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PIÑATA: Pinpoint insertion of intravenous needles via augmented reality training assistance

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ABSTRACT

Conventional needle insertion training relies on medical dummies that simulate surface anatomy and internal structures such as veins or arteries. These dummies offer an interesting space to augment with useful information to assist training practices, namely, internal anatomical structures (subclavian artery and vein, internal jugular vein and carotid artery) along with target point, desired inclination, position and orientation of the needle. However, limited research has been conducted on Optical See-Through Augmented Reality (OST-AR) interfaces for training needle insertion, especially for central venous catheterization (CVC). In this work we introduce PIÑATA, an interactive tool to explore the benefits of OST-AR in CVC training using a dummy of the upper torso and neck; andexplore if PIÑATA complements conventional training practices.. Our design contribution also describes the observation and co-design sessions used to collect user requirements, usability aspects and user preferences. This was followed by a comparative study with 18 participants - attending specialists and medical residents - that performed needle insertion tasks for CVC with PIÑATAand the conventional training system. The performance was objectively measured by task completion time and number of needle insertion errors. A correlation was found between the task completion time in the two training methods, suggesting the concurrent validity of our OST-AR tool. An inherent difference in the task completion time (p =0.040) and in the number of errors ($p = 0.036$) between novices and experts proved the construct validity of the new tool. The qualitative answers of the participants also suggest its face and content validity, a high acceptability rate and a medium perceived workload. Finally, the result of semi-structured interviews with these 18 participants revealed that 14 of them considered that PIÑATA can complement the conventional training system, especially due to the visibility of the vessels inside the simulator. 13 agreed that OST-AR adoption in these scenarios is likely, particularly during early stages of training. Integration with ultrasound information was highlighted as necessary future work. In sum, the overall results show that the OST-AR tool proposed can complement the conventional training of CVC.

1. Introduction

Conventional medical training follows the principle "See one, do one, teach one", i.e., medical trainees start as passive learners and progress by undergoing repeated practice to gain greater responsibility and autonomy until becoming competent practitioners. However, some studies suggest that conventional medical training inadequately prepares trainees for entrance into medical practice, stating that trainees do not gain enough autonomy during residency (LeCompte et al., 2019). Although it is unclear the magnitude of cost savings of introducing more reliable and efficient training methods in medicine, alternative tools are known to reduce medical error (Anderson and Abrahamson, 2017), hence directly benefiting patients (Barsom et al., 2016).

With the recent rebirth of Extended Reality technologies, other approaches to the apprenticeship model of medical professionals

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have begun to appear. Simulators provide a safe way to improve doctors' skills through repeated practice, outside the operating apparatus, and allow to measure and assess their technical skills (Viglialoro et al., 2018; Vavra et al., 2017). However, conventional physical simulators still have several limitations: for instance, simple plastic mannequins provide reduced functionality and non-reusability when subdued to destructive tasks; regarding more complex simulators, their greater realism to mimic medical scenarios implies a higher cost. On the other hand, technologies such as virtual(VR) and augmented reality (AR) offer interesting opportunities for improving medical training (Viglialoro et al., 2018). In particular, Optical See-Through AR (OST-AR)can reduce the complexity of physical simulators by replacing some of its embedded electronics with AR content that can be used to complement the training process (Ferrari et al., 2016).

OST-AR is an integrated technique of image processing, where real objects and computer-generated objects are combined in a real environment (Chen et al., 2015). An OST-AR system consists at least in three components: (i) a tracking component responsible for calculating the three dimensional (3D) location and orientation of the camera in real time; (ii) a registration component that overlays a virtual layer on top of a real scene given the position determined by the tracking component; and (iii) a visualization component that consists of a head-mounted display (HMD) where AR content is projected in the wearer's field of view (Schmalstieg and Hollerer, 2016; Siltanen and teknillinen tutkimuskeskus, 2012).

In this work, we explore the potential of OST-AR for training insertion of needles for central venous catheterization (CVC). This is an invasive procedure that consists of inserting a catheter into the superior vena cava through the internal jugular or the subclavian veins (Reichman, 2018). It allows to measure hemodynamic variables, and to deliver medications and nutritional support while providing a portal for intravascular volume replacement. Such procedure is performed several times in the daily routine of an hospital (Miller et al., 2014; McGee and Gould, 2003), thus it is crucial to train needle insertion next to experienced practitioners. This procedure requires precise placement of the injection needle, which, when not done correctly, can lead to potentially life-threatening adverse events such as arterial puncture and pneumothorax (Barsuk et al., 2009a) - both hazardous to patients and expensive to treat (McGee and Gould, 2003; Yeo et al., 2011). Therefore, it is very important that medical professionals that commonly perform CVC (including internal and emergency medicine doctors, general surgeons and mainly, anesthesiologists (Barsuk et al., 2009a; Evans et al., 2010)) have has much experience as possible before performing this on patients. For that, effective and efficient methods for training CVC are needed. Some studies (Barsuk et al., 2009a; Evans et al., 2010; Barsuk et al., 2010, 2009b) have already shown that a simulation-based training increase residents' skills in CVC insertion and decrease related complications. However, research regarding the potential of AR as a complement to the CVC training is limited.

