & associates.

In this software the geometric entities are represented by Non-Uniform Rational B-Splines (NURBS), which are a mathematical model that represents curves, surfaces, solids and free-form shapes in a very accurate way.

Rhinoceros is intuitive and accessible to everyone; it allows the use of shortcuts and a research bar in which the command can be written.

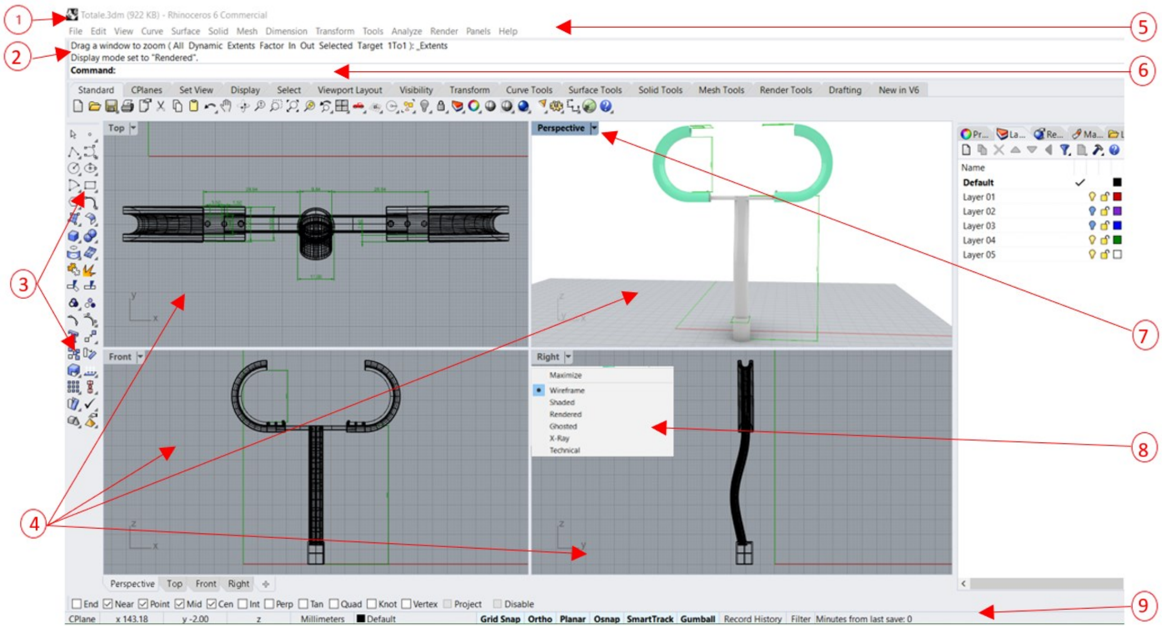


Figure 3.12 Rhinoceros interface

In Figure 3.12 is represented the software interface in which is possible to distinguish:

1. *Title bar*: where current file's name and size are displayed;
2. *Command history window*: shows the previous command and prompts;
3. *Toolbar*: includes all the graphic icons for starting the commands. It is customizable to facilitate the work to the user;
4. *Viewports*: corresponds to Rhinoceros' working environment, including the views' title, the object's visualization, the backgrounds, construction plane's grid and world axis's icon. It is possible to subdivide the model into layers and put them into different levels named by the user;
5. *Menu*: contains the Rhinoceros commands grouped by function;
6. *Command prompt*: shows prompts for command actions allowing to type command names and options;
7. *Viewport title*: by left-clicking the mouse button the viewport is activated without losing the selected objects;
8. *Viewport title menu*: by right-clicking the mouse button or clicking down the little arrow is possible to see the title of the selected view;
9. *Status bar*: displays the current coordinate system and position and the delta of the cursor;

3.3 AR application development

After the CAD 3D model is obtained, in order to develop the AR application, the next steps are:

- Target choice
- Alignment between real and augmented world
- Application development
- Application import onto the device (HMD)

3.3.1 AR application requirements

The development of AR applications has to satisfy two main requirements:

- The target size, shape and type
- The alignment algorithm

The target is needed in order to allow the HMD to recognize it and project the holograms, while the alignment is necessary for displaying the real and augmented world and objects aligned with respect to each other.

3.3.1.1 Target

The target is an image or a 3D object that the SDK (Software Development Kit) through its API (Application Programming Interface) can detect and track in order to augment the content of the application.

The target according to its type, image or object, has to full-fil some requirements: being rich in details, having high contrast, no repetitive patterns, being in JPG or PNG format.

The SDK then will create a database in which the target uploaded will be present and usable during the development of the app in the specific software. The database needs to be downloaded in the right format according to the used software and imported in it.

Generally, the SDK software gives a feedback about the quality of the target chosen through a star rating method. According to the number of fulfilled requirements, the rate will be good or bad. Bad target will not work properly, they could not be tracked or recognized by the application.

First of all, the image target type could have different forms:

- Flat image
- Cylindrical shaped image
- Multitarget image, that is a collection of multiple images combined into boxes.

The 3D object target could be of 3 different origin:

- Object target that is created through the scanning of a physical object
- Model target that requires a CAD model
- Model target from 3D scan

The attributes relative to the 3D object target include that the object needs to be rigid and placed on a stable surface.

Other types of target present in literature are optical markers detected by dedicated cameras, or fluorescent markers used during laparoscopic procedures allowing a good visibility and remaining in the body also after surgery.

Also, electromagnetic system has been proposed as a marker system, but it has the problem of distortion due by all the metal tools present during the procedure [14].

The simplest used targets are image target, they can be obtained via websites aimed to generate image targets which fulfill the requirements above listed.

Example of these websites are:

- www.brosvision.com
- AR.jsMarkerTrainig
- Qr-code generator

Brovision (Figure 3.13) is a website that generates 2D image rich in features as triangles, quadrangles and lines. It gives the user the possibility to choose the density of the features by selecting low, medium or high from a drop-down menu. It also enables to obtain colored images or black and white images. The file can be easily downloaded by right clicking onto the image and then imported into the SDK software to create the database.

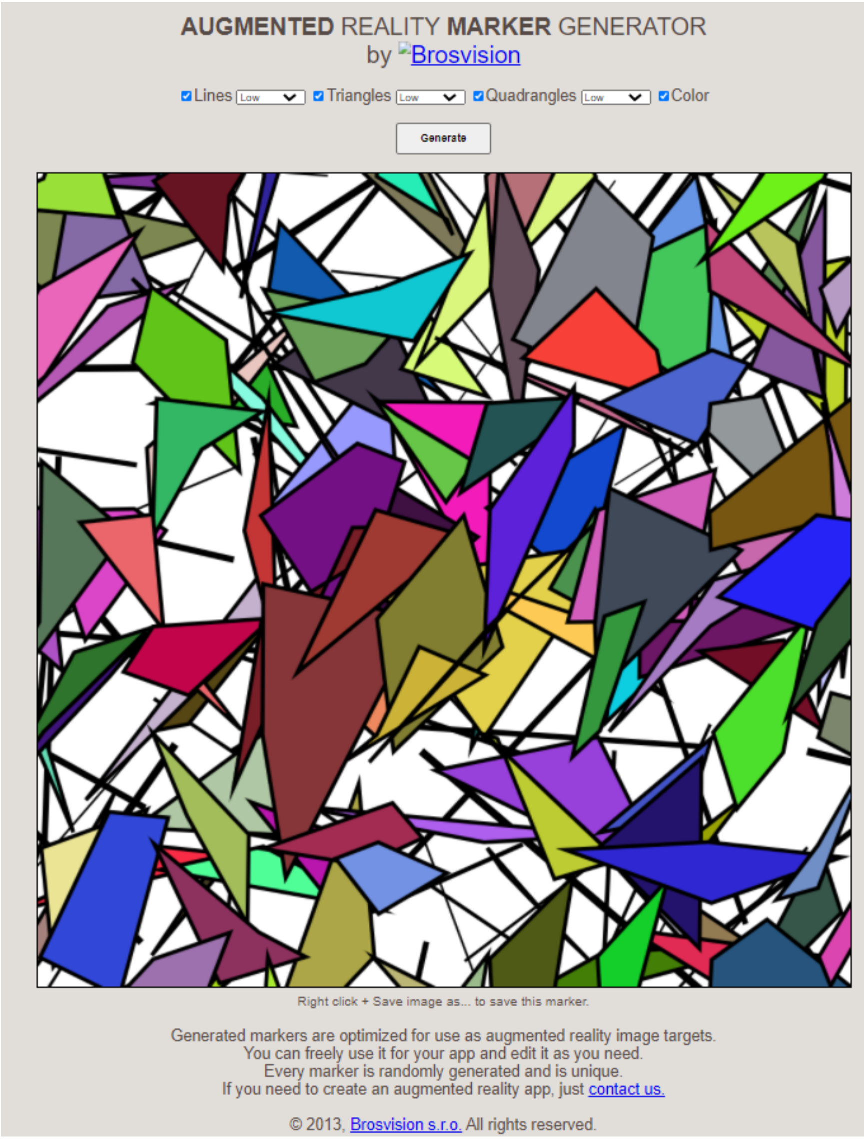


Figure 3.13 Brovision website for target image generation

AR.js Marker Training (Figure 3.14) creates the image target asking the user to upload an image that will be inserted inside the black squared frame. The user can also select the pattern ratio, e.g. how big his image will be with respect to the frame, and the image size in pixels.

The website offers also the possibility to download the image or to download a PDF file containing 1, 2 or 6 copies of the target per page.

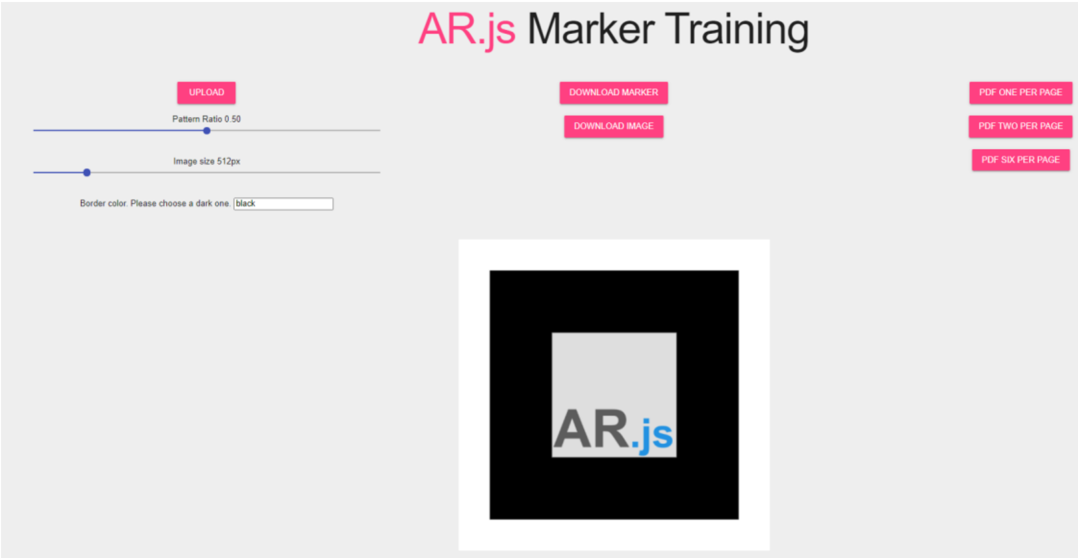


Figure 3.14AR.js Marker Training

Another method to create the image target is to use QR codes, which are rich in feature due to the fact that are made by a lot of tiny squares.

Several QR code generator (Figure 3.15) are present on the internet, they offer the possibility to choose what the code will encode: an URL, a text, a contact and so on.

For the purpose of generating a target image what the code encodes is not relevant, what matters is the image of the QR-code that will be used as target.

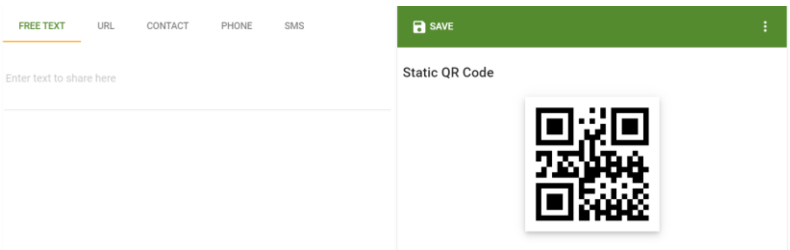


Figure 3.15 QRcode generator

3.3.1.2 Alignment

To obtain the maximum precision during the augmentation is necessary to correctly align the real world and what we want to augment, the computer-generated images.

The alignment can be done either manually or automatically.

The manual method is slower and could also be a bit imprecise but is the simplest between the two. It is made using a set of trackers which track fiducial markers placed on the body structure also during the surgery, they could also be the previously explained image or object target, or also optical marker. By tracking the target, the system has point of reference allowing it to correctly position the computer-generated images onto the real world. In Figure 3.16 is reported an example of manual alignment used by Mitsuno D. et al. [19] in their research.

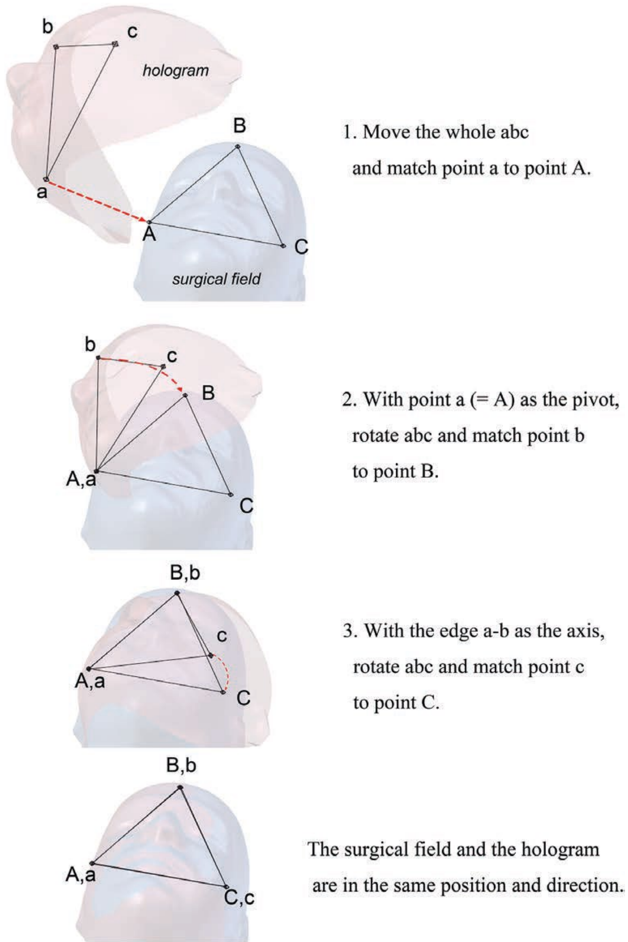


Figure 3.16 Manual Alignment example

As it can be seen in the image, translations and rotations are made in order to make the two sets of points to coincide and be aligned.

The automatic alignment, instead, uses different methods for operative field analysis. The computing power is used to predict the organ movement and see it, also either a RGB camera can be used to make the registration or a laser surface scanning technique which aligns the images scanning a huge number of surface points. The limitation in these cases is the need of a direct line of sight because they are camera-based [14].

3.3.2 Hardwares

Different types of hardware devices are used to develop an AR application, the HMD and the scanner through which obtain a *.vmrl CAD model of the scanned object, making possible the comparation between positions and orientations of scanned objects and planned ones.

Nowadays, there are several HMDs available on the market, produced by Sony, NVIS, eMagin, Microsoft and also Google.

From literature the most used in medical applications are Microsoft's HoloLens, as it can be seen from Table 2-1, but also nVisorST and Z80003DVisor and Sony's HMZ-T1 devices have been used for the same purposes.

Table 3-2 Comparison between the four HMDs used in medical field in literature

Device name	HoloLens1	nVisorST	Z8003DVisor	HMZ-T1
Display technology	Holographic lenses (waveguides)	FLCoS	OLED	OLED
Resolution	2.3 M total light points	SXGA 1280x1024	SVGA 800x600	1280x720
Field of View	34°	60°	360° horizontal FOV	45°
Vision	Binocular	Binocular	Binocular	Binocular
				

In Table 3-2 is shown a comparison between the technical specifications of the four HMDs used found in literature. However, since this work has been made using HoloLens 2, in the next section, this HMD will be deeply explained.

3.3.2.1 HoloLens 2

HoloLens2 is an HMD (Figure 3.17) in the form of smart-glasses designed and manufactured by Microsoft as the successor of the previous Microsoft's HoloLens, released in 2019.

As HMD, HoloLens2 are used to project images and allows the user to see through it, so they are quite suitable for AR application.

Figure 3.17 HoloLens2 HMD

3.3.2.1.1 Working principle

HoloLens2 HMD shows images and holograms just to the user, other people are not able to see what it is augmented. The user wearing the device is still seeing the real world with overlaying images onto it.

HoloLens2 are able to track the user's movements letting him to use hand gestures and gaze gesture to interact with the holograms.

3.3.2.1.2 Characteristics

Hololens2 are composed by a visor which contains the sensors and the displays, the headband used to wear the device, it allows through and adjustment wheel to regulate the fitting of the glasses, the brightness and volume buttons. Hololens2 are charged using an USB-C cable that is used also to connect the device to the computer, the charger power is 18 W, suppling 9V at 2A.

In the Table 3-3 below are listed the device specifications given from Microsoft on the HoloLens2 website.

Table 3-3 HoloLens2 Characteristics

Display	
Optics	See-through holographic lenses (waveguides)
Holographic resolution	2k 3:2 light engines
Holographic density	>2.5k radiants (light points per radian)
Eye-based rendering	Display optimization for 3D eye position
Sensors	
Head tracking	4 visible light cameras
Eye tracking	2 infrared cameras
Depth	1-MP time-of-flight depth sensor
Inertial measurement unit	Accelerometer, gyroscope, magnetometer
Audio and speech	
Microphone array	5 channels
Speakers	Built-in spatial sound
Computer, connectivity and power	
System on chip	Qualcomm Snapdragon 850 Compute Platform
Holographic processing unit	Second generation custom-built holographic processing unit
Memory	4 GB LPDDR4x system DRAM
Storage	64 GB UFS 2.1
WiFi	802.11ac 2x2
Bluetooth	5.0
USB	type

3.3.3 *Softwares*

To develop an AR application different kind of software are needed: a software development kit (SDK) and application programming interfaces (APIs), a cross-platform engine, an integrated development environment (IDE) and a 3D point cloud processing software.

The difference between an SDK and an API is that the SDK is a set of tools used to develop software applications targeting a specific platform. The SDK includes the tools, the libraries, the documentation and example codes which can help to develop the application. An API, instead, is an interface that allows software programs to interact with each other. APIs differentiate between them for their functionality. Summarizing an API can be seen as the simplest version of an SDK.

There are various SDK available including Vuforia Engine and GoogleARCore.

Since the main goal of AR is to accurately project images in precise position onto the real world, it is important to calibrate the real world through the registration process, as mentioned in chapter 2. To do so it is necessary a software in which the user is able to position the operator's point of view, the targets and the holograms that will be displayed. The most used software for AR application development is Unity, a cross-platform engine.

In order to deploy the application on the HMD HoloLens, VisualStudio, an IDE, is the software that lets to deliver the app to the glasses. After the AR app has been tested onto the smart-glasses it is necessary to validate the work done by analyzing if the holograms were displayed in the right place, to do so it is necessary to scan the 3D printed model and then compare the printed model with what was displayed on the HMD by using a 3D point cloud software like CloudCompare.

3.3.3.1 ARCore SDK

ARCore SDK is used with the software Unity to develop AR apps for Android devices. It is provided as a standalone *.unitypackage, downloadable from the ′′downloads′′ page.

Its Augmented Images APIs lets the user build AR app that can detect and augment 2D images in the environments. The images are provided by the user, the ARCore through a computer vision algorithm extract the features form the images and stores a representation of them in one or more databases.

At runtime searches for these features, estimating their position, orientation and size and provide for the augmentation.

ARCore can only respond and track images that are fixed in place on a flat surface or that are moving, but it can't track 3D objects.

This SDK gives score quality of the images rating them from 0 to 100, the recommended score is at least 75. Obviously, the images have to full fil some specific requirements:

- Image's resolution at least 300x300 pixels
- JPEG or PNG format images
- Have the right number of features, not too low but not high as well
- Repeating patterns have to be avoided.

3.3.3.2 VuforiaEngine

Vuforia Engine is an AR SDK designed by Qualcomm for mobile devices, allowing the creation of AR app.

It recognizes and tracks planar images or 3D objects in real-time through the camera by the use of Computer Vision technology, it is able, then, to correctly place the projections on the real environment.

Thanks to this feature, Vuforia allows the creation of target tracking-based applications that could be a 2D image or a 3D object target.

Vuforia is able to recognize different types of targets (Figure 3.18) such as single image, multi target, cylinder and 3D objects.

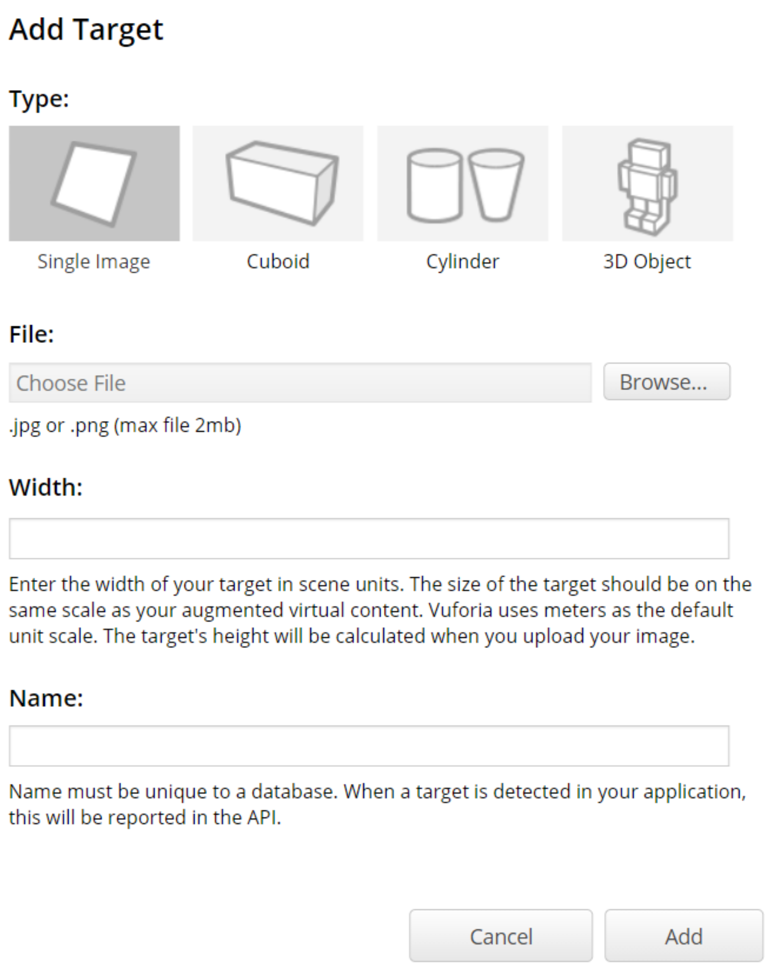


Figure 3.18 Target types accepted by Vuforia

In order to create a 3D object target Vuforia provides the ''Model Target Generator'' desktop application that allows you to quickly convert an existing 3D model into a Vuforia Engine dataset.