As such, the main research questions of our work are:" Does OST-AR assist the training of needle insertion in CVC?" and "How well does OST-AR needle insertion CVC training compare to conventional training methods?" To answer these questions, we developed an OST-AR prototype that assists and guides the CVC trainee. Our hypothesis is that our system can complement conventional training, thus, reducing the dependence of the instructor without affecting the training quality. In sum, the contributions of our work are threefold:

1 We present PIÑATA, the first OST-AR tool for CVC training that supports both the projection of internal structures, and geometrical information about the position and orientation of the user's needle. We highlight the design process of this tool that combined observational studies and a co-design workshop with real-world stakeholders. The former with 23 trainees and seven instructors; the latter with 2 physicians.
2 We report on a comparative study between PIÑATA and a conventional training method for CVC. We recruited nine medical residents and nine specialists, and report on their completion times and number of errors, as well as subjective usability and workload measures.
3 We conclude with insights captured via semi-structured interviews of the 18 participants above regarding their study experience with PIÑATA and future work in this domain.

2. Related work

In this section we present some examples of past VR-and AR-based applications for training needle insertion procedures. Focused on the training of different peripheral nerve blocks, O. Grottke et al. (2009) developed a VR-based simulator based on different patient anatomies. They describe it as a flexible and dynamic learning environment that allows trainees to practise their technical skills (Grottke et al., 2009). Ali et al. (2018) conducted a pilot study about a VR-simulator for fluoroscopy guided lumbar puncture that was considered as a valuable training tool by the users. The developed system virtually reproduced the anatomy of the lower torso, both visually and through tactile or haptic feedback as the spinal needle traversessed various tissues. It also showed the virtual spinal needle and real-time fluoroscopy for imaging guidance (Ali et al., 2018). VR simulators allow repetitive execution of procedures and provide precise metrics for evaluating trainee performance, thus have interesting potential in medical training. However, they also have limitations: the very high costs (range: 80.000–200.000 dollars) and unrealistic simulation of visual and haptic sensations between virtual objects and instruments (Viglialoro et al., 2018; Lahanas et al., 2016).

As for AR-based simulators, they combine the advantages of physical and VR-based simulators within a unique environment, avoiding some of the drawbacks mentioned above (Herron, 2016). For instance, Caitlin T. Yeo et al. (2011) proposed a configuration for Perk Tutor (an open-source training platform for image-guided needle insertions) to augment the effectiveness of computed tomography (CT)-guided facet joint injections. In the proposed method, needle tracking was performed using an electromagnetic tracker sensor and a laser overlay system to guide the procedure in the user's field of view. The results of the user tests showed that AR image overlay can assist medical trainees in learning the correct placement of a needle (Yeo et al., 2011). A similar work was developed by E. Moult et al. (2013) for ultrasound-guided facet joint injections. Their tool allowed training with a synthetic phantom of the vertebral column and surrounding tissues. An external monitor provided visual information regarding the tools positions with respect to the live ultrasound and vertebral column. The performed user tests compared their method to conventional training revealing a higher success rate for the group that used AR. One limitation of their approach consists of requiring the trainee to look away from the phantom to view the image on an external display (Moult et al., 2013). The practice of needle insertion usually resorts to medical images.However, health professionals have to be prepared to execute needle insertion without any sort of image-based guidance. For example, Abe et al. (2013) developed an AR guidance technique to visualize the needle insertion point on the skin and associated 3D trajectory path using an HMD for percutaneous vertebroplasty procedures. Following a similar setup, Rochlen et al. (2017) developed and tested an AR system for CVC needle insertion, in which the trainee wears an HMD that enables the visualization of projected internal anatomy, while revealing the target point for needle insertion. The system provides feedback to the user accord-

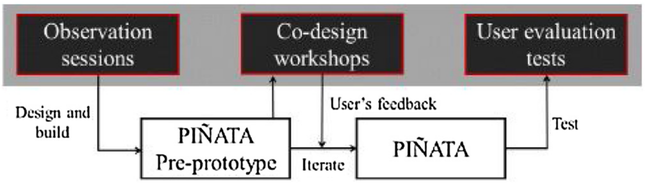

Fig. 1. User studies conducted during our work to design and test PIÑATA.

ing to its performance: if the needle was inserted correctly into the vein, it turned red to simulate blood flow; if the carotid artery was inadvertently punctured, an expanding hematoma was displayed (Rochlen et al., 2017).

The examples presented in this section demonstrate the potential of AR in needle insertion training guided by internal images (synthesised or real) overlaid on simulators. However, 3D registering, i.e., 3D alignment between real and virtual objects, is still a complex problem (Correa et al., 2018). There are also some limitations common to all applications using AR regarding the HMDs available: the tracking accuracy and the field of view (FOV) are sometimes limited and some physical discomfort is often described by the users. Besides that, the systems described here focus only on one of two types of AR content to guide needle insertion: projection of internal structures or geometrical information about the position and orientation of the needle. To the authors' knowledge, the literature lacks an interface design that combines these two aspects with the goal of facilitating the CVC training process.

3. User studies

The design of a new OST-AR solution for CVC training is not a straightforward process; it demands a user-centered approach, not only to understand the needs of the users but to translate those needs into viable design solutions (Tomitsch et al., 2018). The framework that guided this study is described in (Fig. 1).

3.1. Observation sessions

To acquire user requirements and needs, we conducted two informal observation sessions in workshops for training CVC: the first with about 20 trainees (medical residents of anesthesiology) and 6 instructors (attending specialists of anesthesiology); the second with just 3 trainees (last-year medical students) and 1 instructor (attending specialist of anesthesiology with 27 years of experience). The participants' actions, interaction between instructors and trainees as well as the training procedure steps were observed. Some questions were asked to prompt participation and to gain as much information as possible. Besides taking notes, audio and photographic records of one of the sessions were also kept for further analysis with the consent of the participants. The information retrieved from these sessions, combined with the literature review, allowed us to design an early version of PIÑATA prototype described above. To better understand how training sessions were organized, we conducted observation sessions: initially, the trainer explained the procedure and exemplified CVC tasks; then, the trainees executed the procedures, one by one, while the instructor was constantly accompanying their tasks to help the attended trainee improve his/her practice while the remaining trainees were passively observing. Through observation, we noted that conventional training that could complement the instructor's role of assisting the trainee and that could, simultaneously, contribute for a more autonomous training. The main steps during CVC training were observed: (i) the trainee started by identifying anatomical landmarks; (ii) the trainee inserted the needle, advancing in aspiration, according to the anatomical landmarks and the recommended orientation and direction; (iii) the trainee stopped the progression of the needle whenever blood was aspirated to the syringe. We noted that several instructions related to needle orientation were commonly delivered by the trainer (”Is that 30°? That is not 30°!” or” Direct the needle towards the nipple”), while other comments were related to needle insertion depth (”The needle is too deep! Go back to the skin and redirect it.”). These observations were fundamental to determine which type of geometric information is important for CVC training.

Fig. 2. User's first-person view of the early prototype with virtual components.

3.2. Co-Design workshop

Based on the observational sessions, an initial version of PIÑATA was developed. This first prototype consisted of a styrofoam female bust placed upon a poster size AR marker while the needle was tracked with a multi-target AR cuboid. The virtual elements projected through the glasses in this first prototype, represented in (Fig. 2), were for guiding CVC training.

Co-Design workshops were conducted to understand what were the key design requirements and to collect feedback about the initial prototype. Two physicians (attending specialists of anesthesiology with 2 and 27 years of experience) with experience as instructors of medical trainees participated in the workshops. Video and audio of the workshop sessions were recorded with the consent of these participants. These were asked to talk about their experience as medical trainers. Finally, we demonstrated the initial prototype and invited them to try it to capture their feedback. To stimulate their suggestions, the interview included questions such as” What do you currently like/not like about how CVC training currently is performed?” and” What are the features of the demonstrated prototype that you approve/disapprove?”.

In order to analyse the collected data, a structured method was used - thematic analysis. This method consists of establishing themes to summarize the collected data, i.e.,” short words or phrases that assign a summative, salient and/or evocative attribute to a portion of written or visual data” (Tomitsch et al., 2018, p.122). The resulting set of themes were used to iterate early versions of PIÑATA. The main results obtained from the co-design workshop consisted of specific suggestions to improve the early design of PIÑATA and also several requirements that should be met. From the thematic analysis process, the following themes were defined:

- Familiarity

A training tool should resemble conventional CVC training. Quoting one of the participants referring to the way one should handle the needle, “This cube is a bit in the way. Since we do not handle a needle with a cube mounted on it, your training solution should simply consider the same needle without anything attached to it”. Given this, it was possible to conclude that the AR target design should be simple, should not affect needle maneuverability, and present very few distracting elements in order to promote the habitual training workflow to which they are already familiar with.

- Stability

While experimenting with the early version of PIÑATA, the professionals mentioned that sometimes the virtual elements disappeared or changed position. This was already an expected limitation related to the shape, size and design of the image targets. Therefore, this was one of the improvements applied in PIÑATA after the co-design workshop.

- Virtual elements

When asked about the virtual information displayed, the professionals agreed that it was useful. They also suggested" it makes sense to project the carotid and jugular, that way we can have further visual references". The main implication of this feedback for PIÑATA was the necessity to extract the 3D model of the vessels so that this information could be overlaid onto the simulator.

- Complement the instructor

This theme expressed some of the advantages of PIÑATA relatively to the conventional CVC training practices. According to the participants," This is useful for trainees as they become more autonomous, and it even allows them to train more frequently". Therefore, it is expected that, with the additional information provided by PIÑATA, the trainees could be capable of training without relying constantly on a trainer.

- Training debriefing

This was also an advantage of PIÑATA pointed by the professionals:" This allows them to understand if they are performing well". Nowadays, there is not a formal way to evaluate CVC simulation or training. As PIÑATA allowed instructors and trainees to measure needle angulation and depth over time, it becomes possible to define performance measures. These could be useful to evaluate the trainee's performance. Moreover, the proposed colour coding also helped the trainees to understand and correct their gestures in real time.

4. PIÑATA

Our system consists of four essential components as illustrated in (Fig. 3). The application was developed in Unity3D (version 2018.3.14f1), a game engine with built-in support for AR applications, particularly the Vuforia Engine (version 8.1.7) and Aryzon SDK (version 2.1) (Kickstarter, 2020).