Another feature of Vuforia is the LicenceManager, which provides the tools and information that the user needs to create and manage the licenses. Each license key is usable just in a single app, so for each Vuforia app developed an unique license key is needed.

The license will be after added to Unity in order to be able to develop the application.

After that the target database can be downloaded and imported with the *.unitypackage format into Unity.

3.3.3.3 Unity

Unity is a software used to create and develop computer games and AR applications.

Through this software it is possible to import databases with the targets, add what has to be augmented, add various components to our objects to create animations, position the objects in the space and add tools such as MixedRealityToolkit or ARfoundation useful for AR applications.

The app created can be made for different platforms, android, apple and windows, after the scene is created is then saved and built to be imported in VisualStudio.

The scene includes all our objects, either the ones that will be augmented and the ones used as reference, the background if there is one, the position of the camera and the light source.

Unity gives the possibility to create 2D and 3D games and applications using as a primary scripting API the language C#. It possesses an AssetStore in which are present assets that can be buy and used in the own project.

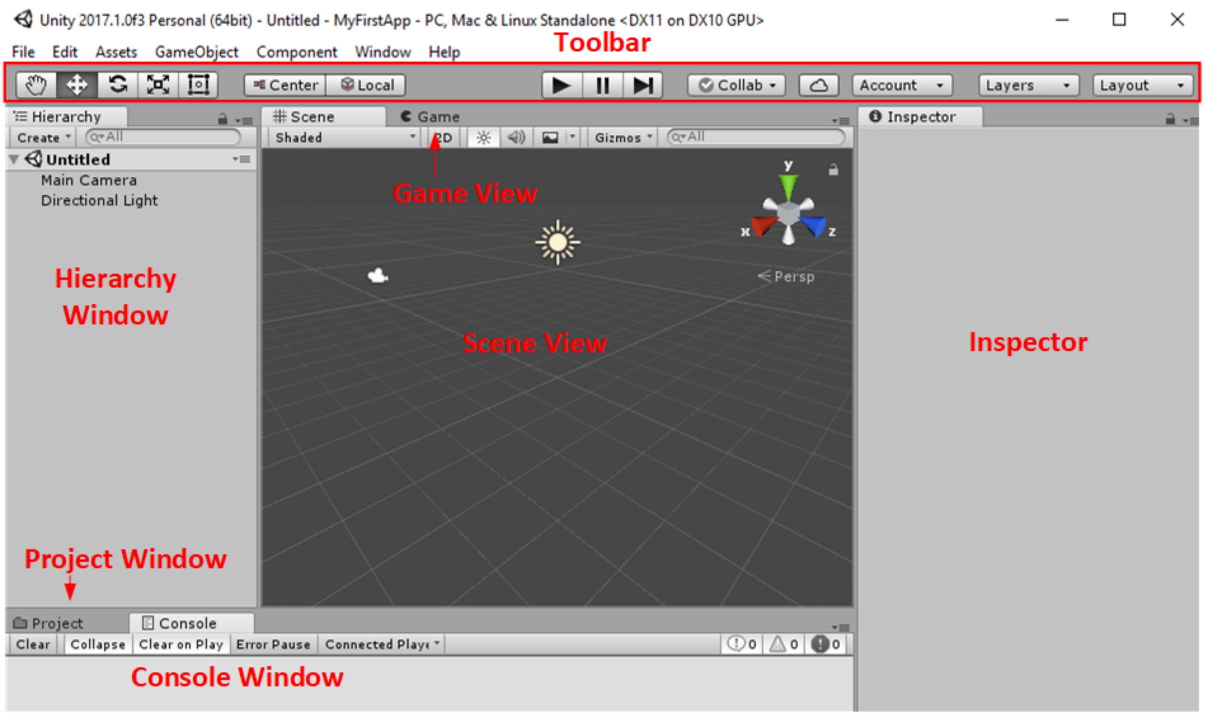


Figure 3.19 Unity interface

The main interface of Unity shows different windows (Figure 3.19):

- *Menu*: contains Unity commands based on function;
- *Toolbar*: is divided into 7 sections, each one related to a different section of the editor;
- *Hierarchy windows*: is used to manage the current scene, all the items inside it are referred as ''GameObjects''. In the Hierarchy textual representation of all the game objects available can be found.
- *Game view*: is the user interface showed when the application is run;
- *Scene view*: corresponds to the visual representation of the current scene. It can display in 2D or 3D view;
- *Inspector window*: is used to inspect and edit the properties of the game objects and assets, to add components to the game objects;
- *Project window*: contains all the available assets usable in the project. Any imported unity package is also imported into this window;
- *Console window*: is the window where errors or warnings appear during the development and after the run of the application.

In order to develop and AR application, the first thing to do is to change the platform for which the app will be created. There are several options to choose:

- PC, MAC, Linux
- Android
- Universal Windows Platform (UWP)
- iOS
- tvOS
- XboxONE
- PlayStation

After the switch of the platform, it is important to start importing the target databases and toolkits that will be used to develop the app.

3.3.3.4 Visual studio

VisualStudio is an IDE (Integrated Developing Environment) created by Microsoft and also includes a code editor supporting 36 different languages including C#.

It is used to develop games, applications as it has been used in this thesis work and websites.

For AR application visual studio is necessary to import the scene created in Unity into the HMD such as HoloLens in order to make them to augment the various contents.

The VisualStudio interface is made of four main components (Figure 3.20):

- Code editor: is where to write the code
- Solution explorer: shows the files the user is working with.
- Properties panel: gives additional information and context about selected parts of the project.
- Output window: displays debugging and error messages, compiler warnings, status messages, and other output.

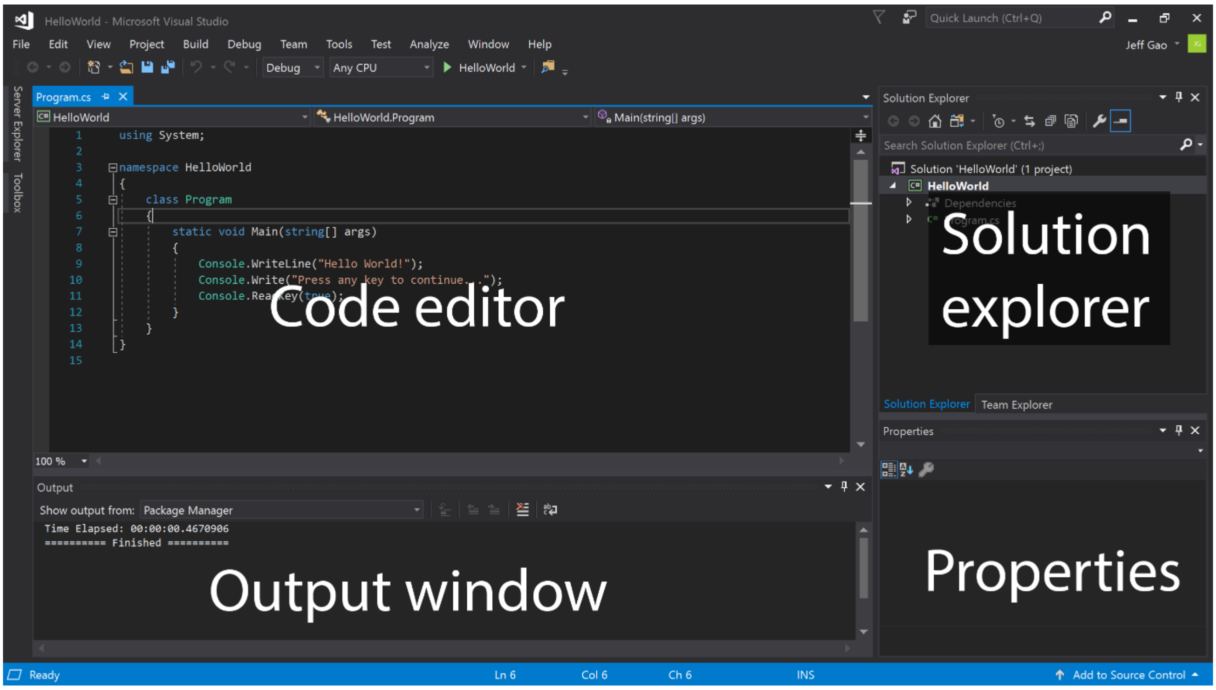


Figure 3.20 VisualStudio interface

For HoloLens2 is necessary to run the compiler with these configuration settings (Figure 3.21):

- Configuration→ release
- Platform→ ARM64

Then it is possible to run the debugger and the application appears on the HMD.

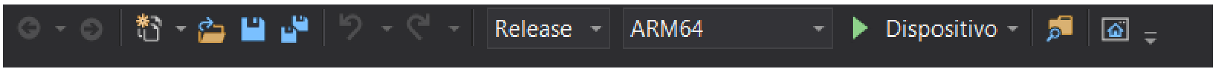


Figure 3.21 Configuration settings to run the AR app on HoloLens2

3.4 AR application validation

3.4.1 Scanner device

After the 3D model has been printed, in order to verify the validity of the work it could be necessary to scan the model so the user is able to compare the scanned images with what he was seeing on the device. In this way it is possible to calculate the deviations and the errors that appear.

Several kinds of 3D scanner exist, from desktop scanners to handheld portable ones (Figure 3.22).

3D scanners are used to generate free-form 3D data as point cloud or triangle mesh, by capturing the images with the help of structured light.

The main advantage of this kind of scanner with respect to the usual technologies (e.g., CT scan, MRI scan, Ultrasound) is that 3D scanning gives information about the texture and outer surface of the scanned object. In fact, this technology is expanding also in the medical field, since it helps to create prosthetic parts, dental implants, custom implants. Due to the use of 3D printing techniques, it is possible to give the printer the 3D digital file from the scanner as input, allowing to produce parts which look and feel like a real object [26].

Figure 3.22Different types of 3D scanners

3D scanners can be classified in 5 different categories based on the physical principles on which they rely on (Table 3-4).

Table 3-4 3D scanner's categories

Laser triangulation-based 3D scanners	Use a laser line or a single laser point to scan across an object. The initial trajectory of the laser light reflected off the object is modified and detected by a sensor. By trigonometric triangulation is possible to evaluate the deviation angle which is directly linked to the distance between the object and the scanner. Once enough distances are collected the scanner maps the object's surface creating a 3D scan.
Structured light-based 3D scanners	Use trigonometric triangulation with the projection of linear patterns series onto an object. The edges of each line are examined, and the distance object-scanner is calculated. The used light is either blue or white.
Photogrammetry-based 3D scanners	Use a mix of computer vision and computational geometry algorithms. Several photographs from different viewpoints are analyzed and pixels corresponding to the same physical points are detected. Focal length and lens distortion of the camera are needed as input.
Contact-based 3D scanners	Use a probe with which touch the object in different points to record 3D information.
Laser pulse-based 3D scanners	Measure the time needed by a casted laser to hit an object and to come back. The speed of light is known, so the time the laser takes to come back gives the distance between the scanner and the object.

Several companies produce different kinds of 3D scanner based on different physical principles, such as:

- Javelin which produces ''Artec 3D scanners'' both in desktop and handheld modalities
- MantisVision
- Creaform3D
- V-GER

All these companies develop different types of professional scanners, but, since for this thesis work the Go!Scan3D by CreaForm was used, it will be the one explained in details.

The Go!Scan3D (Figure 3.23) is one of the most recent scanner devices present on the market. It is developed by CreaForm corporation, a Canadian society, in 2019.

Figure 3.23 Go!Scan3D device

This scanner allows the user to easily scan the object in a very accurate way, in fact, it also registers the texture of the object. It is a laser triangulation-based 3D scanner working by calculating the laser light angle deviation to obtain information about the object surface. To have precise scans, the device includes 2 packages of markers used to accurately select the reference plane where the object is positioned on and to calibrate the scan itself.

In the Table 3-5 are listed the technical specifications of Go!Scan3D.

Table 3-5 Technical specifications of Go!Scan3D

ACCURACY	Until 0.05 mm
VOLUMETRIC PRECISION	0.05 mm + 0.15 mm/m
MEASUREMENTS’ RESOLUTION	0.100 mm
MESHES’ RESOLUTION	0.200 mm
MEASUREMENT’S FREQUENCY	1500000 measurements/s
LIGHT SOURCE	White light
POSITIONING METHODS	Geometry and/or color and/or target
SCAN AREA	390x390 mm
WORKING DISTANCE	400 mm
DEPTH OF FIELD	450 mm
TEXTURE RESOLUTION	From 50 to 200 DPI
TEXTURES’ COLOR DEPTH	24 bits

The scan comes with a dedicated software called ′′VXelements′′ where it is possible to manage the scans and export them in different format, e.g., .dae, .fbx, .ma, .obj, .ply, .stl, .txt, .wrl, .x3d, .x3dz, .zpr, .3mf.

3.4.2 CloudCompare

CloudCompare is a 3D point cloud processing software able to handle triangular meshes and calibrated images too. It was developed by a collaboration between Telecom ParisTech and the R&D division of Electricitè de France, but nowadays is an independent open source and free software.
It provides a set of basic tools for rendering 3D points clouds and triangular meshes along with various advanced processing algorithms to perform:

- Projections
- Registration
- Distance computation
- Statistics computation
- Segmentation
- Geometric feature estimation

The user can interactively segment 3D entities, rotate or translate single or multiple entities with respect to each other and pick group of points.

The software run on windows, Linux and MacOSX, for both 32- and 64-bits machines.

In

Figure 3.24 is possible to see the merge of two different models, the scanned one (red) and the nominal one (yellow) in order to see their alignment.

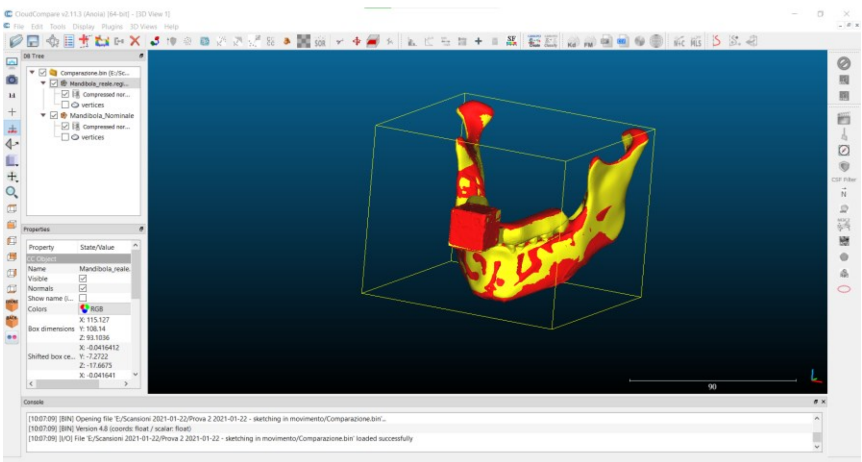


Figure 3.24 CloudCompare interface

4 Case study

The aim of the present work is to deploy an AR application for maxillofacial surgeries onto Microsoft newer smart-glasses, HoloLens2.

The existing studies have been made on HoloLens1 or other HMDs, so this research is brand-new in medical field.

As already mentioned, HoloLens2 are the latest version released from Microsoft with improved features with respect to version 1.

The main goal of the thesis is to augment the surgical guides, usually physically made, as holograms onto a model of a real mandible to measure the deviation between what is seen through the glasses and the surgical guides preplanned in the surgery planning in the CAD software.

A guideline in surgical field is a small, customized tool designed starting from the surgical planning phase, used to guide the surgeon seeing or drilling in the planned direction. Surgical guides are made from a sterilizable materials and are removed after the surgeon have made the cut or the drill.

A surgical guide fits perfectly the part of the patient's bone that has to be cut, allowing the surgeon to be sure about cutting in the right place, at the right angle and depth.

With the standard approach, the surgical guides are developed through a CAD software specifically for the patient starting from a CT scan, allowing the guide to perfectly adapt to the bone. The CAD software allows to define the cutting planes on the scan and to see how the bone will be resected after the surgery. Then the guides are 3D printed and used during the surgery. Usually, this navigation system is attached through screws directly on the jawbone, then the surgeon sees where he will cut the bone in a very accurate and precise way (Figure 4.1).

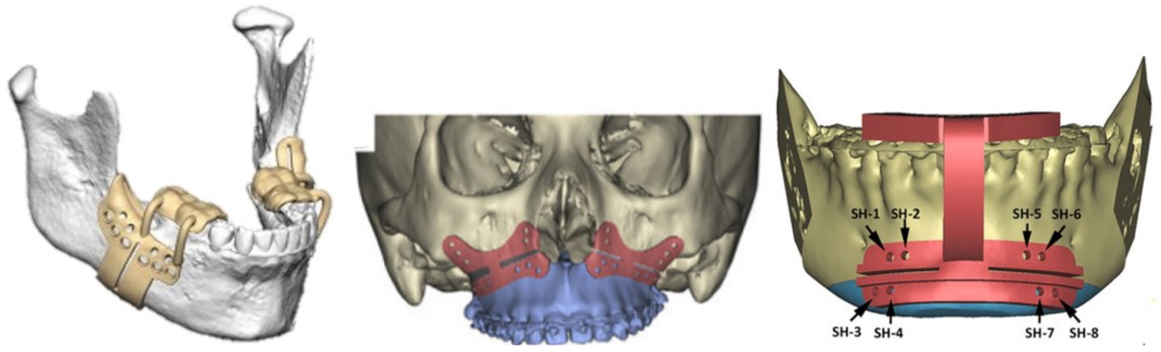


Figure 4.1Physical surgical guides used in orthognathic surgery

The main drawback of physical surgical guides is the cost, in fact they are custom-made so for each patient there is the need to create and customize a different guideline which will require to be 3D printed in a specific sterilizable material. This procedure has to be repeated for every single patient, increasing the costs for the developing of such navigation systems.

After the advent of AR and HMDs, the scientific community has begun to ask if this new technology could be applied also to the medical field. In this way researchers have started to deploy applications appliable during surgeries that would decrease the cost of custom-made 3D printed surgical guides and the time in order to obtain also a shorter procedure.

The aim of the present work is to create such an application on the new HoloLens2 smart glasses, since, as already mentioned, all the previous works were made using the past version.

In this section the whole procedure will be explained in detail, enhancing the advantages and disadvantages of this approach.

The procedure consisted into eight main steps showed in the flowchart (Figure 4.2).

Figure 4.2 Flowchart of the steps followed

Each of these steps consists of more detailed sub-steps better explained in the following sections.

This thesis is a first approach to AR application development appliable to maxillofacial surgery, it proposes a target-based recognition strategy in order to allow the HMD to correctly augment the lines in the right place. At the end a test has been made asking to different people, none of them a surgeon, to try to outline the augmented lines onto the 3D printed model in order to assess if this method can be usable during a surgery or needs other future improvements.

4.1 Surgical guides development on Rhinoceros[6]

The CT scan of the mandible was already processed, so the CAD model was already available in the laboratory.

From the 3D model of the patient's face, just the lower jawbone with attached the bite (Figure 4.3) has been selected for this work.

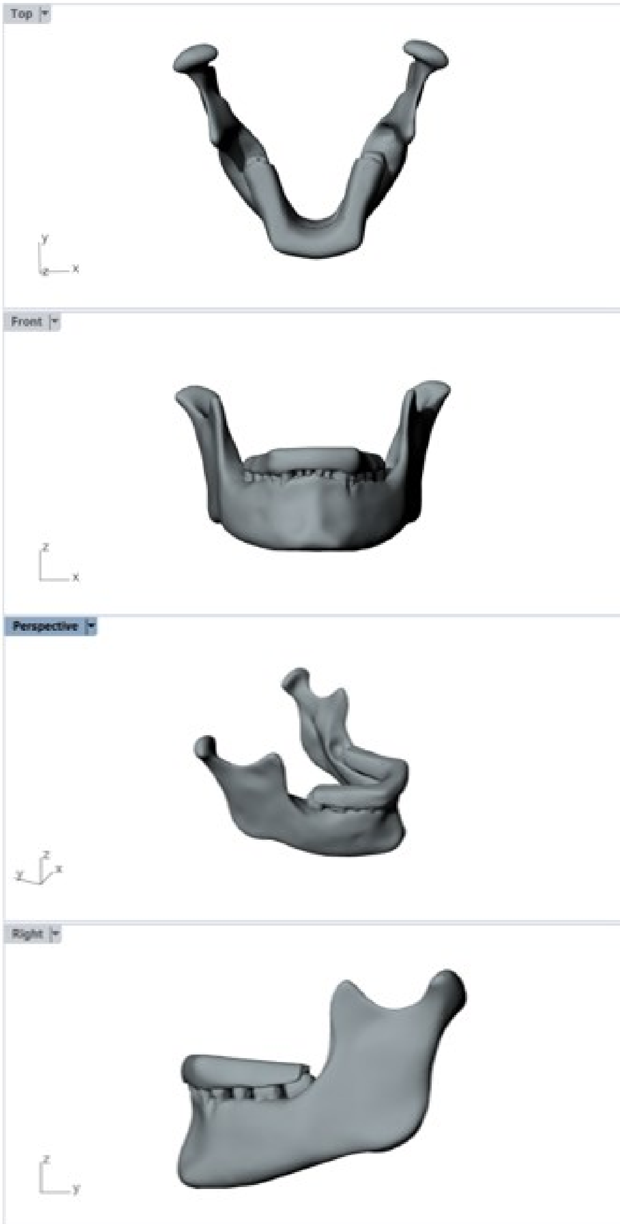


Figure 4.3 Viewports of the mandible

Starting from different videos about the maxillofacial surgeries, the usual cutting lines in order to perform different kinds of surgeries, e.g., genioplasty and mandibular osteotomy, along with other possible cutting points have been selected.