4.1. Real world component

This component consists of the real objects that the user interacts directly, namely, (i) the syringe and Seldinger needle, and (ii)the physical simulator (or dummy) of an upper torso and neck (CentraLineMan® System). The physical simulator features clinically relevant, accurate, and palpable landmarks, either represented via surface anatomy or by vascular structures (Simulab, 2019).

4.2. 3D dummy reconstruction

In order to register the virtual surface anatomy and vascular structures onto the physical simulator, it was necessary to extract the 3D model of both the simulator's external surface and the underlying vessels from CT images of the dummy simulator.

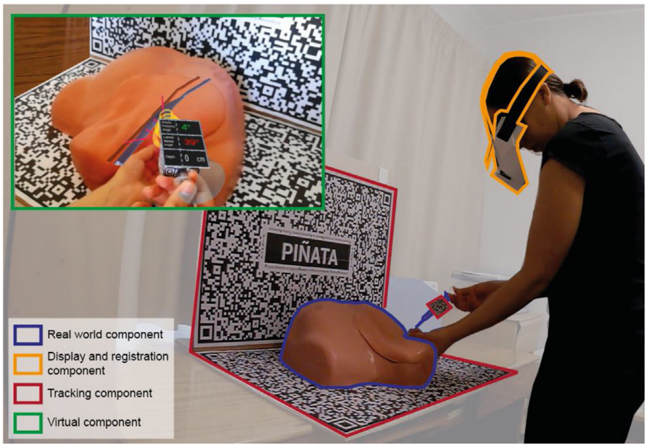

Fig. 3. Overview of the PIÑATA components highlighted in different line colours: real world component (blue lining), registration and display component (orange lining), tracking component (red lining), and first-person view of the virtual component (green lining). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

The 3D reconstruction process followed the pipeline described by Ribeiro et al. (2009) (Ribeiro et al., 2009). The first step consisted of 3D segmentation of the image dataset to identify the simulator surface and vessels using ITK-(SNAP (2020)). To segment these structures we used semi-automatic active contours, which deform to fit the boundaries of the desired structures - either based on image intensity or image gradient values (Fig. 4). While the simulator surface was segmented based on intensity values, the inside vessels were better segmented by considering edge-based or gradient values. Note that image segmentation based on global thresholding results in a mesh with a characteristic stair-step shaped surface, which is more difficult to smooth and decimate (Ribeiro et al., 2009). Hence, we opted for active contours as a segmentation technique to extract the simulator's surface and inner vascular structures, as the resulting mesh is less jaggy and thus, easier to smooth and decimate.

After the segmentation stage, the generated 3D models present a non-smooth appearance and an excess of vertices which are geometrically redundant and contribute to memory overload.. To deal with these issues, the 3D mesh was smoothed and decimated in Paraview (ParaView, 2020). Since we are only interested in the outer surface of the simulator, the resulting mesh was then imported into MeshLab (MeshLab, 2020) to remove the inner mesh. Finally, the mesh was exported as an. obj file to be read inside the Unity environment.

4.3. Registration and display component

We used the Aryzon as our HMD device - a$30 headset for OST-AR. This HMD contains a slot for a a smartphone, where its screen will display a stereo image of the graphical elements that belong to our interface. The displayed stereo image then passes through a mirror, lightweight stereoscopic lenses and a combiner glass, making it possible for the user to perceive the real world overlaid with virtual objects.. .

4.4. Tracking component

The tracking component was developed using Vuforia (version 8.1.7) (Vuforia, 2020). We used marker-based tracking to capture

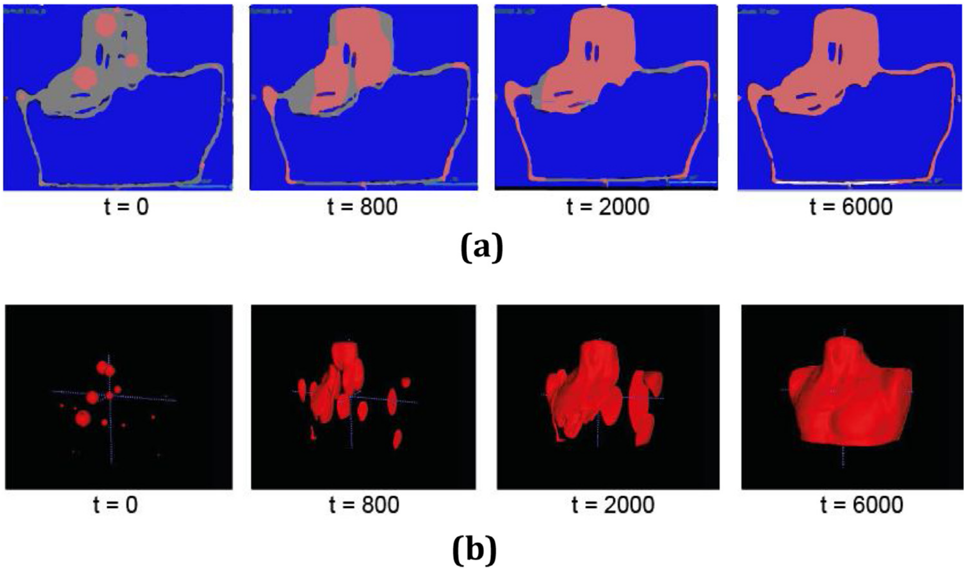

Fig. 4. Active contours progression at different time steps: t = 0, t = 800, t = 2000 and t = 6000. **(a)** Coronal cross-section of the dummy's CT images. **(b)** 3D view of the evolving contours forming the 3D dummy model at t = 6000.