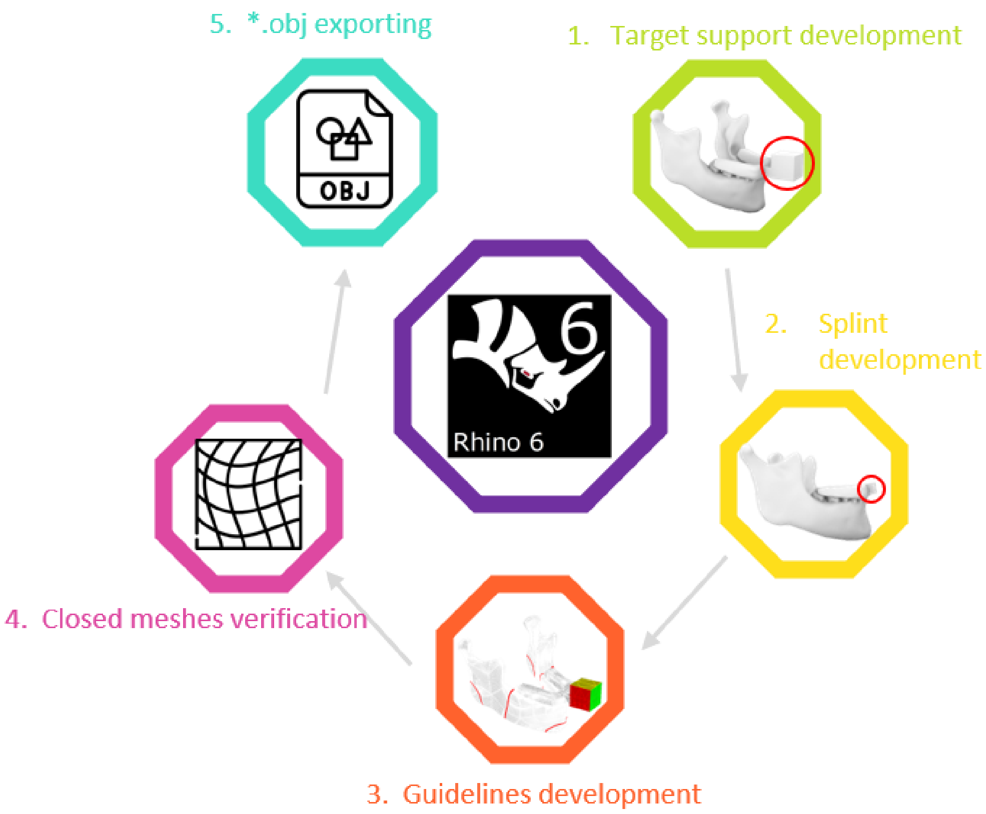


Figure 4.4 Diagram of the steps made in Rhinoceros

On Rhinoceros the steps followed are listed into the diagram above (Figure 4.4)

4.1.1 Target support development

A similar procedure has been used to create the target support used after to attach the target images.

Before the development on Rhinoceros, hypothetical measures and shape of the support have been established following these criteria:

- The size should not be too large because it could be cumbersome during the surgery
- The shape has to be a volume and not flat in order to allow to use a multi target (e.g., a target made by different images)
- Light weight since during the printing if the support is too heavy could break

After these considerations, the shape chosen is a hallow cube with one side attached to the splint.

For the size choice different CAD model on Rhinoceros have been made in the measurements of 1x1x1 cm, 1.5x1.5x1.5 cm, 2x2x2 cm and 2.5x2.5x2.5 cm. At the end 4 Rhinoceros files are obtained. This was necessary to verify which was the smaller size of the target image that the HoloLens2 were able to detect.

Different trials on Unity and HoloLens2 have been made before choosing the right size of the cube to be printed with the model.

The command used are (Figure 4.5):

- *Box: Corner to Corner, Height*: draws a solid box
- *Shell closed polysurface*: creates a hollowed-out shell from a solid
- *Mesh from surface/polysurface*: creates a polygon mesh from a surface or polysurface

Figure 4.5 Commands used to create the cube support

To develop the hallow cube the first command used is *Box: Corner to Corner, Height* and the different measures for height, width and length have been inserted in the command bar.

The command *Shell closed polysurface* is used to hallow the cube with 1 mm thickness (Figure 4.6)

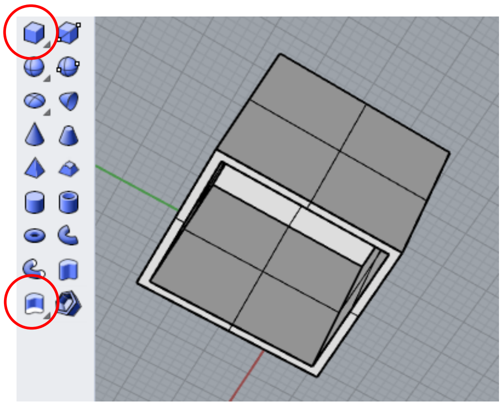


Figure 4.6 Hallow cube creation

Then the support is converted into a mesh with the command *Mesh from surface/polysurface*.

The center of the cube is aligned with the center of the reference system.

The cube size chosen is 2x2x2 cm.

4.1.2 Splint development

The first issue was how to attach the marker support to the MAD in order to be fixed with the mandible. This has been solved by creating a splint attached to the MAD that is connected directly with the support.

Figure 4.7 Commands used to create the splint and linked it to the support and to the mandible

The commands used to develop the splint are (Figure 4.7):

- *Box: Corner to Corner, Height*: draws a solid box
- *Mesh from surface/polysurface*: creates a polygon mesh from a surface or polysurface
- *Mesh Boolean union*: trims away the shared areas of selected meshes, polysurfaces, or surfaces and create a single mesh from the unshared areas

To develop the splint a parallelepiped (Figure 4.8) has been created with the command *Box: Corner to Corner, Height*, measuring 9 mm in width, 8 mm in height and 20 mm in length.

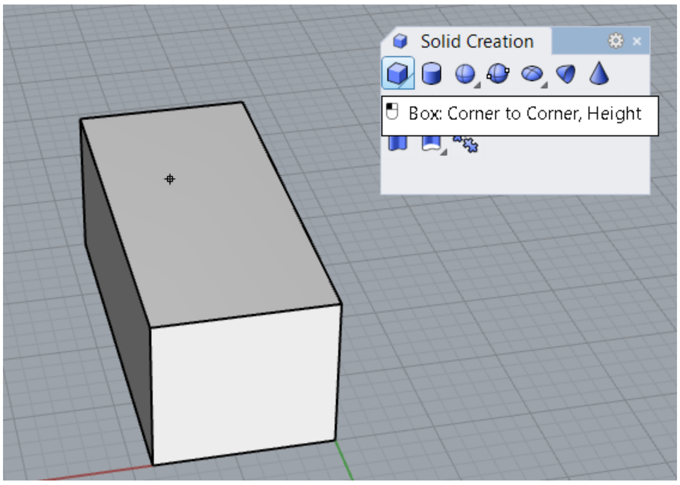


Figure 4.8 Parallelepiped splint created with the Box command

Using the command *Mesh from surface/polysurface* the volume is transformed into a mesh.

The splint is moved to be aligned with a side of the cube.

Then the command *Mesh Boolean union* is used to merge the two meshes into a single one, resulting into a complete support for the multi target.

After the support is merged with the MAD mesh with the *Mesh Boolean union* command, so the MAD and the support are rigidly attached to each other in a single mesh maintaining the alignment between the center of the cube and the center of the world reference system (Figure 4.9).

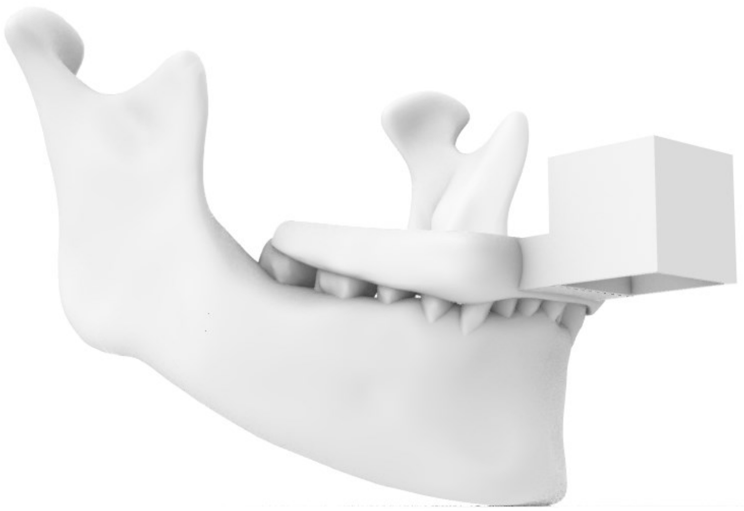


Figure 4.9 Target support linked with the MAD and the mandible

4.1.3 Surgical guides development

As already explained, the surgical guides positions have been selected by under surgeon's indications in a generic way since the study was not on a specific patient.

For this thesis purpose 5 lines have been selected to be drawn, one on the chin to simulate the genioplasty surgery, two on each mandible side in correspondence of the last molars to simulate the osteotomy and the last twos molars (Figure 4.10).

Figure 4.10 Surgical guides' positions

Figure 4.11 Used commands to create the surgical guides

The following commands (Figure 4.11) have been executed to create surgical guides colored in red:

- *Control point curve*: allows to draw curves that pass through selected points
- *Offset Curve on Surface*: copies a curve on a surface so that all locations on the copied curve are a specified distance from the original one and lie on the surface
- *Extrude Curve*: creates a surface by tracing the path of the curve in a straight line
- *Mesh from surface/polysurface*: creates a polygon mesh from a surface or polysurface
- *Mesh Split*: divides mesh into parts with another object

The curves are created through points following the mandible surface, then they are thickened of 1 mm through the *offset* command. The two curves, the original and the offset created, are used to create a surface by using *Extrude Curve* and then they are transformed into mesh. To color each guideline in red it is necessary to use the *Mesh Split* command, applying it to the mandible and selecting as cutting objects the mesh. Then with the newly created portion selected, the color is changed through the inspector panel.

Figure 4.12 shows the final result composed by the mandible attached to the target support and the surgical guides visible over the mandible.

The mandible is now divided into 6 different parts connected through the 5 surgical guides meshes.

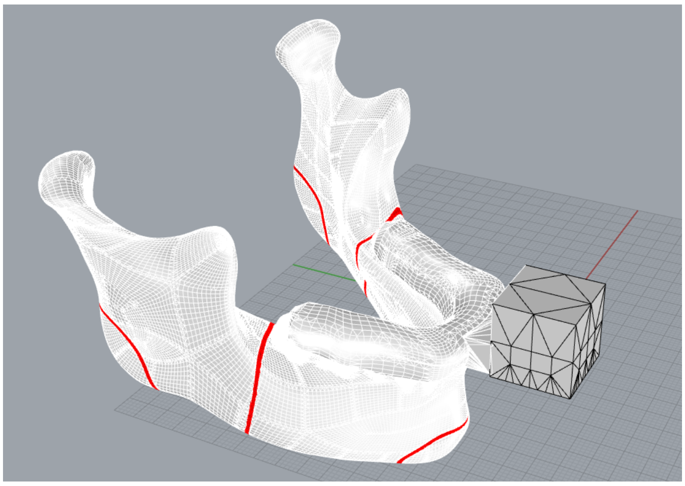


Figure 4.12 Final result shows the red surgical guides and the target support attached to the mandible

As final steps there are the verification that all the mesh created are closed and the exportation of the model in *.obj format to be imported into unity.

To verify if the meshes are closed, in the inspector panel, with the mesh selected, under ''properties'' is possible to see if the mesh is open or not. If it is open the command *Fill Mesh Holes* is used to close all the holes present.

This is necessary otherwise the 3D printer is not able to print the model.

4.2 3D print

The model is 3D printed using the 3D printer system ''Z Printer 450'', developed by Z-Corporation and now acquired by 3D-System company.

ZPrinter 450 uses selective laser sintering (SLS) technique to print out the 3D models, also colored printings are possible.

SLS is an additive manufacturing technique which uses laser as the power source to sinter the powdered material, binding it together to create a solid structure.

The printer is composed of 2 main chambers, the build chamber and the fine-powder removal chamber, and the LCD panel (Figure 4.13).

The build chamber is where the model is printed, while the powder removal chamber is used to final remove any powder left.

Figure 4.13 ZPrinter 450

The process starts by adding the 3D file to the ''ZPrint Software'', which converts the file into cross-sections between 0.089-0.102 mm thick.

The software evaluates the geometries and checks if the printer has been filled with enough material to print all the layers.

The used material is a high-performance mixture powder containing calcium sulfate hemihydrate combined with a binder.

A binder is a solution dispensed through the print head and applied to the powder.

After the printing, a drying cycle occurs to add strength to the parts. The longer the parts dry the stronger they become. After the drying, the model is cleaned off of the left powder and post-processed.

The post-processing part is made using an infiltrant, which soaks into the part and bonds the printed powder together to give more durability.

The CAD model exported from Rhinoceros is prepared in Autodesk Netfabb, a software used to maximize machine efficiency minimizing the risks of print failure. This software prepares 3D files and converts them into 2.5D slice files.

Depending on the file, the printing could last differently, for this work it took 6 hours to finish the printing plus 2 hours to let the infiltrant drying.

Once the whole process was finished, the resultant mandible is obtained, as show in Figure 4.14.

The chosen model is the one with the cube of 2 cm per side, since it was the smaller target measurement that HoloLens were able to detect while the 2.5 cm cube was too large to be used during a surgery.

Since the printer can print also colored parts, the model has been printed with the red surgical guides planned in the CAD file.

Figure 4.14 3D printed mandible

4.3 Target

The target is chosen so that it could fulfill all the requirements.

It is a cube of 2 cm per side which on the top, frontal, left and right sides displays 4 different QR codes generated through the QRcode generator website.

In Vuforia the target model chosen is the cuboid multitarget to which the width, height, and length of 2 cm each is given.

The portal asks to insert a proper name for the target and after allows the user to import the different images. Since the target is a cube, 6 images are needed in this phase (Figure 4.15). However, onto the real cube just 4 of them have been glued onto the support because it is a hallow cube. In fact, the bottom image is not necessary, because the bottom side is not present, and the back image as well because the back size is not visible during the surgery.

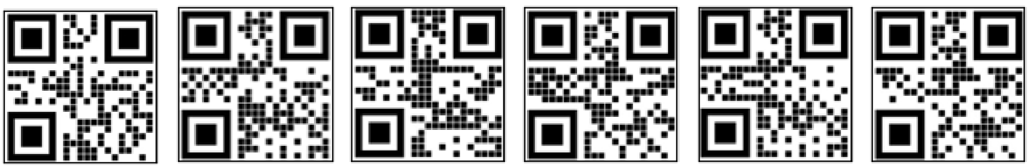


Figure 4.15 Target images used to create the database in Vuforia and attached to the real support

The images have been printed onto a piece of A4 paper with the dimensions of 2x2 cm and cut.

The created database is then downloaded as *.unitypackage file (Figure 4.16).

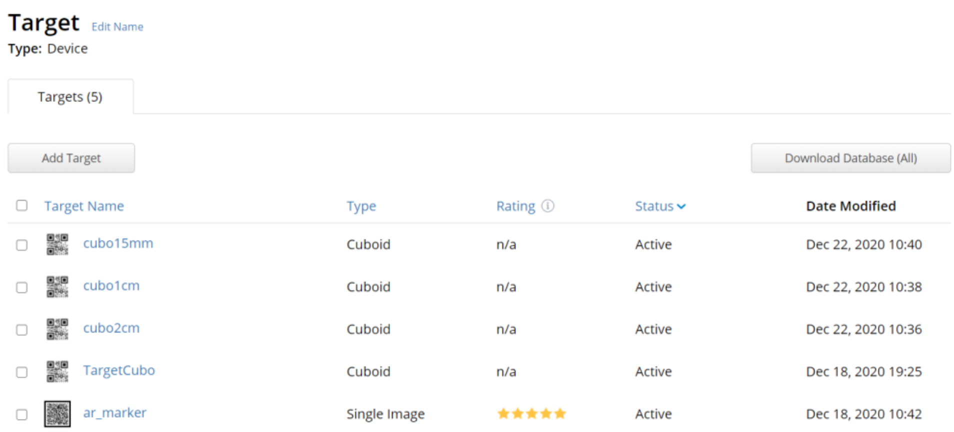


Figure 4.16 Target Manager page

The license is generated clicking on ''Get Development Key''. It is asked to the user to insert a name for the license (Figure 4.17) and once created, it can be copied and pasted into Unity.

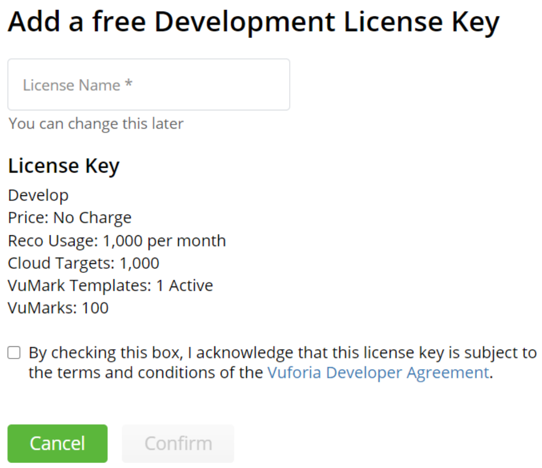


Figure 4.17 Licence Key page

Then, the VuforiaEngine needs to be downloaded from the ''Downloads'' page of VuforiaDeveloperPortal. This is a *.unitypackage file necessary if the user wants to develop an application in Unity using the target created with Vuforia.

In the flowchart below (Figure 4.18) is explained how the choice of the target size has been made, starting from create a database containing all the 4 measurements. The database is imported into Unity, as will be explained in the next session, and a simple scene is created using each time one of the 4 different measurements targets. Then this simple scene has been deployed onto HoloLens and it has been verified if the chosen target was detectable by the HMD, if not all the process was re-done, otherwise the choice depended on how cumbersome the chosen target would have been during the surgery.

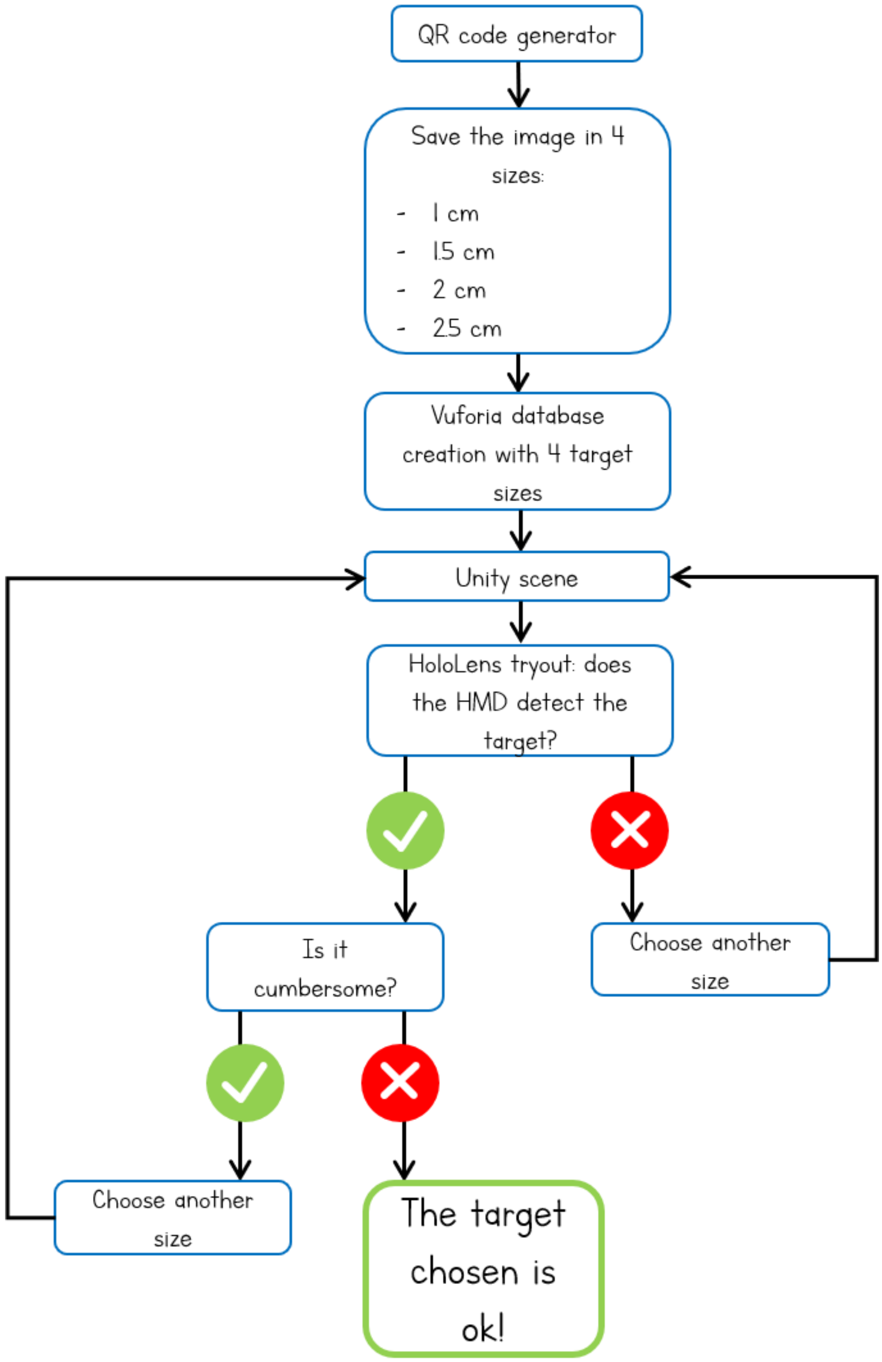


Figure 4.18 Flowchart to choose the right target sizes

4.4 Application development

Once the model has been printed and the target database created with the correct target, the application development begins.