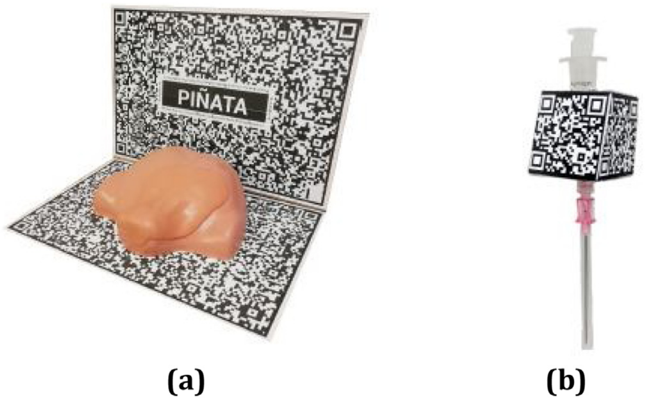

Fig. 5. Tracking objects. **(a)** Simulator placeholder with dummy and L-shaped AR target. **(b)** Needle with cube-shaped AR target.

the positions and orientations of the grounded simulator and the handheld needle (Fig. 5). Image targets with printed QR code patterns were used as AR markers.

Use relied on multi-image targets to improve object recognition during their manipulation, as at least one target per object would always be visible. . To track the simulator, we devised a multi-image target composed of two 50 × 72 cm rectangular posters assembled in a L-shape (Fig. 5(a)).To track the needle we designed a right trapezoidal polyhedron (Fig. 5(b)) where the target facing the user has a slight inclination so that its surface normal becomes better aligned with the camera viewing direction. A trapezoid width of 4 cm was chosen as it represents a trade-off between an acceptable size for tracking and a comfortable size that does not perturb the user too much during needle handling.

Manual calibration to position, align and scale the 3D model of the simulator, in relation to the simulator's target, was performed using a computer with keyboard that was remotely connected (i.e., TeamViewer) to the smartphone running PIÑATA. Manual adjusts were performed until the 3D model fully overlapped the real simulator (Fig. 6). Once calibrated, the transformation applied to the 3D model is used to calculate the relative position, orientation and depth of the needle (see Section? .?).

4.5. *Virtual component*

This component consists of the elements required to be registered to the real world in order to accurately guide the needle insertion. In PIÑATA, three different spaces are augmented: the tsimulator's surface, the simulator's interior and the needle.

The 3D model of the vessels is projected inside the simulator. This model includes part of the superior vena cava, the subclavian

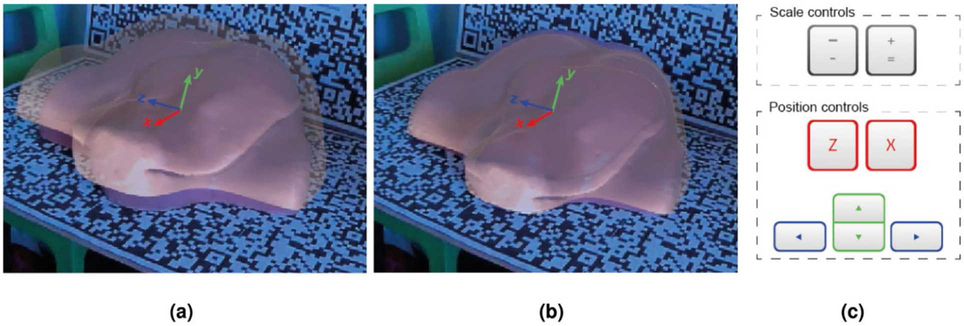

Fig. 6. Manual adjustments using a keyboard to define the position, alignment and scale of the 3D model of the simulator (a) before and (b) after the calibration process; (c) keyboard calibration controls: up/down arrows to move the model in the y-axis; left/right arrows to move the model in the z-axis; Z/X keys to move the model in the x-axis; plus/minus keys to scale the model.

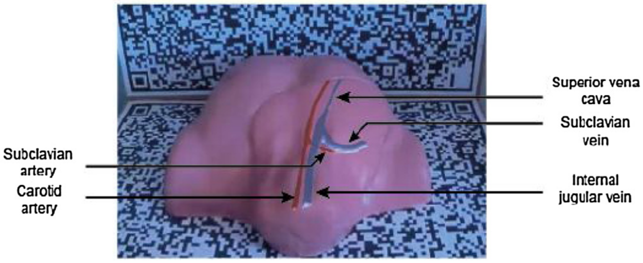

Fig. 7. AR projection of the vascular anatomy overlaid with simulator. Veins represented in blue and arteries in red. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

artery and vein, the internal jugular vein and the carotid artery (Fig. 7).