The software used are Unity 2020 and VisualStudio 2019.

The application development process consists of 5 main steps show in Figure 4.19

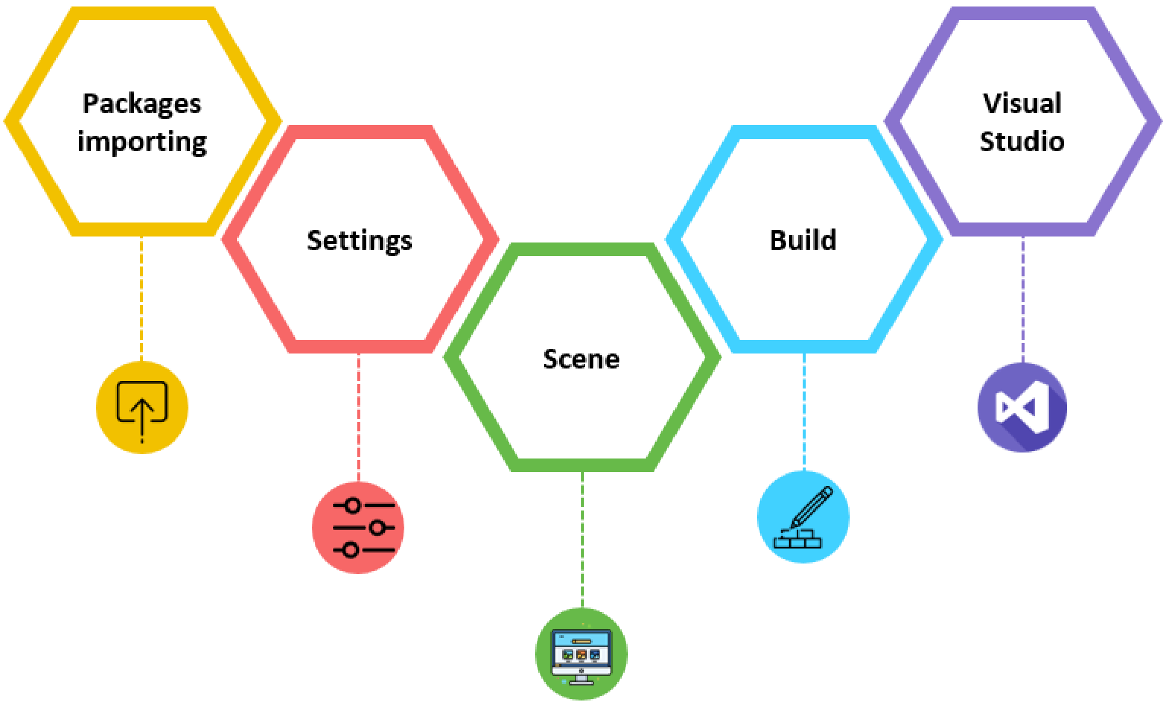


Figure 4.19 Application development steps

Except for the last step, all the other are made in Unity to create the scene of what the user will see once using HoloLens. Visual Studio is used in the last step to deploy the application to the glasses.

4.4.1 Packages import

Firstly, it is necessary to create the Unity project using ''Unity Hub'', a standalone application that streamlines the way Unity Projects and installations are found, downloaded, and managed. The requirement is to create a 3D project and saving it with a name, then a folder will be created in the path chosen from the user (Figure 4.20).

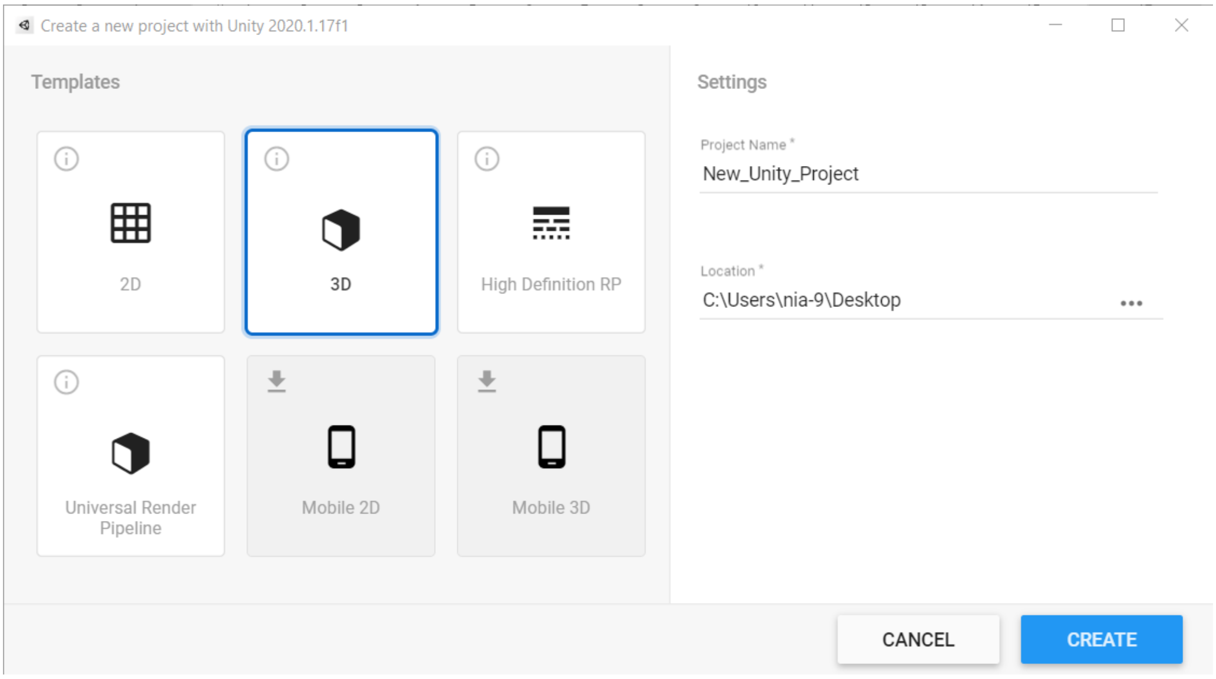


Figure 4.20 Unity Hub creation project interface

The first thing to do, once the project has been created, is to import *.unitypackage files, so the user will be able to use the features of these files to improve its application.

The packages used in this work are 2:

- MixedRealityToolKit package
- VuforiaEngine package
- Database package

The Mixed Reality Toolkit (MRTK) is a cross-platform toolkit for building Mixed Reality experiences for VR and AR.

The VuforiaEngine package is the package used to import the Vuforia SDK into unity in order to use the target database created on the website.

The database package is the one downloaded from the Vuforia Developer Portal.

The MRTK packages available are 5:

- Foundation
- Extensions
- Tools
- Test utilities
- Examples

Among these five packages, just the Foundation one is strictly necessary for MRTK to work on Unity for this application.

This step allows to import the packages:

- *Assets*→*Import package*→*Custom package*: allows to select the *.unitypackage files that need to be imported into unity. Each package must be imported by conferming it in the specific window (Figure 4.21)

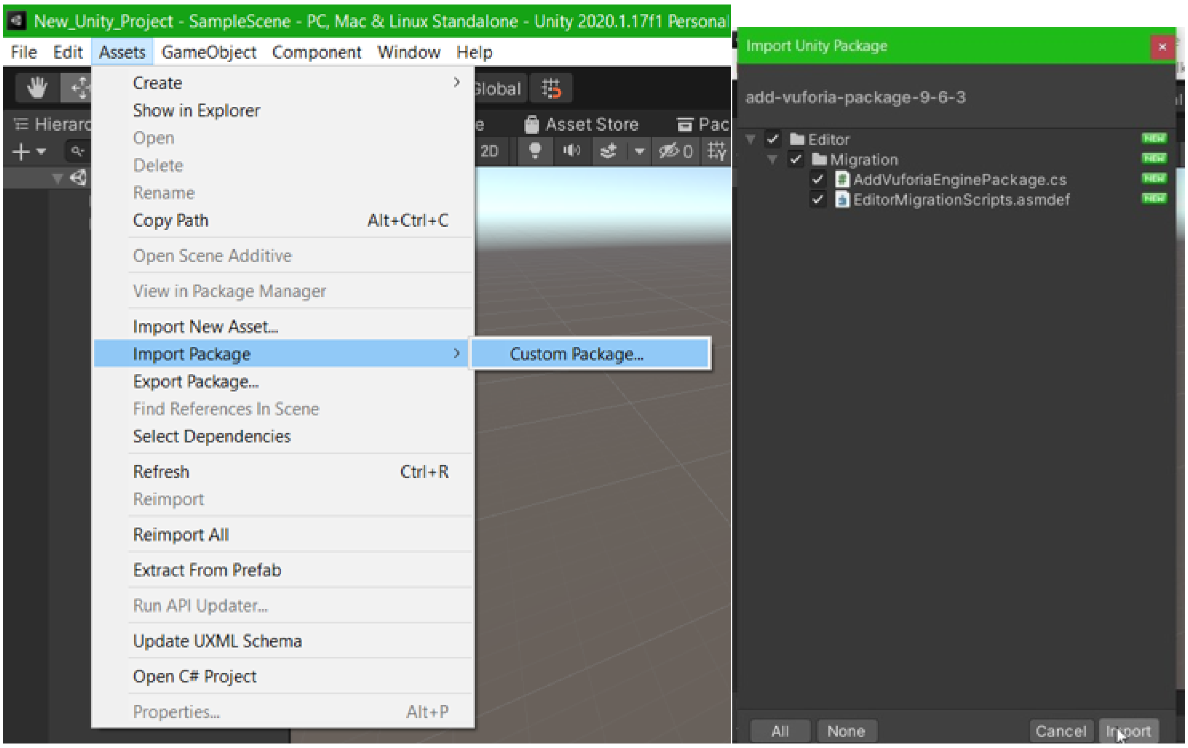


Figure 4.21 Importing packages step

4.4.2 Settings

The following steps have been followed to configure the settings of the project in Unity:

- *File→Build Settings→ Switch Platform*: allows to switch to the required platform (Figure 4.22), in this case UWP (universal windows platform).

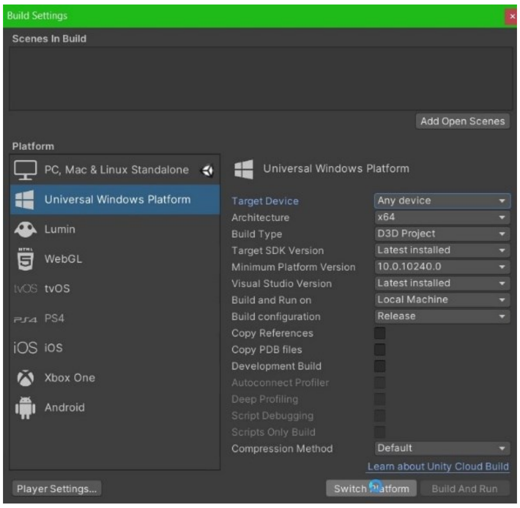


Figure 4.22 Switching platform step

- *Edit→ Project Settings→Player*: allows to set some parameters necessary to deploy the application (Figure 4.23). Under *Publishing Settings-Capabilities*, ''internet client'', ''microphone'', ''webcam'' and ''spatial perception'' boxed are checked.

Under *Publishing Settings-Supported Device Families* the ''holographic'' box is checked.

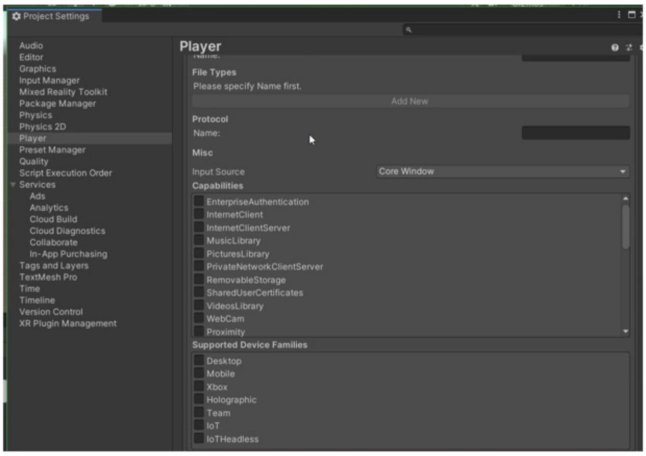


Figure 4.23 Player settings step

- Edit→ Project Settings→XR Plug-in Management: allows to set the parameters for windows Mixed Reality (Figure 4.24). The Plug-in is installed and under Windows Mixed Reality the depth buffer format is set at 16 bits and ''Shared Depth Buffer'' is enabled.

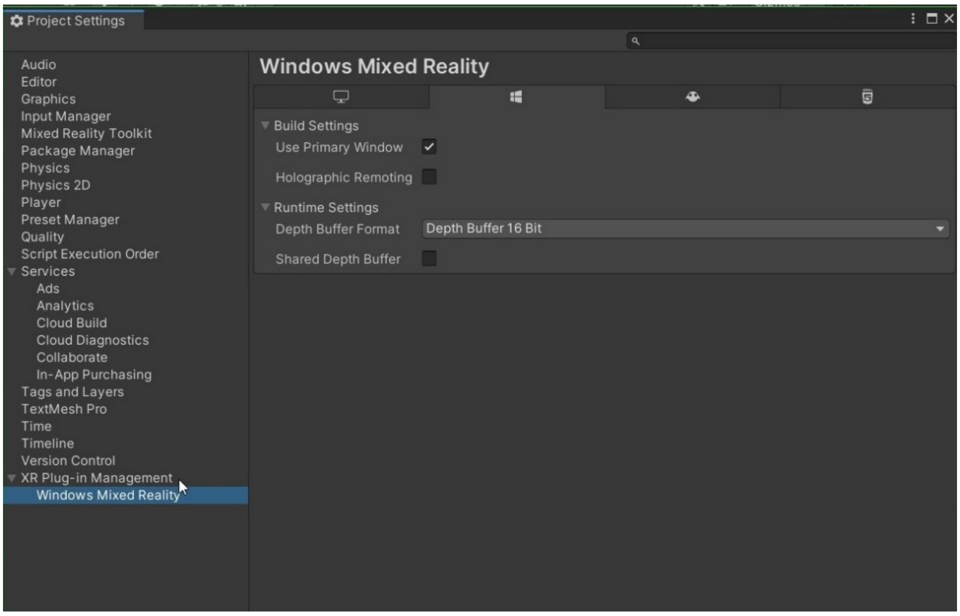


Figure 4.24XR Plug-in Management settings step

A way to configure the MRTK is through the profiles available in the foundation package: *Camera, Input, Boundary, Teleport, Spatial Awareness, Diagnostic, Scene System, Extensions* and *Editor.*

The toolkit provides a set of default profiles covering most platforms and scenarios supported by MRTK. This default profiles are not optimized for any particular use case, so if there is the need of more specific settings is necessary to clone the default profile, in this way the user is allowed to apport the modifications that he/she needs.

It has to be kept in mind that each of these following steps have been made by cloning the default profiles and modifying the new ones.

The following steps allows to prepare the scene with the MRTK and the use of Vuforia target:

- *Mixed Reality Toolkit→Add to scene and configure…*: The Mixed Reality Toolkit and Playspace are added to the scene and ready to be configured (Figure 4.25)

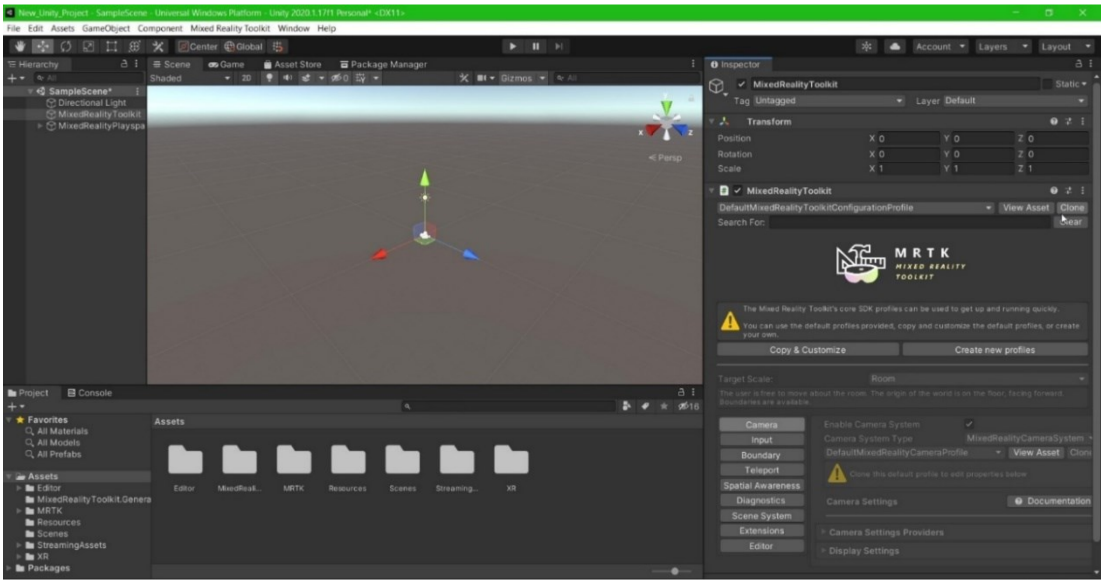


Figure 4.25 MRTK addition to the scene

- *Mixed Reality Toolkit→Inspector Panel→Input*: this section is used to configure the input providers. To avoid seeing the hands meshed during the augmentation it is necessary in this step to set the *hand mesh visualization modes* as ''nothing'' (Figure 4.26), otherwise the hands will be seen as meshed and they could be annoying during the surgery.

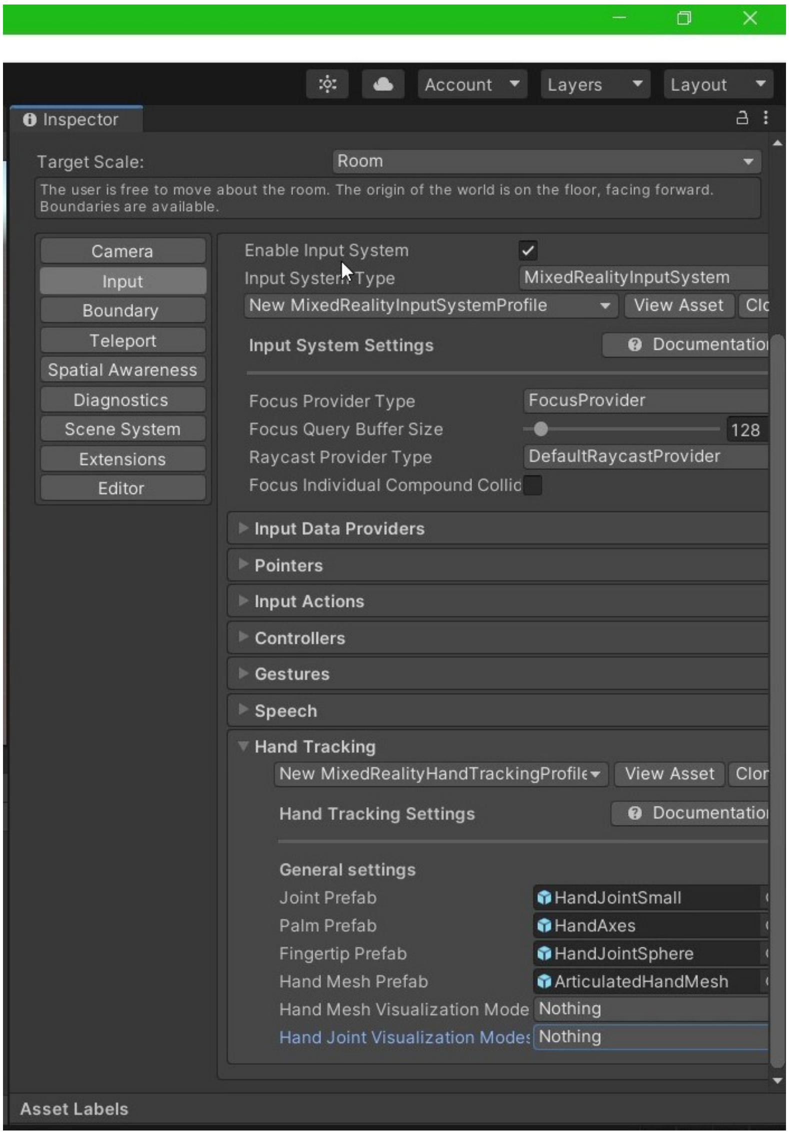


Figure 4.26 Input providers setting configuration

- *Mixed Reality Toolkit→Inspector Panel→Spatial Awareness*: the spatial awareness system provides a collection of meshes representing the environment's geometry, feature that could be annoying during the use of the application in the operating room. For this reason, the meshes need to be hidden by setting as ''None'' the *display option* under *display settings* (Figure 4.27).