On the simulator's surface, we represented the point of insertion using four arrows pointing inwards along with a conical shaped placeholder for the needle. This inverted cone suggests the orientation in which the needle should be inserted. These visual aids were implemented for two different cannulation routes: for the internal jugular vein the arrows were placed pointing to the superior apex of the triangle formed by the two heads of the sternocleidomastoid muscle and clavicle, whereas the conical placeholder makes an angle of 45° with the coronal plane pointing toward the ipsilateral nipple (Fig. 8(a)); for the subclavian vein, the point of insertion is just above the clavicle at the midclavicular line and the conical placeholder is placed in the coronal plane pointing toward the sternal notch (Fig. 8(b)) (Reichman, 2018).

Regarding the needle visual guides, we designed a set of yellow annulus with decreasing diameter around the needle to give depth perception, and also considered a line that joins the tip of the needle to the correct point of insertion - similar to an elastic band (Fig. 9). Furthermore, we placed an information panel on top of the handheld needle that presents antero-posterior and lateral-medial angles including the depth of needle insertion (Fig. 9(a)). This panel is shown inside the field of view of the user next to his/her hands, thus assisting hand-eye coordination.

Interacting with the virtual components is achieved through direct manipulation of the needle and associated visual aids. We relied on the following colour coding to guide the user during training: green encodes the correct orientation of the needle, and red means that the needle is not oriented in correctly. When interacting with the needle close to the simulator, the conical placeholder changes its appearance: as the needle enters the conical placeholder, it starts to become progressively transparent to give the idea of correct approximation during tasks execution.

5. Performance study

A user study was performed to assess the benefits of OST-AR in CVC training and if PIÑATA can complement conventional training practices. The independent variables are defined based on the training paradigm (conventional or PIÑATA) and on the access site (jugular or subclavian). For the purpose of this study, the dependent variables considered are task completion time and number of errors (objective measures) along with participant preferences (subjective measures).

5.1. Participants

A total of 18 invited participants performed the user study (6 male and 12 female), 9 medical residents considered novices (8 of anaesthesiology and 1 of general surgery)) and 9 attending specialists of anaesthesiology with experience ranging between 3 and 32 years (66.7 % between 3–10 years of experience)- considered experts. Participants were selected to match the user profile of trainees and instructors. From all the participants that had previous experience in CVC training (83.3 %), only 4 participants (26.7 %) had already used VR/AR systems and almost all (86.7 %) had already trained with upper torso and neck dummies. All participants agreed that the access site more frequently trained for CVC was the internal jugular vein. They received no compensation for taking part in our study.

5.2. Apparatus

The study took place in an office room inside a local hospital's operating theatre. The setup of the study consisted of the PIÑATA prototype placed over a table and the Aryzon headset using an Android smartphone (16 nm Octa core 2.36GHzx4 + 1.7GHzx4 3GB RAM with 2160 × 1080 pixels screen) that ran oursupport application (see Section 3). A portable computer was used to fill the questionnaires.

5.3. Tasks

In order to receive as broad feedback possible, each participant took part in our user study that considered a single group (i.e., within-group design), i.e, all participants execute tasks from both the conventional training and PIÑATA training. Initially, users were asked to perform an habituation task (to puncture the needle near the access sites) so that they could get used to the systems. Then participants were asked to complete a total of 4 different tasks (2 access sites x 2 training paradigms). A task was considered successful when the liquid that circulates in the vein was aspired to

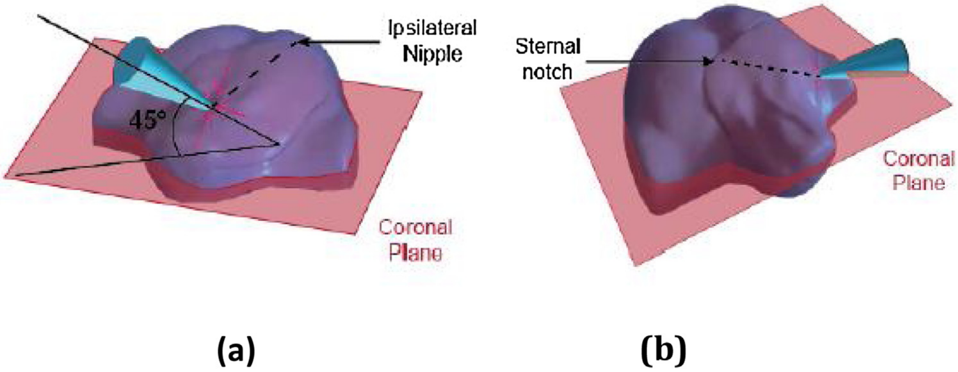

Fig. 8. AR representation of the point of insertion and the needle conical placeholder overlaid with the simulator for CVC training through the **(a)** internal jugular vein and **(b)** subclavian vein. Important anatomical landmarks for each access site are also illustrated..