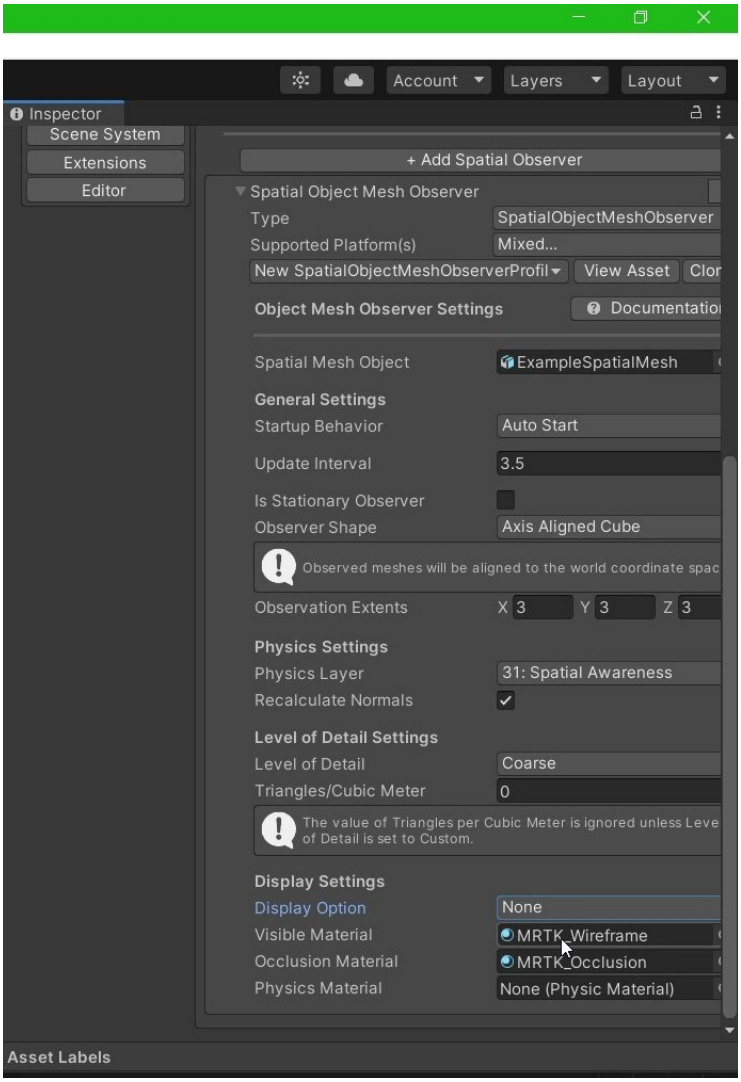


Figure 4.27 Spatial Awareness settings configuration

- *Hierarchy→ MixedRealitySpace→ Main Camera→ Inspector→ Add Component→Vuforia bheaviour*: this allows to add the Vuforia License to the camera to use the target. To insert the license, it is necessary to copy and paste the code on Vuforia Developer Portal (Figure 4.28, Figure 4.29)

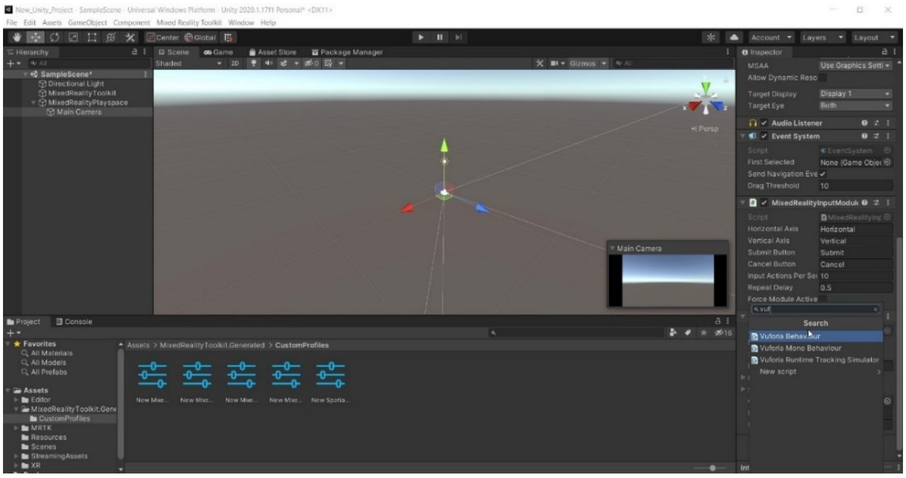


Figure 4.28Adding Vuforia Beahviour to the main camera

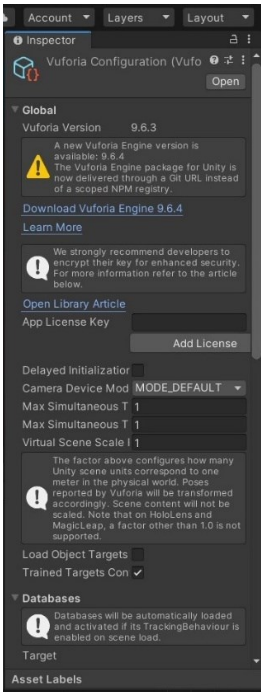


Figure 4.29 Vuforia license key insertion

- *Hierarchy→ MixedRealitySpace→ Directional Light→ Inspector→ Point Light*: allows to transform the light source from directional to point.

4.4.3 Scene

The scene is built by adding the multi-target marker and the *.obj file of the surgical guides.

The surgical guides and the marker have been aligned before the exportation in Rhinoceros to obtain the highest precision.

In fact, Unity, as mainly used to develop videogames, is not the easiest software where align objects that need a very high level of precision.

The surgical guides are inserted as ''child'' of the game object ''multi target'', doing so Unity will display the surgical guidesjust after having recognized the marker. Using a multi target allows the user to avoid using several target images, each of them used for a specific orientation of the game object child. In fact, with a multi target the software knows by itself how to re-orientate the lines depending on which side of the cube the user he is seeing through the HMD.

To summarize, the following steps have been performed to create the scene that will be deployed onto the HoloLens2:

- *Mixed Reality Space*→ *Game object* → *Vuforia* → *MultiTarget*: this step allows to import into the mixed reality space the target with the dimensions defined in Vuforia Developer Portal (Figure 4.30).

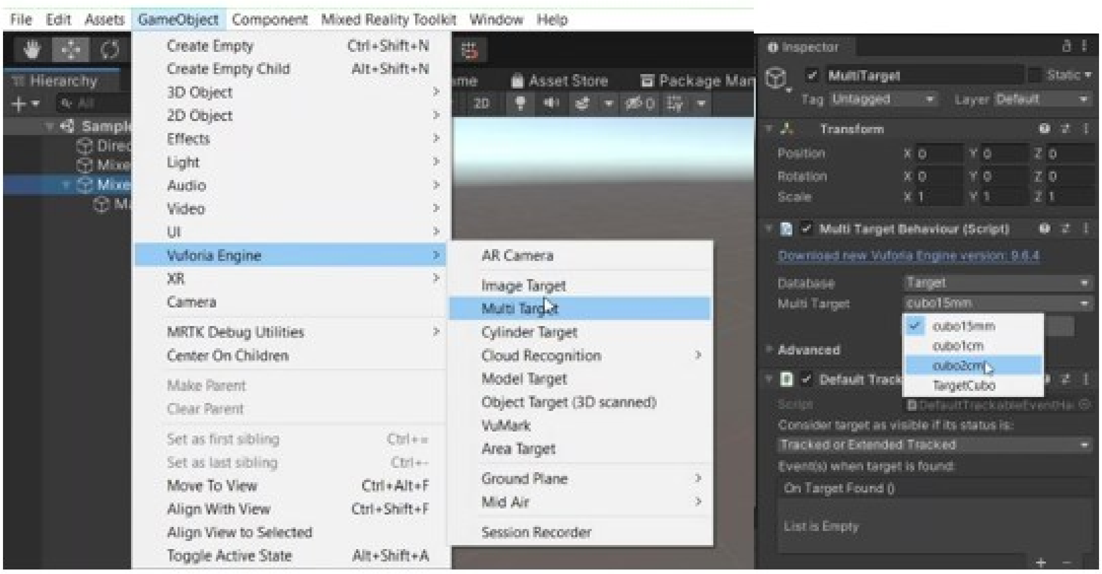


Figure 4.30 MultiTarget insertion to the scene

- *Project Window →Assets → drag and drop the *.obj file of the surgical lines*
- *Project Window → Select the surgical guides→ Inspector panel*: here it is possible to configure the object model, rig, animation, and material (Figure 4.31).
    - *Model*: the scale factor is set at 0.001 because Unity works in meters, but the surgical guides size is in millimeters. The box ''baking conversion axis'' is checked because Unity uses a left reference system, so it converts to its

      system the system of the object (Figure 4.31 a).
    - *Rig*: this panel is used to create an avatar for the object so it can be displayed onto the HoloLens (Figure 4.31 b).
    - *Animation*: for this thesis work an animation was not necessary
    - *Material*: in this panel it is possible to assign a specific material to the object surgical guides (Figure 4.31 c). The material was created by right-clicking onto the surgical guidesin the project panel, selecting create a new material (Figure 4.32 a).

      The chosen material is red with the smoothness set at 0 to create an opaque material that does not reflect the light (Figure 4.32 b).

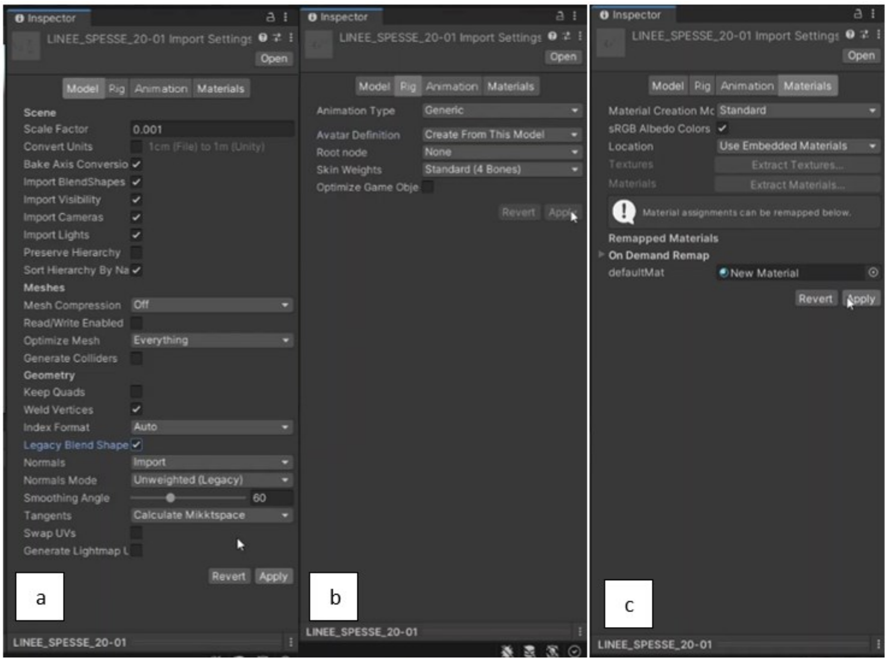


Figure 4.31 Surgical Lines' Inspector panel

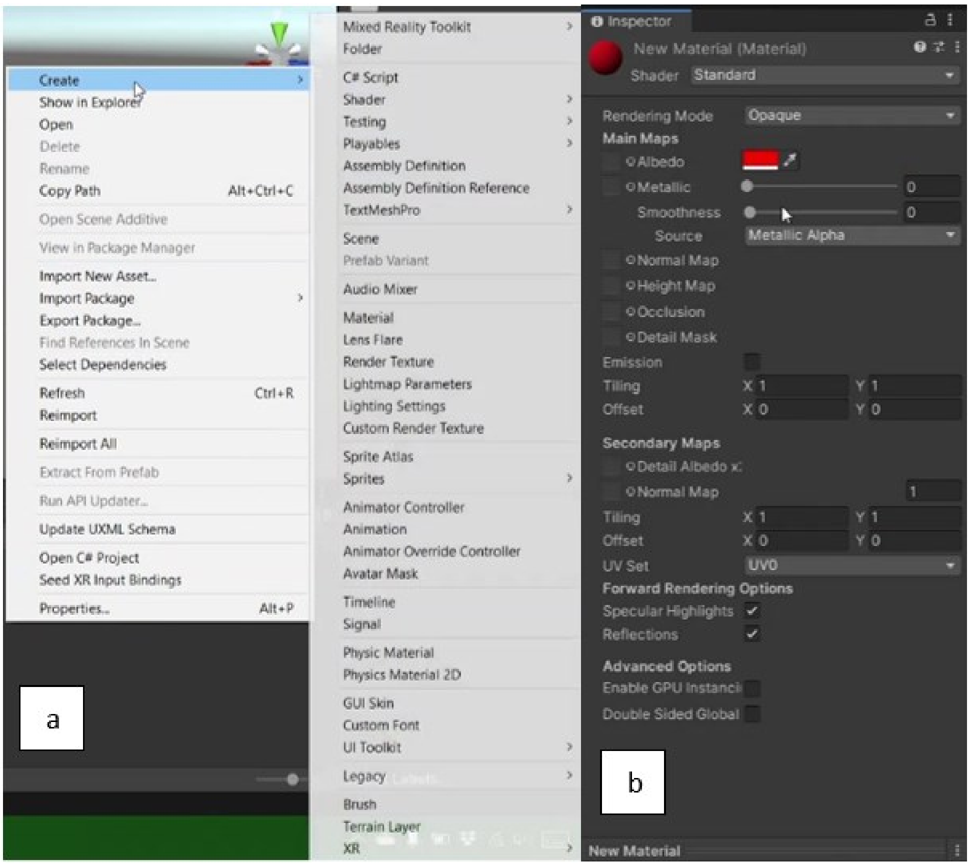


Figure 4.32Creation of a new material for surgical lines

- *Select the surgical guides→ drag and drop the lines over the MultiTarget game object*: with this step the surgical guidesobject becomes the child object of the MultiTarget in the hierarchy. This is necessary to display the lines just when the target is detected.

4.4.4 Build

A build is the process of converting source code files into standalone software artifact that can be run on a computer. It includes the compilation of the files to let them run on VisualStudio.

The building phase of this study consisted in:

- Saving the scene
- Adding the scene to the project
- Building the project

These 3 steps have been made through these actions (Figure 4.33):

- *File→save the scene*
- *File →Build Settings→Add open scenes*
- *Build Settings Panel → Build*

The build command asks the user to select a folder where to save the compiled files, this folder needs to be outside the folder of the created project, otherwise VisualStudio will not compile.

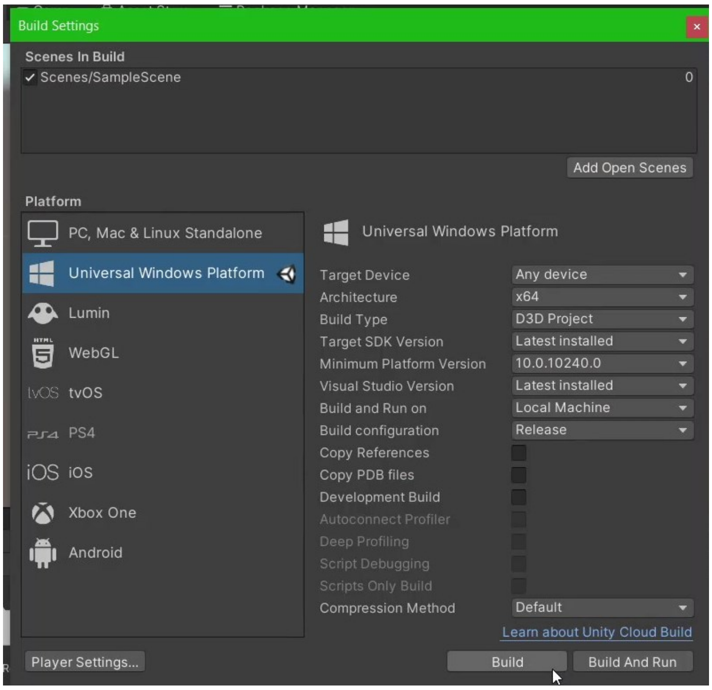


Figure 4.33 Build settings

4.4.5 Deployment

The deployment phase allows to distribute the application onto HoloLens2 through VisualStudio. To do so it is necessary that the smart-glasses are attached to the laptop via USB-C, then the paring will begin.

The pairing consists in matching the laptop and the device through a PIN. On the HoloLens, it is necessary to go in *Settings*→*Update*→*For Developers*→*Pair*. Then a PIN will be displayed on the device and the user must type it into VisualStudio.

Once the pairing is completed, the deployment begins (Figure 4.34):

- Open in VisualStudio the *.sln file created from the building
- Select ''Release'' in the solution configuration drop-down menu
- Select ARM64 configuration
- Set ''Device'' in the deployment target drop-down menu
- *Debug*→*Run without debugging*

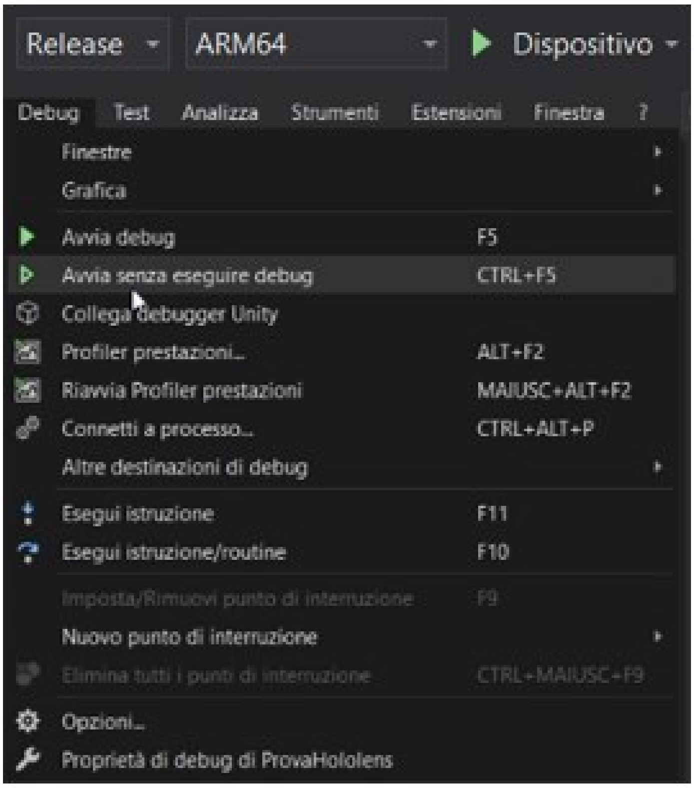


Figure 4.34 Deployment via VisualStudio

4.5 HoloLens 2 tryouts

Once the application has been deployed onto HoloLens2 the tryout phase starts.

Five people, students, and PhD researchers, were asked to try to perform what the surgeon would have done during a surgery wearing the HMD (Table 4-1).

The task was relatively simple: with the HoloLens on, the user was asked to look directly at the MultiTarget cube of the 3D printed mandible, wait until the device recognizes the marker and displays the surgical lines, and try to draw over the mandible where he/she was seeing the augmented curves.

Before starting the tracing, each candidate made the calibration on the device, HoloLens2 allows the user to calibrate them according to user vision, in this way the device is always adapted to the user performing the task.

The calibration is a simple process made directly from HoloLens2, which steps are the following:

- *Impostazioni*
- *Sistema*
- *Calibrazione*

At this point, the device will start to augment little squares that the user must follow with the eyes keeping the head and the neck still.

The mandible was covered with paper scotch, such as the printed red lines were not visible anymore and giving the possibility to directly draw over the mandible without ruining it (Figure 4.35).

Figure 4.35 Paper scotch covering of the mandible

Firstly, the user traced what he/she was seeing with a pencil and after without the device on, he/she went over the pencil lines with a red pen. In this way a more visible lines to be scanned with the scanner (Figure 4.36).

Figure 4.36 Surgical guides' holograms displayed by the HoloLens2

The user was also asked to perform the task by not being in a fixed position, but he/she was able to move around the model and start tracing when he/she felt more comfortable, e.g., when the user was able to see better the lines from his/her point of view, he/she had to start drawing. The user could also trace a line in a specific position and then move, stand and trace the other lines (Figure 4.37).

Figure 4.37 Example of the requested task performance

Since none of the participants had experience in medical field, also the time to perform the task was taken for each of them.

Two trials have been made to compare if during the second attempt there was improvement.

Among the five, just one person had already had experience with the HoloLens device, whilst the other had never ever tried them also for different purposes.

Qualitatively, the distance between the user face and the 3D printed model varied from 5 cm to 30 cm depending on which line was been drawing, the frontal one on the chin or the lateral ones.

The 3D model was positioned over a table onto a box, to reproduce the height of an operating table as it can be seen in Figure 4.37.

Table 4-1 Partecipants'list to the HoloLens trials. On the column are shown the name, the profession, the previous experience with HoloLens2 and the time taken to do the task

Nome	***Profession***	***Experience with HoloLens2***
User 01	Univpm student	No
User 02	Univpm student	No
User 03	Univpm PhD researcher	Yes
User 04	Univpm PhD researcer	No
User 05	Univpm student	No

4.6 Validation

To assess whether this approach is valid or not, a validation process has been made using the *.vmrl files from the scanning phase, Rhinoceros and CloudCompare software.

The validation consisted in the comparison between the lines obtained from the scans, reconstructed in Rhinoceros, and the lines planned obtained from the CAD file used also for the 3D printing (here called ''reference curves'').

In CloudCompare the comparison is made and 10 graphs, one for each trial, are obtained. For each graph there is a legend box displaying the deviations in mm between the line traced during the trial and the lines projected in Rhinoceros.

4.6.1 Scan

The scanning phase consisted in scanning the 3D mandible with the red lines drawn over the paper scotch covering, obtaining a *.vmrl file representing the mandible with all its textures.

This phase allows to acquire the mandible and the surgical guides to compare them with the previously created CAD model.

The used scanner is Go!Scanner 3D, a handheld scanner which allows to take the scans in very little time.

Before scanning the object is necessary to calibrate the scanner, to do so over a piece of paper standing on the table, 6 markers have been attached in a non-aligned way. The paper is then scanned, and the scanner is calibrated.

After the mandible has been positioned between the markers over the paper, it has been fixed to the plane with two pieces of playdough so that the mandible leaned on its condyles as during the task (Figure 4.38).

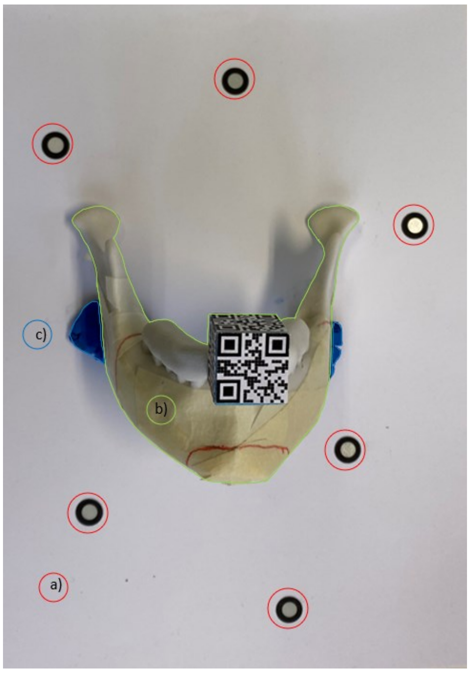


Figure 4.38 Set for the scanning phase: a) markers, b) mandible covered with paper scotch, c) playdough supports

Once the set for the scanning is ready, the mandible has been scanned by moving the scanner over it and around it. The scanner gives a green light feedback if the distance between it and the object is right otherwise it gives a red-light feedback. Simultaneously on the pc, using the software VX elements, appears the scanned object with its texture (Figure 4.39).