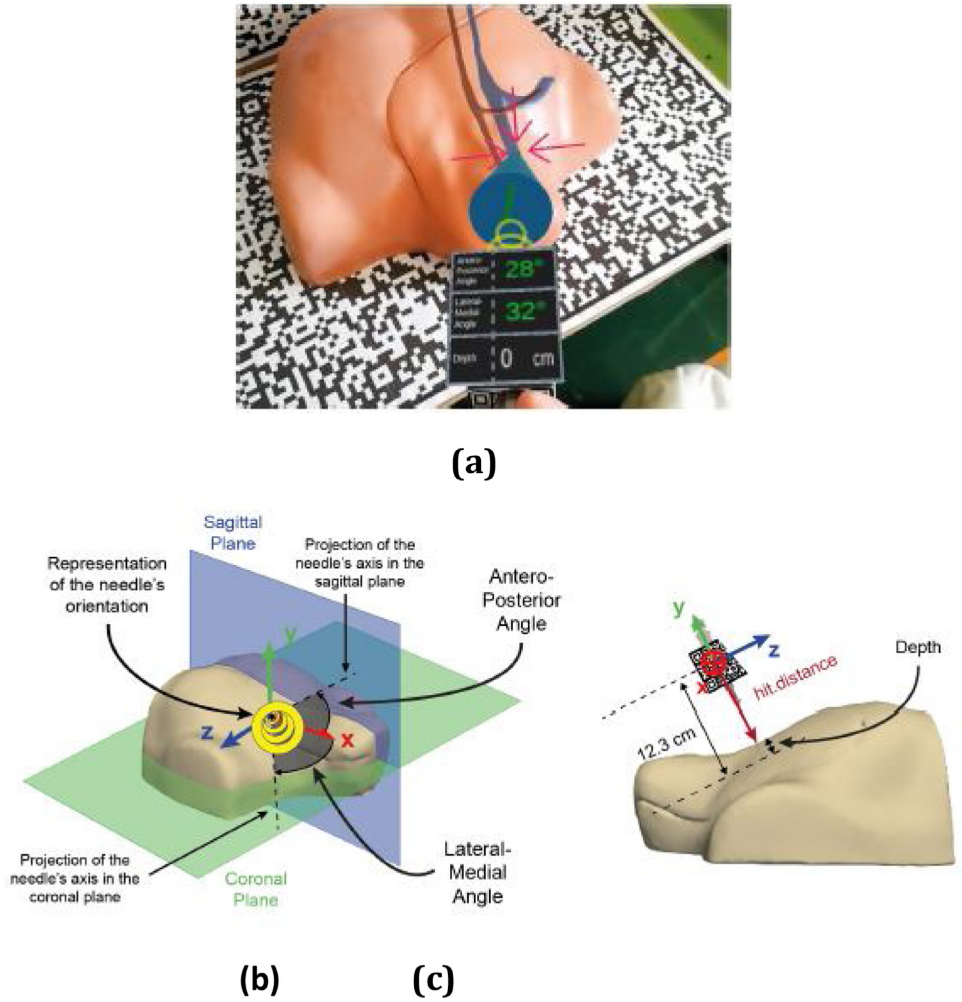

Fig. 9. Virtual elements associated to the needle. **(a)** First person view of a user maneuvering the needle is in the right orientation (i.e., aligned with the conical placeholder) **(b)** Representation of the antero-posterior and lateral-medial angles in 3D: these angles are defined in relation to the anatomical planes. **(c)** Representation of how the needle insertion depth is calculated: aligned with the needle's body, a ray is cast passing through the tip of the needle until it collides with the 3D surface mesh of the simulator; the relative distance between the tip and the 3D surface define needle penetration..

the syringe. For each task, the participant had at most 5 trials, after which the task was interrupted and considered unsuccessful. A trial is defined as a needle insertion without pricking the skin again. Task completion time was measured from the beginning of each task, where the user states its intention to initiate the task, until the task is completed. The number of errors accounted the number of trials before the previous trail where the participant completed the task. We considered two types of errors: (i) needle removal from the skin for redirection and (ii) arterial puncture.

5.4. Procedure

At the beginning of each session, participants filled in a consent form and a demographics questionnaire regarding their gender, level of expertise and previous AR experience. The sequence of tasks for each participant was previously defined using Latin squares' permutations across initial access site and training paradigm. After explaining the steps of the user study, participants were asked to execute a habituation task. Afterwards, participants performed the four set of tasks (Fig. 10). The time required for task completion was measured and the number of errors was registered.

After each set of two tasks (for the same access site), the participant was asked to complete a satisfaction questionnaire comparing aspects of the two forms of training: (1) easiness to identify anatomical landmarks; (2) ease of use; (3) learnability; (4) usefulness; (5) recallability; (6) easiness for debriefing. The responses were given on a 6-level Likert scale from 'strongly disagree' to 'strongly agree'.

After performing all four tasks, each participant was asked to complete a general questionnaire that was divided in three sections: face and content validity, participants' satisfaction using the System Usability Scale (SUS)and perceived workload using the NASA task load index (NASA-TLX) assessment tool. At the end of the study we wconducted a semi-structured interview with each participant that included previously prepared questions such as" In your opinion, does PIÑATA complement the conventional training system for CVC needle insertion?"," What were the difficulties that you felt while using PIÑATA?" and" Do you think that the adoption of this kind of technology for medical training is possible?". This allowed us to collect more detailed and broad feedback. The interviews were documented via voice recording. A full session lasted approximately 20 min.