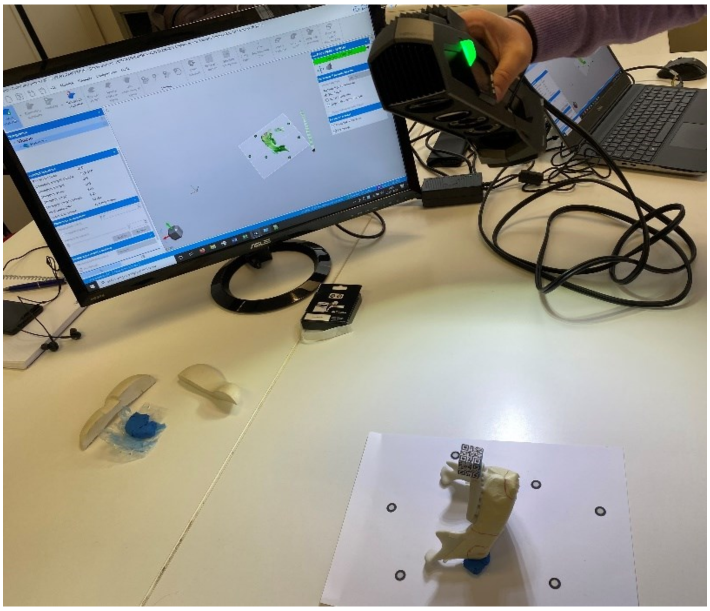


Figure 4.39 Scanning phase with simultaneously object view on pc

The parameters inserted for the scan are:

- *Metodo di posizionamento*: Target/Geometria
- *Risoluzione*: 0.50 mm

After the scan is completed 3 markers are chosen allowing the software to save just the object and not the plane under it and then the file is exported as *.vmrl and saved.

4.6.2 Rhinoceros procedure

The reconstruction was made on Rhinoceros because the curves need to be thickened as the reference curves.

The steps followed on Rhinoceros to recreate the lines traced during the trials are the following (Figure 4.40):

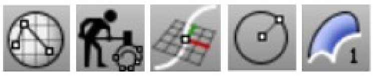


Figure 4.40 Rhinoceros' commands to recreate the surgical guidesfrom trials' scans

- Import the *.vmrl file of the scan (Figure 4.41)

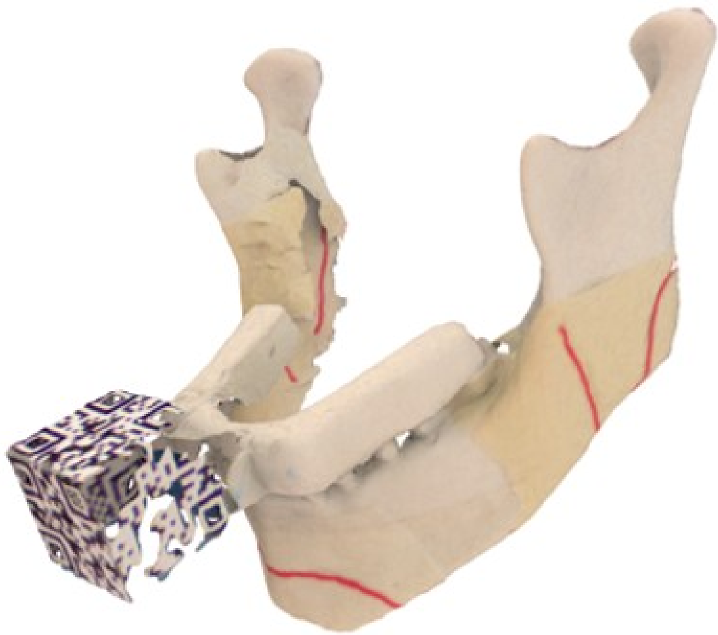


*Figure 4.41 Import of the *.vmrl scanned file*

- *PolylineOnMesh:* allows to create a polyline over the scan mesh. With this command the surgical guidesare traced over to reconstruct these curves on Rhinoceros (Figure 4.42).

Figure 4.42 Polylines recreated from the red surgical lines

- *RebuildCurveNonUniform*: allows to rebuild the created curves making them smoother by setting these parameters:
    - *RequestedTolerance = 0.2 mm*
    - *MaxPointCount = 10*
    - *DeletInput = no*

  The obtained curves are continuous and not segmented anymore (Figure 4.43).

Figure 4.43 Rebuilt curves (in black) from the polylines (in green)

- *Perspective View→Set C-Plane→ Perpendicular to curve*: allows to set the cutting plane in correspondence of one of the curve's extremity (Figure 4.44).

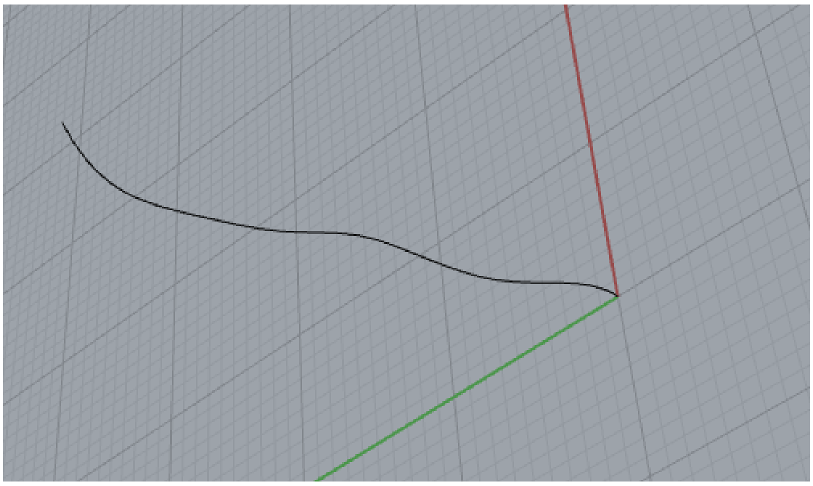


Figure 4.44 C-Plane set perpendicular to a curve

- *Circle*: allows to create a circle with a specific diameter, 1 mm in this case, in a specific point, the extremity of the curve in this study. The circle's diameter is chosen as 1 mm since the reference curves are 1 mm thick either (Figure 4.45).

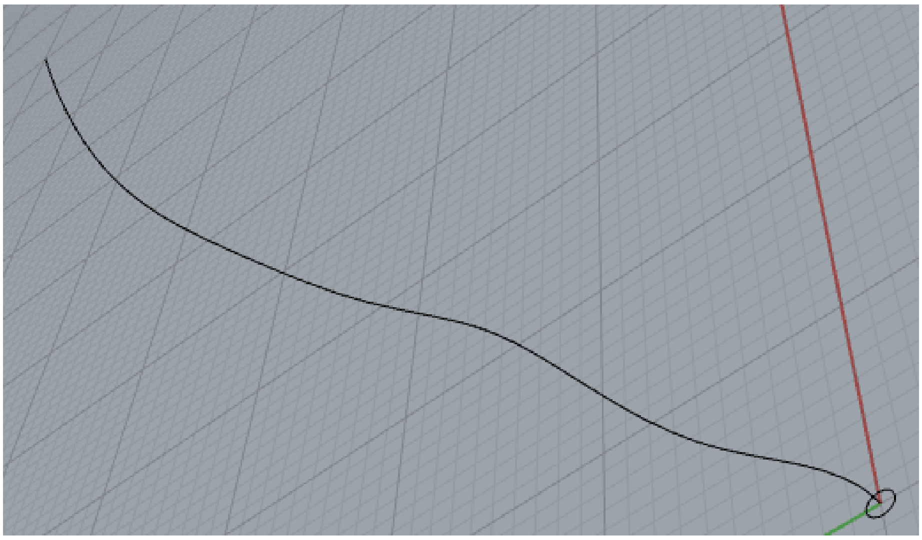


Figure 4.45 1 mm diameter circle at the base of the curve

- *Sweep1*: allows to fit a surface through a series of profile curves, that define the surface cross-sections, and one curve that defines a surface edge. After this command, the lines looks like thin tubes (Figure 4.46).

Figure 4.46 Thickened curves ready to be used for the comparison

- *Select the curves→Export selected as *.stl*
- *Select the scan→Export selected as *.stl*

There is the need to export both the curves and the scan separately since it is necessary for making the comparison in CloudCompare.

4.6.3 CloudCompare procedure

CloudCompare software is used to make a comparison between the curves obtained during the trials and the curves projected in the surgical lines' development at the beginning of the study.

For simplicity, for each comparison, the rebuilt curves and mandibles from the scans are called ''Curve_Reali'' and ''Mandibola_Reale'', respectively, whilst the reference curves and reference mandible are called ''Curve_Nominali'' and ''Mandibola_Nominale''.

After having imported the four files, ''Curve_Reali'', ''Mandibola_Reale'', ''Curve_Nominali'', ''Mandibola_Nominale'', the comparison process starts.

CloudCompare software differentiates by colors the reference meshes with respect to the comparing ones; the reference meshes are colored in yellow, whilst the comparing ones in red.

To fasten the work, after the importing, the 4 files have been colored as consequence: the reference mesh and curves in yellow and the comparing mesh and curves in red (Figure 4.47).

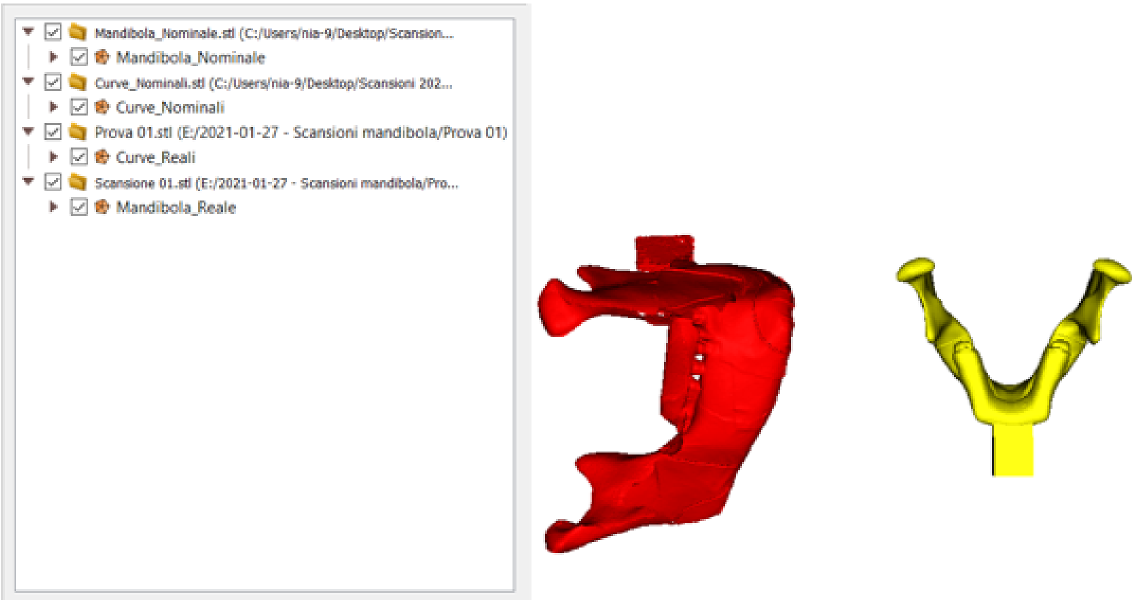


Figure 4.47 CloudCompare interface displaying the 4 files in different colors

The steps (Figure 4.48) to do so are:

- *Edit*
- *Colors*
- *Set Unique→Choose the color*

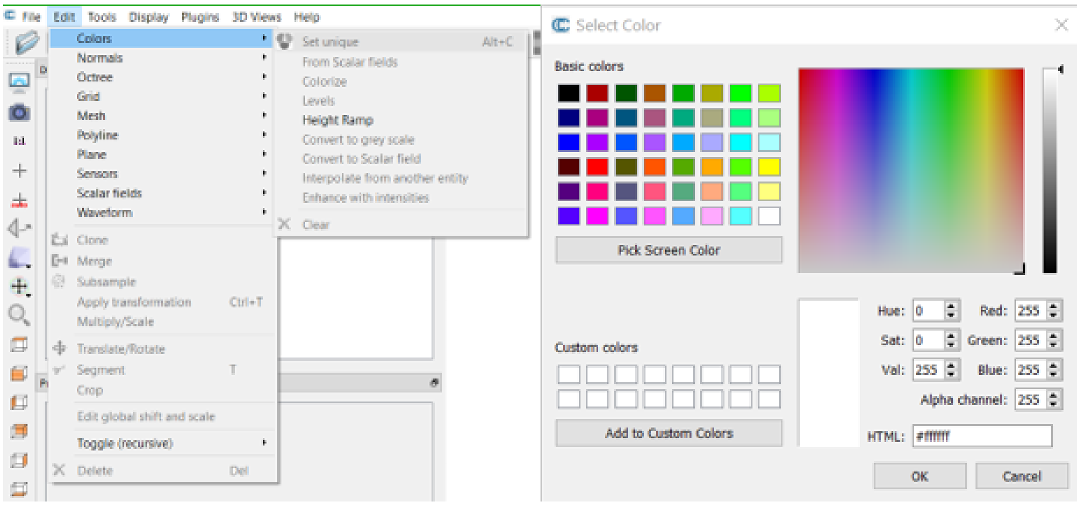


Figure 4.48 Change color process

The alignment process consists of 5 steps, listed below:

- Select ''Mandibola_Reale'' and ''Mandibola_Nominale'' → *Aligns two clouds by picking equivalent points* (Figure 4.49)→ Select ''Mandibola_Reale in ''select aligned entities window'' (Figure 4.50)

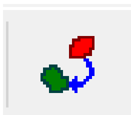


Figure 4.49''Aligns two clouds by picking equivalent points'' command

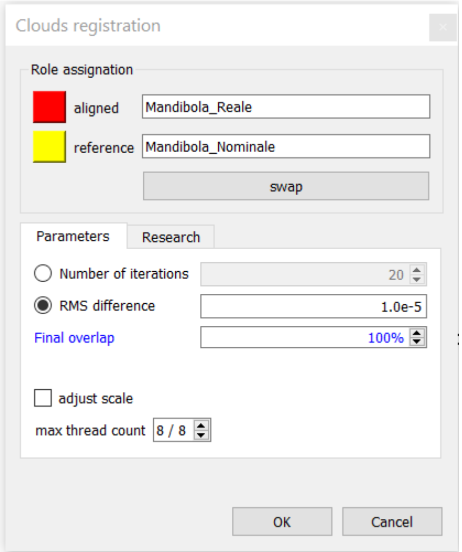


Figure 4.50 Reference and aligned settings

- Select at least 3 pairs of matching points on both mandibles (Figure 4.51)

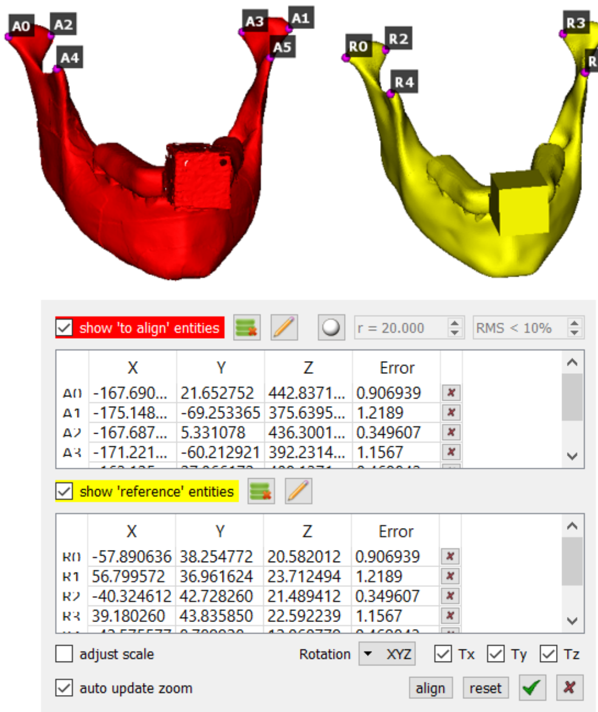


Figure 4.51 Matching points selection

- Select ''Mandibola_Reale'' and ''Mandibola_Nominale'' → *Finely registers already aligned entities* (Figure 4.52*)*

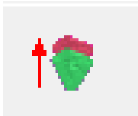


Figure 4.52 ''Finely registers already aligned entities'' command

- Select ''Mandibola_Reale.registered''→Copy the Transformation Matrix showed in the ''Properties'' panel (Figure 4.53)

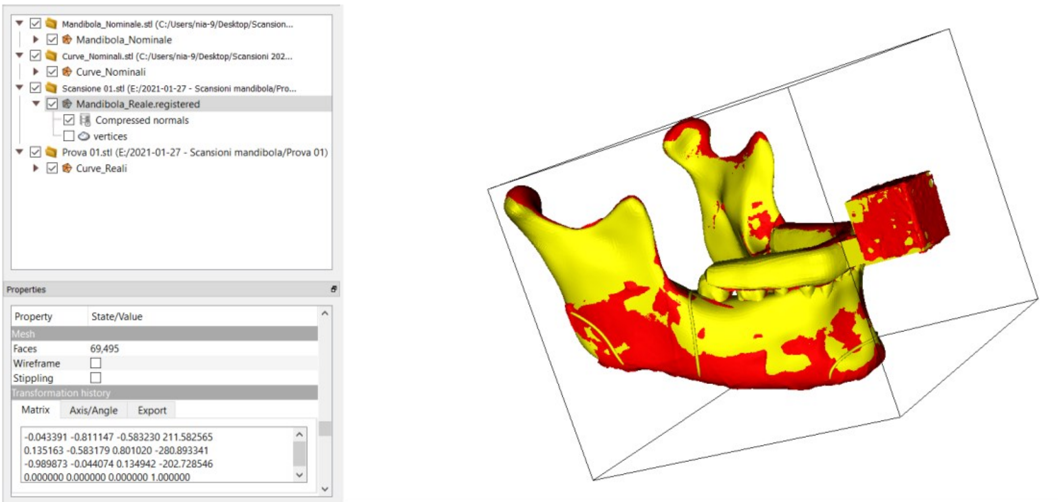


Figure 4.53 Aligned mandibles and Transformation Matrix displaying

- Select ''Curve_Reali''→ *Edit*→ *Apply Transformation*→ paste the transformation matrix (Figure 4.54)

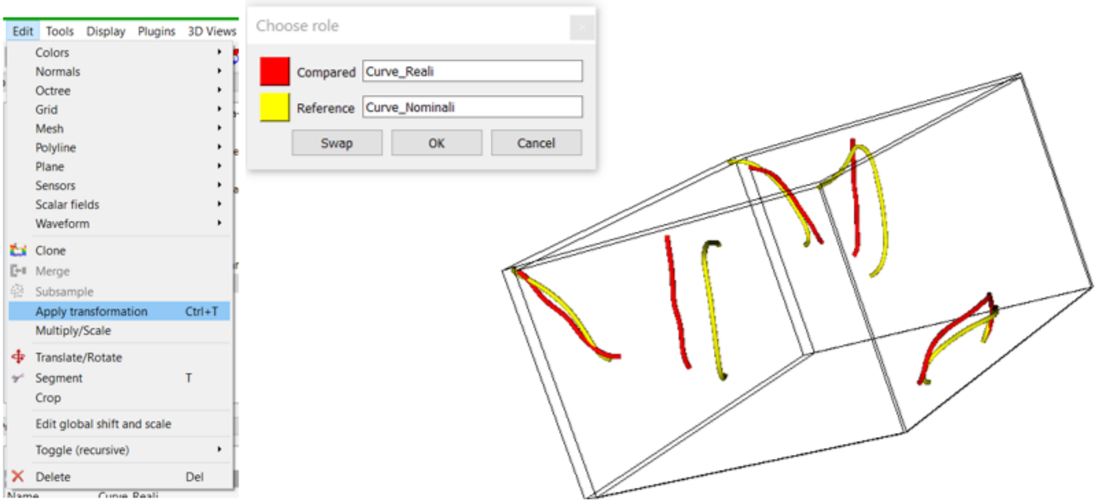


Figure 4.54 Transformation matrix application

- Select ''Curve_Nominali'' and ''Curve_Reali''→ *Compute Mesh distances*→set the maximum distance as 10 mm (Figure 4.55)

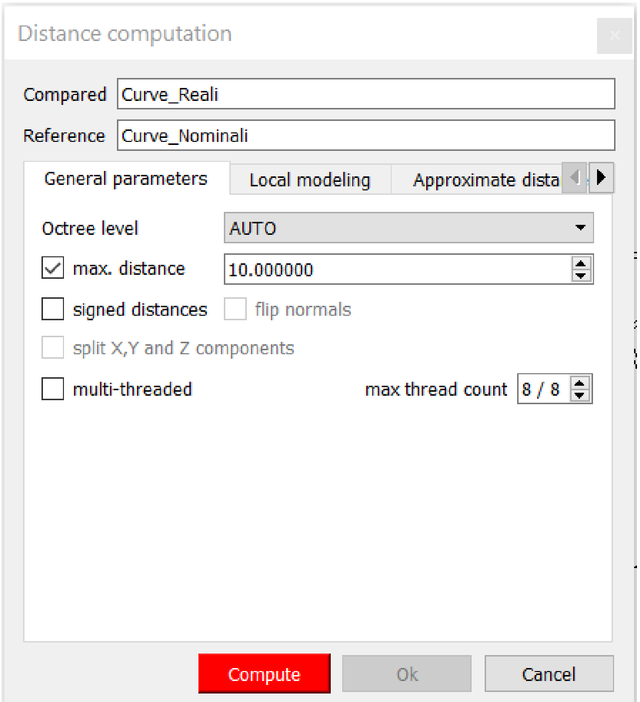


Figure 4.55Distance computation

The result obtained after these steps is showed in Figure 4.56.

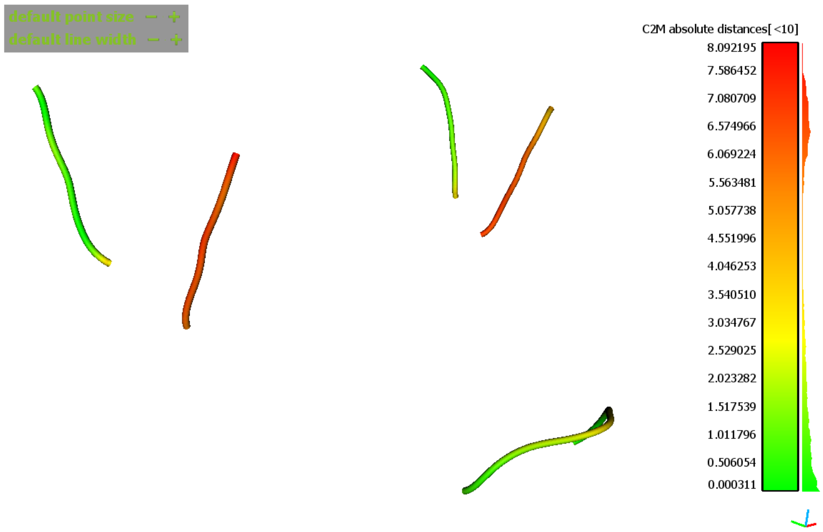


Figure 4.56 Obtained result from the alignment displaying the absolute distances from the planned surgical lines

On the side is displayed the box legend by which it is possible to see how the traced lines were away from the planned ones: the green indicates lower deviations while red indicates too much higher deviations.

It is also possible to obtain a histogram that shows the deviations as well (Figure 4.57).

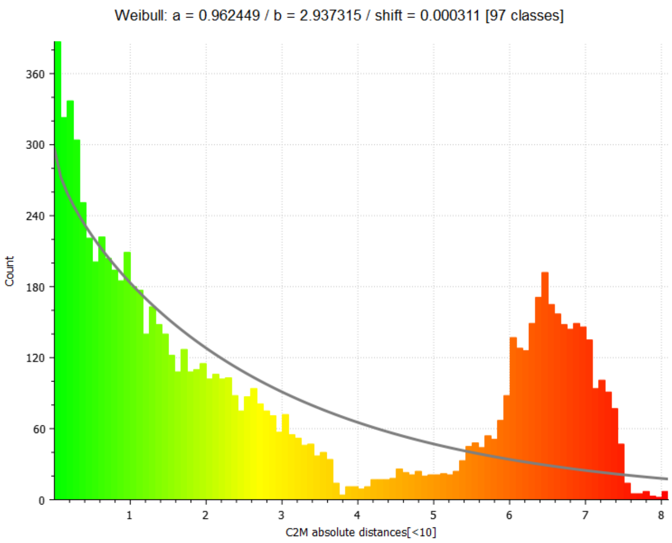


Figure 4.57 Histogram of the deviations: on the x axis it is displayed the absolute distances, on the y axis the count

5 Results and Discussion

This thesis work proposed a first approach to develop an AR application for maxillofacial surgeries using the newest Microsoft's HMD, HoloLens2.

The aim consisted into project where surgical guides should be made during the surgery, create an AR application with the goal to display augmented lines over a 3D printed model of a mandible and deploy the application onto HoloLens2. After that, it was asked to five different, inexpert, users to try the application by tracing over the model the red lines displayed by the HoloLens.

The obtained results refer to these trials, 2 for each participant, from which the comparisons between the traced lines during the trials and the planned ones are got. What has been inspected with this work is if the application can be applied during a real surgery, its accuracy in augmenting the lines in the right place and the deviations with the reference lines.

The results are showed using a graphic method in which the deviations are displayed by different gradations of colors, histograms of the deviations, tables showing the mean distances and standard deviations and graphs illustrating for each trials the percentage of sample points under certain deviation ranges.

To be applied during a real surgery it is necessary that the lines are displayed with deviations equal or lower than 1 mm, otherwise the surgeon will cut too much distant from the planned cutting site.

The accuracy evaluation is assessed, also, by determining how the lines' color was well visible, how or if the lines were unstable once projected, and which was the feeling sensed by the user during the task.

It is important that the user feels comfortable and sure about where the surgical guides are displayed onto the real bone, so if they are unstable, too much transparent or with too low contrast to not be well visible, the application is not appliable in the operating room.

5.1 Deviations evaluation

As already explained, to calculate the deviations in mm between the surgical guides traced during the tests and the planned ones, both Rhinoceros and CloudCompare software were used. The first to reconstruct the curves from the scans and the second to compare the reference curves and mandibles with the trial's ones.

Five people performed the task of tracing, while wearing the HoloLens, the surgical guides augmented onto the 3D printed mandible with a pencil. During the test, the users were allowed to move around the mandible in order to find a comfortable position allowing them to better trace the lines. After that, the lines were over-traced with a red pen to be better visible by the scanner.

Each tester computes the task twice, to assess if in the second trial the user was improved in performing the assignment, and the time taken to accomplish it was taken for each person (Table 5-1).

The participants were chosen among students and PhD researchers at Università Politecnica delle Marche, just one of them has already had experience with augmented reality application and HoloLens.

Here below are showed the comparison images obtained from CloudCompare, with the legend box on one side that displays the absolute deviation with a colored scale. The green color indicates lower deviations while the red indicates higher and worst deviations.

Table 5-1 Time taken to perform the 2 trials

Name	***Trials' Time***	
	1° trial	***2° trial***
User 01	4′	5′
User 02	3,21′	3,29′
User 03	2,10′	2′
User 04	2,40′	2,35′
User 05	3,15′	2′

Table 5-2 Mean Distances and Standard Deviations for each user's trial

User	**1° trial**		**2° trial**	
	Mean Distance [mm]	**Standard Deviation [mm]**	**Mean Distance [mm]**	**Standard Deviation [mm]**
1	2,983305	2,587184	3,157488	2,898531
2	1,937439	1,415495	1,884291	1,609807
3	1,866397	1,467729	1,605601	1,264795
4	2,900265	2,986354	3,284013	1,947789
5	3,200462	2,183031	2,226419	2,278647

The mean and standard deviations are listed in Table 5-2, divided per trials.

The mean distance improved in 3 out of 5 users, user 2, user 3 and user 4, between the 2 trials whilst users 1 and 5 increased the mean distance in similar way.

Below are shown the figures (Figure 5.1, Figure 5.2, Figure 5.3, Figure 5.4, Figure 5.5) representing the surgical guides traced with AR guidance in function of the absolute distance from the reference ones for each user and for each trial, the trial is recognize by the circled number on the figure, 1 or 2.

The green color indicates a lower deviation while the red one a higher deviation.

The maximum deviation is set at 10 mm, the results show that just user 04 (Figure 5.4) had reached this maximum, while the others remained under the 10 mm.

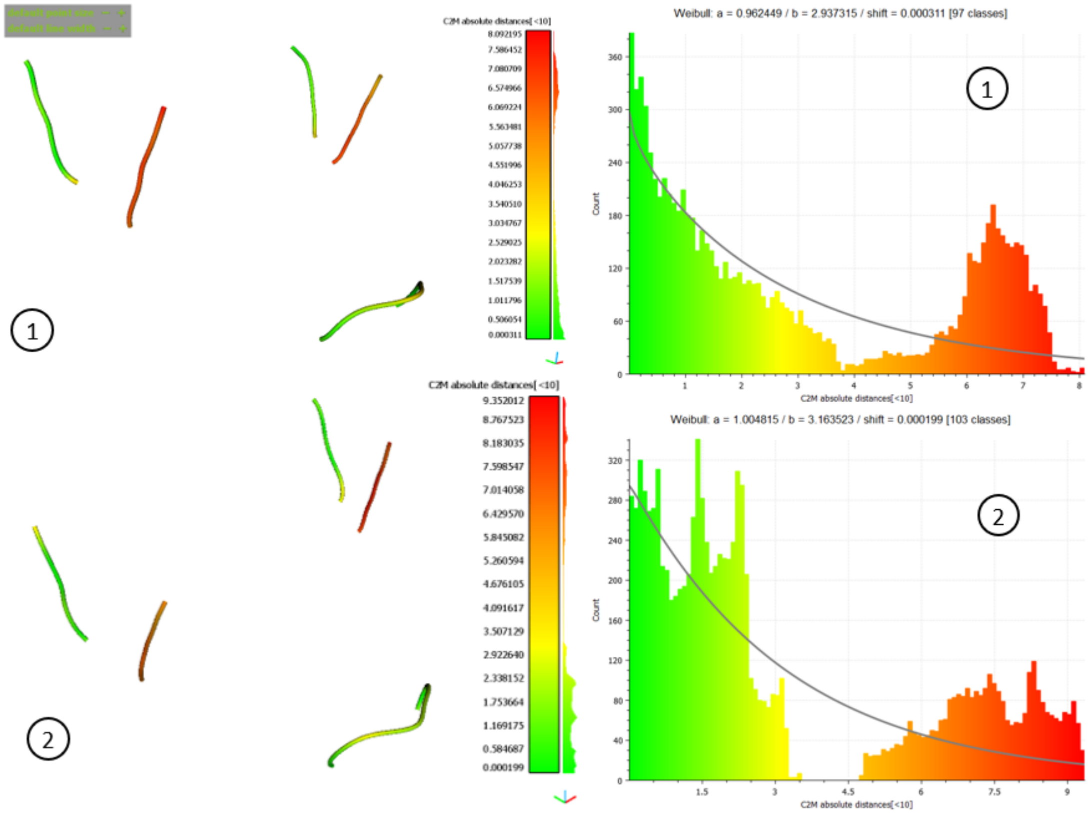


Figure 5.1 User 01

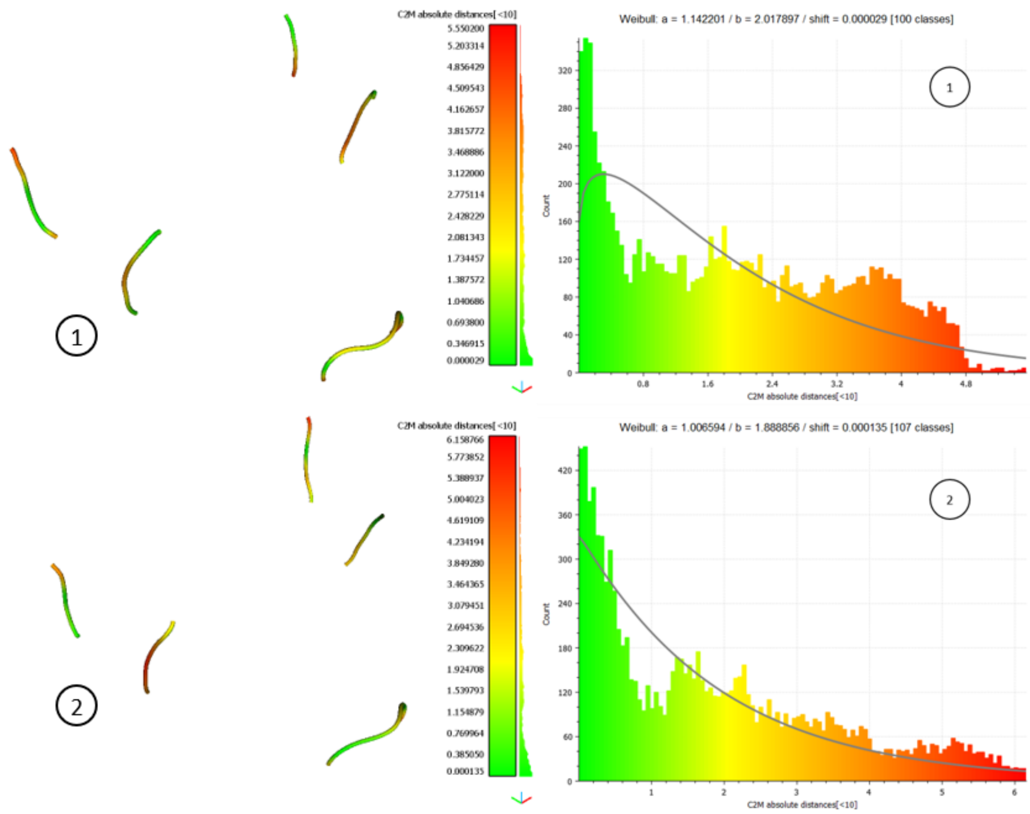


Figure 5.2 User 02

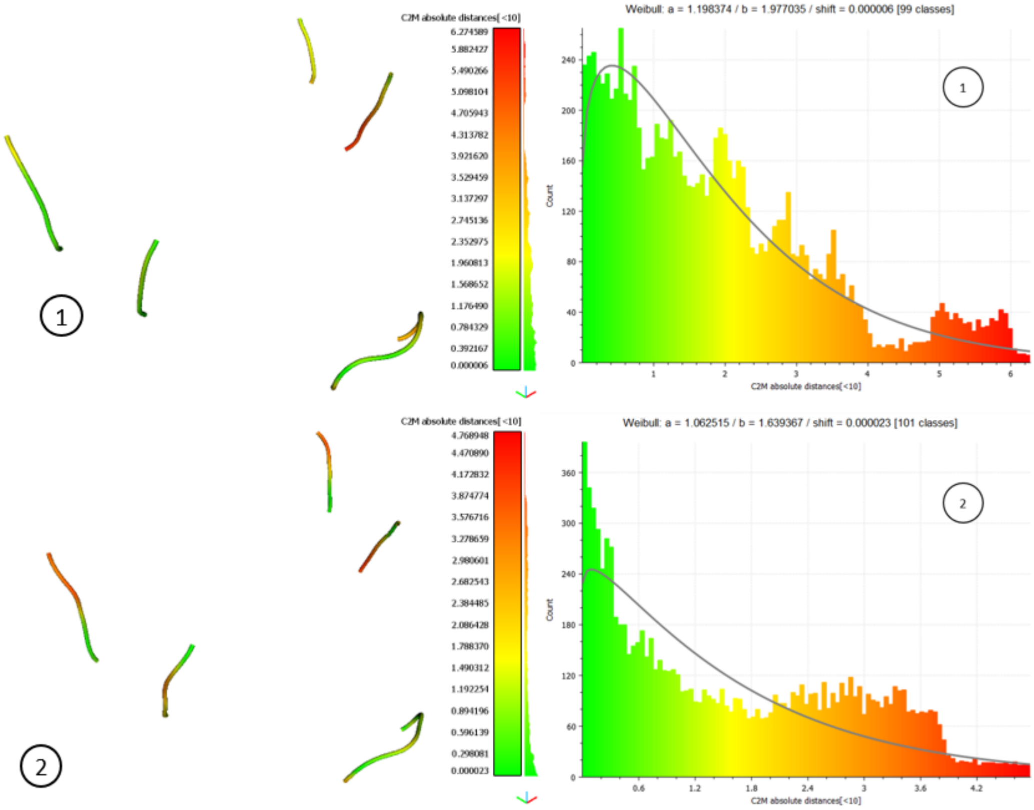


Figure 5.3 User 03

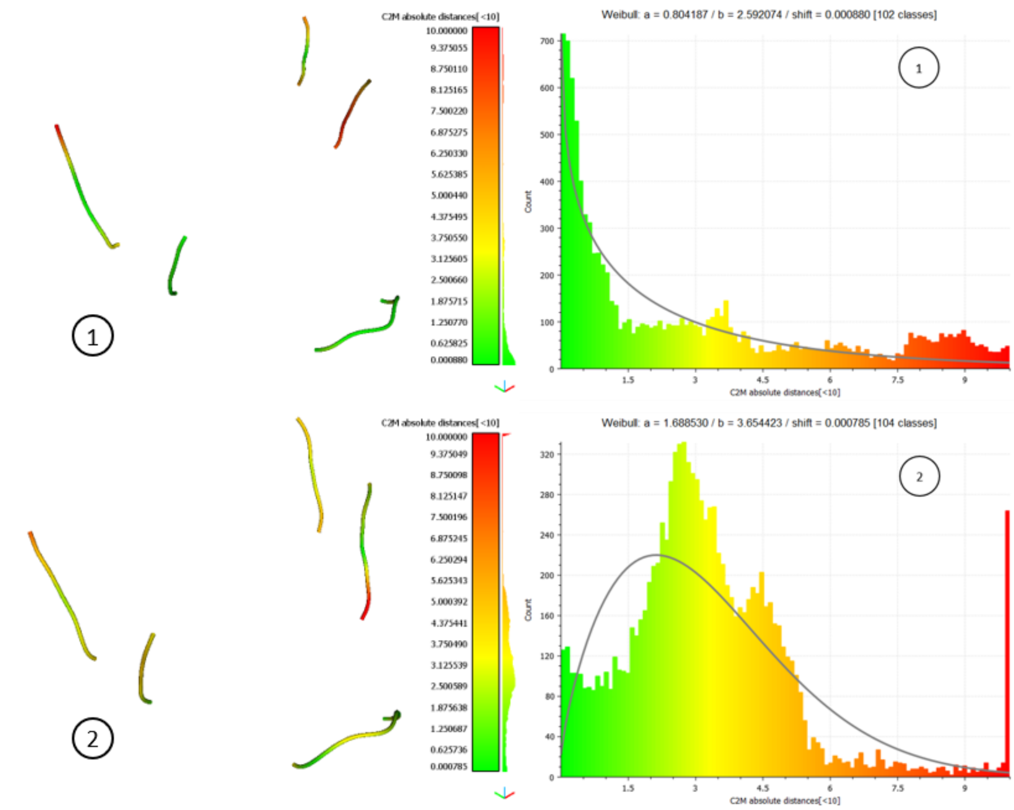


Figure 5.4 User 04

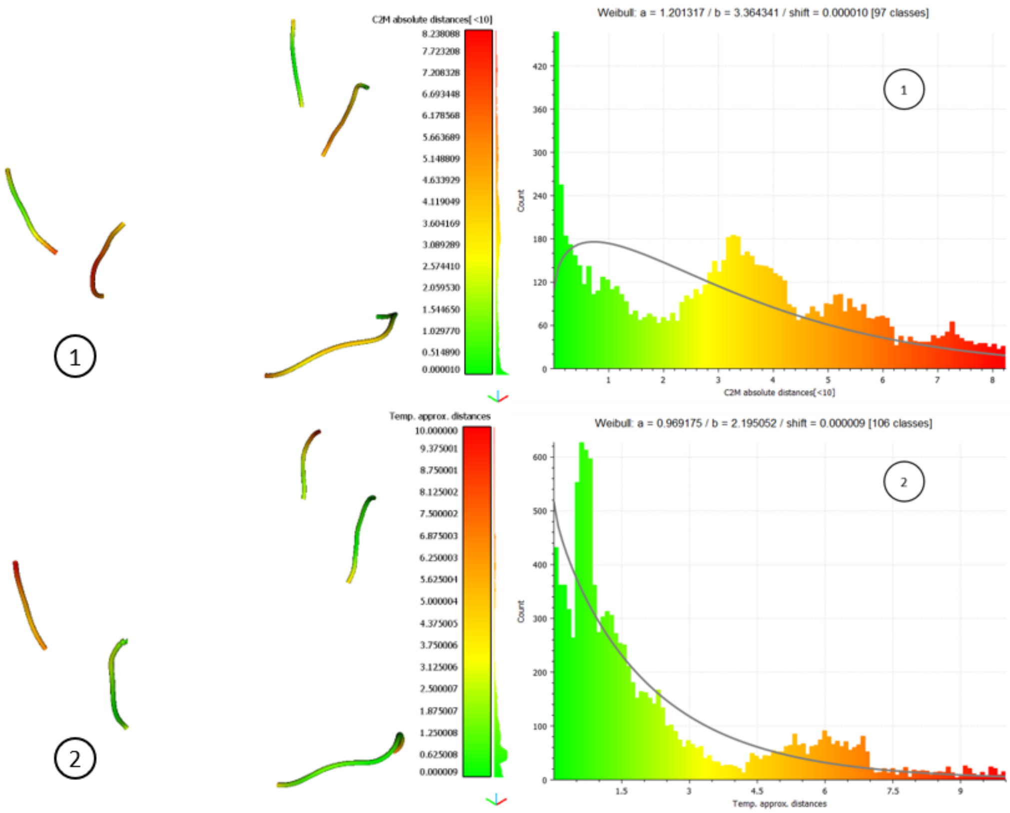


Figure 5.5 User 05

To better understand these results, for each trial, it has been calculated the percentage of sample points in function of the deviation in mm (Figure 5.6).

The obtained graphs help to analyze and comprehend what percentage of points has been drawn under a certain deviation, allowing to understand how good or bad was the trial.

The graphs have been made by taking the number of samples and their corresponding deviation, then for each sample group the percentage with respect to the samples' total has been made.

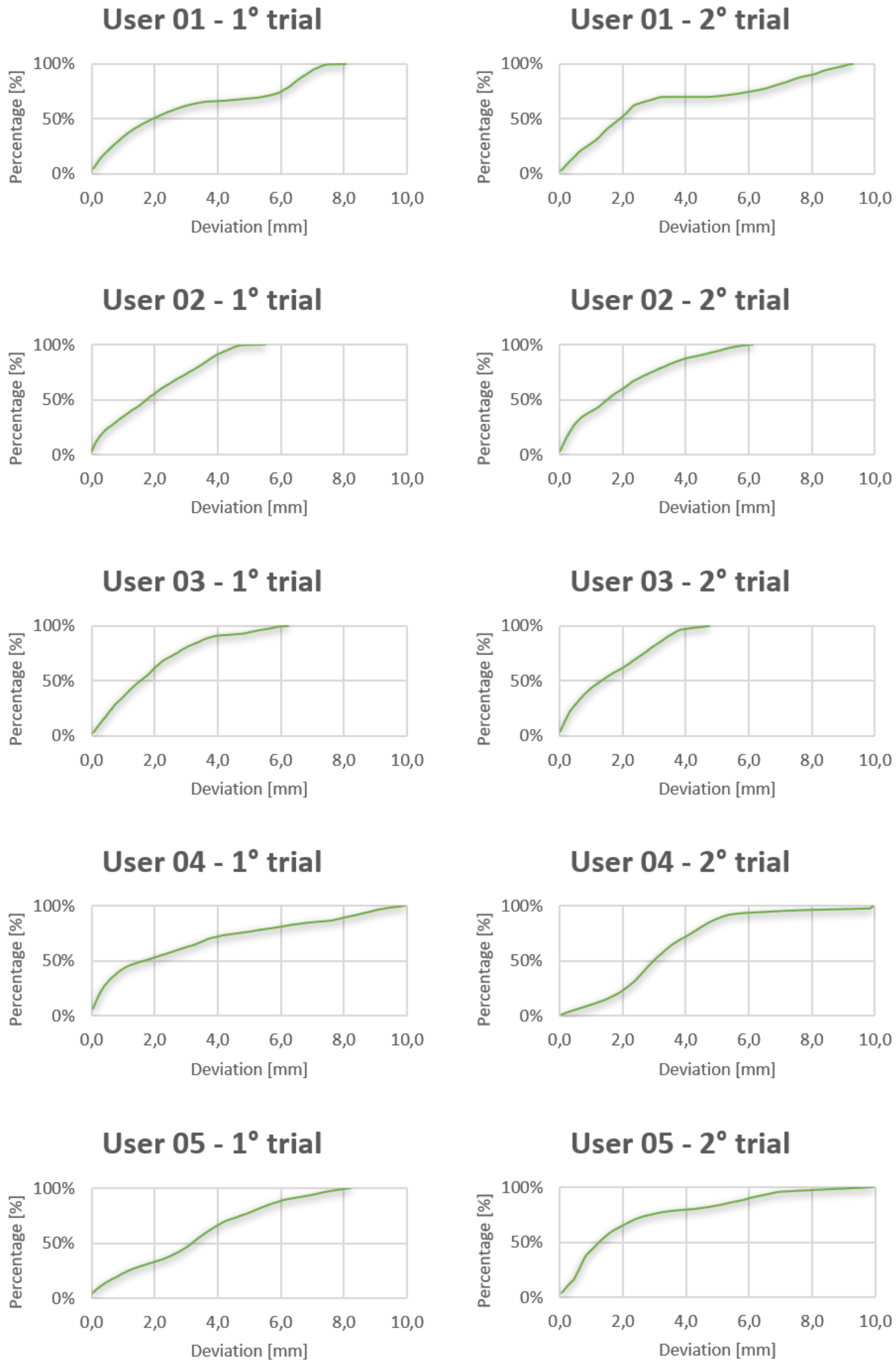


Figure 5.6 Graphs showing percentage's samples in function of the deviations [mm] for each user and trial

5.2 Results analysis

Through the analysis of the above graphs the following Table 5-3 has been obtained in which on the columns are displayed the users, which one is divided into two more columns to represent the trials, on the rows there are the percentage's values taken as threshold to investigate how big the deviations at each step percentage.

Four thresholds have been taken, 100%, 75%, 50% and 25%, and by using the obtained results the deviations have been obtained.

Table 5-3 Deviations' analysis in function of the percentage of samples

	User 01		***User 02***		***User 03***		***User 04***		***User 05***	
Sample	***1°***	***2°***	***1°***	***2°***	***1°***	***2°***	***1°***	***2°***	***1°***	***2°***
100 %	8 mm	9.3 mm	5.5 mm	6.1 mm	6.2 mm	4.7 mm	10 mm	10 mm	8.1 mm	10 mm
75 %	6 mm	6 mm	3.1 mm	2.9 mm	2.6 mm	2.7 mm	4.7 mm	4.1 mm	4.7 mm	3 mm
50 %	1.9 mm	1.9 mm	1.8 mm	1.5 mm	1.5 mm	1.3 mm	1.6 mm	2.9 mm	3.1 mm	1.2 mm
25 %	0.6 mm	0.8 mm	0.5 mm	0.4 mm	0.6 mm	0.4 mm	0.3 mm	2 mm	1.1 mm	0.5 mm

Figure 5.7 is obtained from Table 5-3 and displays for each user the trend for each trial, in green it is showed the first trial trend, in blue the second.

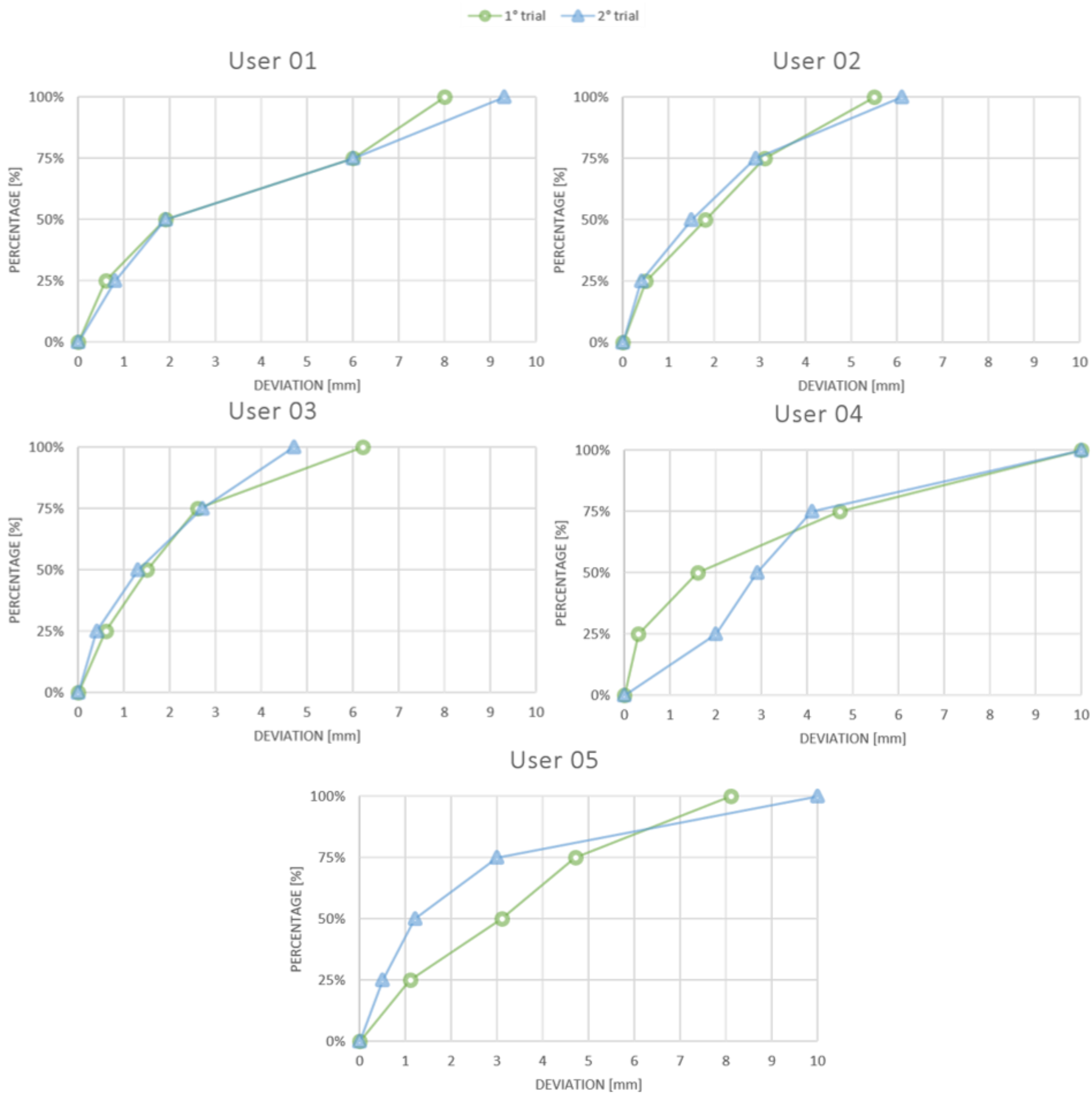


Figure 5.7 Users' deviations' trends

User 01 had not improved between the 2 trials, in fact during the first test all the samples were under 8 mm of deviation while in the second the maximum deviation is increased to 9,3 mm. However, the 75 % of samples stayed under 6 mm of deviation in both trials, which means that only a quarter of sample have reached the maximum distances.

User 02's trials have all the sample under 6,1 mm deviation, with just very little improvement between the 1° test and the 2° at 75% of samples.

User 03 obtained the best results among the five and improved from the first to the second trial. In the 2° trial all the sample were under 4,7 mm deviation, the 75% under 2,7 mm, 50 % under 1,3 mm, and 25 % under 0,4 mm.

User 04 did not improve in the second task, in fact while in the 1° trial the 25 % of the sample were under 0,3 mm deviation, in the 2° trial this value increased to 2 mm. In both trials the user reached 10 mm in deviation which is set as the maximum.

User 05 also had reached the 10 mm in maximum deviation in the 2° trial; however, he/she had slightly improved since the 75 % of samples were under 3 mm of deviation (vs 4,7 mm in the 1° trail), the 50% under 1,2 mm (vs 3,1 mm) and the 25 % under 0,5 mm (vs 1,1 mm).

Meulstee et al. reported a mean error of 2,3 ± 0,5 mm in their loose-fit experiment consisted in comparing the position of a cube placed in 21 different position on a measuring board and the planned positions of the cube [20].

Mitsuno et al. reported a mean error of 2,89 ± 0,67 mm when trying to align anatomical holograms on a 3D human phantom [19].

Frantz et al. in their study to assess holograms' stability using Vuforia SDK, reported a mean error of 1,41 mm, with a perceived drift under 2 mm in 53 %of placements, the 40 % was between 2 and 5 mm, the 7 % between 5 and 10 mm and 0 % over 10 mm deviation [21].

Rae et al. study about the displaying of a hologram floating in the patient's head to mark a burr hole on the skull to assess deviations, reported that for low experienced users the 50 % of marker placements was under 2 mm deviation, the 24 % between 2 and 5 mm, the 39 % between 5 and 10 mm and 2 % over 10 mm [27].

Liu et al. reported deviations in headset positions of 5,6 mm for slow movements, 20,6 mm for quick movements and 133,8 mm for rapid movements during the trial consisted into moving the visualized hologram to overlap with the real box as exactly as possible and then to take three photographs of the overlapped boxes from the front, side, and top views [28].

Auvinet et al. reported headset deviations of 5,6 mm along x axis, 4,4 mm along y axis and 5,2 mm along z axis [29].

Better results have been obtained from studies that used different HMD than HoloLens:

- Lin et al. using Sony's HMZ-T1 HMD reported a lateral mean deviation of 0,47 ± 0,27 mm.
- Jiang et al. reported mean distance deviation of 1,29±0,7 mm by using nVisor ST60.
- Badiali et al. research using the eMagin Z-800 HMD a mean error of 1,70 ± 0,51 mm.

5.3 Results discussion

The obtained results are comparable with the literature on HoloLens, although in the present study HoloLens 2 have been used, the most recent version of Microsoft's HMD.

The accuracy in oral and craniomaxillofacial surgery is considered acceptable if it is between 1 to 2 mm [20], however from this study the results are not in this acceptable range at all, in fact the mean distances for each trial are respectively, 2,58 mm and 2,43 mm.

These bigger drifts are caused by the perceived drift during the test since the users reported that the holograms were sensed with an offset with respect to the mandible surface. Moreover, the users could move during the trials, and this cause bigger errors in the tracking and position of the surgical line holograms with respect to a test performed in a stationary position.

Another problem was the holograms' stability, the holograms appeared unstable during the trials, so it was difficult to easily trace the guides with precision.

In addition, HoloLens 2 works better when the holograms and tracked object are positioned at an optical distance approximately 2.0 m away from the user, otherwise discomfort between convergence and accommodation appears. However, in applications where holograms and user are stationary, the holograms appear good also at 50 cm.

The issue in this research is the fact that the target with the mandible and the holograms cannot be placed at 2 m distance from the user, and moreover, the user needs to move around the mandible to find a position that he/she finds comfortable to perform the task.

It is possible to reduce the instability of the holograms by changing the clipping plane of the camera game object in Unity and set it at 85 cm, but it is recommended to create scenarios in which the users and holograms stay fixed for at least the 25 % of the time.

To better stabilize the holograms, HoloLens2 offers the option called ''Depth Reprojection'', which is a hardware-assisted holographic stabilization technique that refers to the movements and changes of the position of the camera (point of view) when the scene is animated. Enabling this option all the parts of the scene are stabilized with respect to their distance from the user in an independent way. To enable the Depth Reprojection it is necessary to check the ''Shared Depth Buffer'' option in WindowsMixedRealitySettings panel in Unity and activate the ''Depth Reprojection'' on the device through the WindowsDevicePortal website.

In conclusion, the results obtained in this study are not usable for real application during a real surgery, but they are coherent with the results found in literature research about the using of HoloLens in maxillofacial surgery.

Since this is one of the first works regarding the use of the HoloLens2, some improvements need to be done to the present application by improving the Unity application by setting the above explained option to avoid the holograms' instability.

6 Conclusions and Future Directions

The aim of the present study was to develop an AR application appliable in maxillofacial surgery using HoloLens2 device.

The whole process started from digital CAD model obtained from CT scans of a jaw, with the CAD software Rhinoceros a target support has been attached to the mandible through an already present lower arch splint.

Then the surgical guides have been digitally planned, created, and exported as 3D objects to be imported into Unity software and to be augmented.

The CAD model of the mandible has been printed using the 3D printer Z400, through selective laser sintering technique, and a 3D mandible with the target support has been obtained.

Using Vuforia SDK, the multitarget database with the 6 target images chosen, has been downloaded and imported into Unity, where the whole application has been developed.

The Mixed Reality Playspace has been set and in the scene have been added the multitarget cube (2x2x2 cm) and the surgical guides previously developed in Rhinoceros.

The cube and the guides were already been aligned, before been exported, in Rhinoceros.

The application has been, then, deployed by VisualStudio IDE, and tests have been made to test the accuracy and applicability of the app.

Five people, students and PhD researches, have made 2 trials in which they were asked to trace over the printed mandible the guides augmented by the HoloLens.

At the end of each trial, each traced mandible has been scanned using the 3D scanner, Go!Scan3D, to obtain digital models of the drawn guides. These lines were then rebuilt in Rhinoceros to obtain thickened lines allowing to make the comparison in CloudCompare.

From the comparison the deviations from the planned positions for each guide have been obtained and analyzed.

In terms of validation, the obtained results are not suitable, in fact the drawn surgical lines were too much distant from the planned ones; on average the 75% of curves' sample points were under 6 mm of deviation, 50% under 2,15 mm and 25% under 1,15 mm.

These numbers suggest that more improvements are needed to validate this process.

However, also in literature not so different results have been obtained, confirming the needs of more research.

AR application in surgical field, precisely in maxillofacial surgery, can be very interesting, since this technology allows to lower the production's costs of physical surgical guides, lower the time required to position the guides since no drilling is required and allow the surgeon to be more hand-free during the procedure.

Several problems, though, are already present that do not make this application suitable to real applications, in fact the surgical guides during the augmentation displayed an offset, making the user feel as if they were not precisely over the surface of the printed model. In addition, the users were moving around the model and the holograms' stability is deprecated by this.

HoloLens2 have an optimal distance at which the holograms and object are visualized and displayed for the best comfort, this distance is 2 m, lowering this distance the holograms' stability decreases.

To overcome these problems, it is necessary to study how to improve the application, in particularly the holograms' stability, precision and accuracy and to better understand which are the settings to obtain good and not moving holograms.

Future work could regard the improvement of the feedback provided to the surgeon during the maxillofacial surgeries, especially during the mandibular advancement procedures, and more tests to improve the accuracy and precision of the present application.

It could be interesting trying to use an image target instead of the multi target, since the HoloLens2 allow the extended tracking, which makes the holograms to remain in their positions even if the target is not visible anymore.

Another implementation should be to create the surgical guides in Rhinoceros with a thinner offset and symmetric with respect to the bone surface, in order to decrease the feeling that the projected lines are too much thick.

A new application could consist in the use of two different target images, one used to display and position the piece of jawbone at its final position and the other should be just placed over the to be moved jawbone.

When the second target, positioned on the jaw, will reach the first one displaying the final jaw position, these holograms become green giving the surgeon a visual feedback, so he/she can quickly understand when and if he/she is positioning the advancing jaw in the correct position.

To implement such application is necessary to precisely calculate the transformation matrices of the advancing jaw and of the final jaw.

In conclusion this study has confirmed the potentiality of the use of AR in surgical field, but further improvements and tests are necessary before being able to apply this technology in a real operating room during a maxillofacial surgery.

7 Bibliography

[1] J. Wang, H. Suenanga, L. Yang, E. Kobayashi, I. Sakuma, *Video see-through augmented reality for an oral and maxillofacial surgery,* International journal of medical robotics and computer assisted surgery (2017) https://doi.org/10.1002/rcs.1754;

[2] G. Badiali, V. Ferrari, F. Cutolo, C. Freschi, D. Caramella, A. Bianchi, C. Marchetti, *Augmented reality as an aid in maxillofacial surgery: validation of a wearable system allowing maxillary repositioning,* Journal of cranio-maxillofacial surgery (2014) https://doi.org/10.1016/j.jcms.2014.09.001;

[3] S. Aukstakalnis, *Practical augmented reality: a guide to the technologies, applications, and human factors for AR and VR,* Pearson Inc (2017) chapter 1;

[4] I.E. Sutherland, *A head-mounted three dimensional display,* Fall Joint Computer Conference (1968), pp. 757-764;

[5] M.A. Callahan, *A 3-D display head-set for personalized computing*, M.S. thesis, Dept. of Architecture, Massachusetts Institute of Technology, pp 110. (1983);

[6] S. Feiner, Bl. Macintyre, D. Seligmann, *Knowledge-based augmented reality*, Volume 36, Issue 7, pp.53-62 (1993);

[7] A. Dad, B. Arora, N. Parkar, T. Rachh, *Augmented reality: tracking methods,* International Journal of Engineering Research & Technology (2017);

[8] L. Chen, F. Zhang, W. Zhan, M. Gan, L. Sun, *Optimization of virtual and real registration technology based on augmented reality in a surgical navigation system,* BioMed Eng OnLine (2020) 19:1, https://doi.org/10.1186/s12938-019-0745-z ;

[9] R.T. Azuma, *A survey of augmented reality*, Teleoperators Virtual Environments, 6 (1997), pp. 355-385;

[10] Y. Uematsu, H. Saito, *Vision-based registration for augmented reality with integration of arbitrary multiple planes*, International Conference on Image Analysis and Processing (2005), pp. 155–162;

[11] D. Schmalstieg, T. Höllerer, *Augmented Reality: Principles and Practice*, Addison-Wesley (2016), chapter 5;

[12] J. Keil, F. Schmitt, T. Engelke, H. Graf, M. Olbrich, *Augmented Reality Views: Discussing the Utility of Visual Elements by Mediation Means in Industrial AR from a Design Perspective*, Springer International Publishing (2018), pp. 298-312 https://doi.org/10.1007/978-3-319-91584-5;

[13] R.T. Azuma, *Predictive tracking for augmented reality*, (1995), chapter 2;

[14] P. Vavra, J. Roman, P. Zonča, P. Ihnàt, M. Němec, J. Kumar, N. Hbabib, A. El-Gendi, *Recent development of augmented reality in surgery: a review,* Journal of healthcare engineering (2017) https://doi.org/10.1155/2017/4574172;

[15] J.T. Gibby, S.A. Swenson, S. Cvetko, R. Rao, R. Javan, *Head-mounted display augmented reality to guide pedicle screw placement utilizing computed tomography,* Internation Journal of Computer Assisted Radiology and Surgery (2018) https://doi.org/10.1007/s11548-018-1814-7;

[16] C.A. Agten, C. Dennler, A.B. Rosskopf, L. Jaberg, C.W.A. Pfirrmann, M. Farshad, *Augmented Reality-Guided lumbar facet joint injection*, Investigative Radiology 00 (2018);

[17] L. Lin, Y. Shi, A. Tan, M. Bogari, M. Zhu, Y. Xin, H. Xu, Y. Zhang, L. Xie, G. Chai, *Mandibular angle split osteotomy based on a novel augmented reality navigation using specialized robot-assisted arms- a feasibility study*, Journal of cranio-maxillofacial surgery (2015) https://doi.org/10.1016/j.jcms.2015.10.024;

[18] Y.K. Lin, H.T. Yau, I.C. Wang, C. Zheng, K.H. Chung, *A novel dental implant guided surgery based on integration of surgical template and augmented reality,* Clinical implant dentistry and related research, volume 17, number 3 (2015);

[19] D. Mitsuno, K. Ueda, Y. Hirota, M. Ogino, *Effective application of mixed reality device HoloLens: simple manual alignment of surgical field and holograms,* PRSJournal (2018);

[20] J.W. Meulstee, J. Nijsink, R. Schreurs, L.M. Verhamme, T. Xi, H.H.K. Delye, W.A. Borstlap, T.J.J. Maal, *Toward holographic guided surgery,* 2018;

[21] T. Frantz, B. Jansen, J. Duerinck, J. Vandemeulebroucke, *Augmenting Microsoft's HoloLens with Vuforia tracking for neuronavigation,* IET journal (2018);

[22] T. Itamiya, T. Iwai, T. Kaneko, *The holographic human for surgical navigation using Microsoft's HoloLens,* EPiC Series in Engineering (2017), pp. 26-30;

[23] P. Scolozzi, C. Zulma, *Applications de la chirurgie maxillo-faciale assistée par ordinateur,* Revue médicale suisse (2019) 15: 1226-30;

[24] S. Ting-shu, S. Jian, *Intraoral digital impression technique: a review*, Journal of prosthodontics (2015), 24:313-321, https://doi.org/10.1111/jopr.12218;

[25] R. Richert, A. Goujat, L. Venet, G. Viguie, S. Viennot, P. Robinson, J.C. Farges, M. Fages, M. Ducret, *Intraoral scanner technologies: a review to make a successful impression,* Journal of healthcare engineering (2017) https://doi.org/10.1155/2017/8427595;

[26] A. Haleem, M. Javaid, *3D scanning applications in medical field: a literature-based review,* Clinical Epidemiology and Global Healt 7(2019), pp. 199-219;

[27] E. Rae, A. Lasso, M. S. Holden, E. Morin, R. Levy, G. Fichtinge, *Neurosurgical burr hole placement using the Microsoft HoloLens*, https://doi.org/10.1117/12.2293680, Conference: Image-Guided Procedures, Robotic Interventions, and Modeling, 2018;

[28] Y. Liu, H. Dong, L. Zhang, A. El Saddik, *Technical evaluation of HoloLens for multimedia: a first look,* IEEE Multimedia (2018), pp. 1-7;

[29] E. Aouvinette, B. Galna, A. Aframian, J. Cobb, *O100: Validation of the precision of the Microsoft's HoloLens augmented reality headset head and hand motion measurement*, 2017;