5.5. Statistical analysis and interpretation of results

Statistical analysis was performed using the Mann-Whitney *U* test, the Wilcoxon signed-ranks test and the Spearman's rank order correlation test. All statistical analyses were carried out using IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, N.Y.,

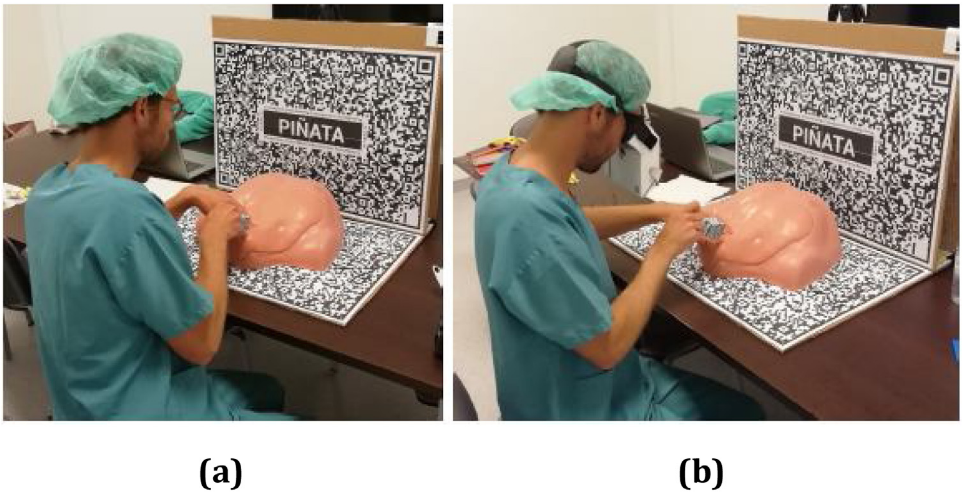

Fig. 10. Participant performing CVC training tasks via internal jugular vein, **(a)** using the conventional training system and **(b)** using PIÑATA.

USA) (Spsssoftware, 2020). For all tests, a p-value of less than 0.05 was considered statistically significant.

We used the SUS score to interpret the results of the SUS questionnaire, a single number that represents a measure of the overall usability of the system. SUS scores have a range of 0–100, that have a corresponding interpretation: 100 is a great user experience with high acceptability; 68 is considered average; anything below 68 is considered as not acceptable for the users (Brooke et al., 1996).

To analyse the results of the NASA-TLX questionnaire we calculated unweighted scores between 0 and 100 from the answers in a 21-item scale. This score correlates with the workload of the system: 0–9 is considered low; 10–29 medium; 30–49 is considered somewhat high; 50–79 is high; and 80–100 indicates a very high workload (NASA, 2020).

The subjective data obtained from the semi-structured interviews was analysed through a thematic analysis method.

6. Results and discussion

The data collected during user evaluation tests included performance metrics using both PIÑATA and the conventional training method, as well as user preferences (i.e., satisfaction questionnaires) while more detailed opinions, comments and suggestions were obtained via structured interviews.

6.1. Face and content validity

In the context of this work, assessing the face validity of PIÑATA consists of verifying if training with our prototype resembles real working situations. To verify the content validity of PIÑATA it was necessary to verify if the educational content can be uniformly and positively evaluated by the professional.

The central tendencies of responses to each statement were summarized by using median (Mdn), with dispersion measured by interquartile range (IQR) in Table 1. The median of all the responses is higher than 3.5, meaning that the participants positively evaluated the realism and content of PIÑATA. A one-sample Wilcoxon signed-ranks test was used to determine the significance of the responses evaluating if the operators were significantly more likely to agree or disagree with each of the statements. For that, the considered null hypothesis (H_0) was” the difference between the median of each Likert item and the median of the scale (3.5) is zero”.

All the results are statistically significant ($p < 0.05$), attesting to the face and content validity of PIÑATA. It is relevant to note that the item the participants most strongly agreed with (*Mdn* = 6.0) was related to the projection of the vessels, which in fact was one of the features incorporated in our prototype after suggestions provided by the instructors during the co-design workshops. By contrast, the item less agreed upon (*Mdn* = 4.0) was related to the usefulness of graphical elements to indicate the orientation of the needle, which can be explained by the fact that graphical elements may be distracting and partially occlude the insertion site.

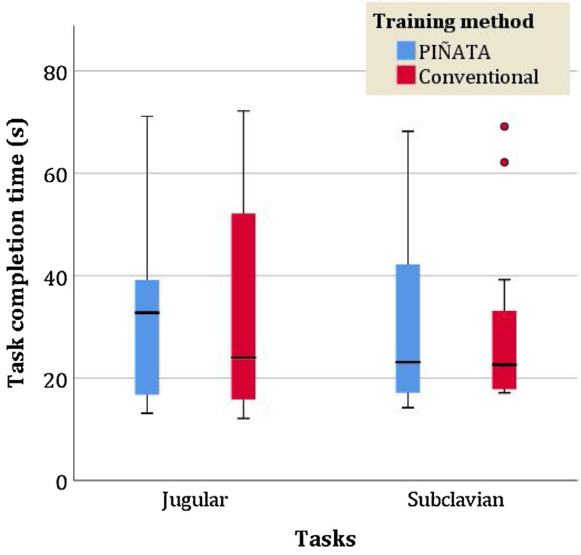

Fig. 11. Comparison of task completion time (in seconds) for the jugular and subclavian access sites between PIÑATA and conventional training methods.

6.2. Concurrent validity

To infer about PIÑATA’s concurrent validity, it was important to demonstrate that the training performance measures (time and number of errors) are correlated to the ones observed in conventional training methods. In this context, concurrent validity is understood as the training performance of PIÑATA and the conventional approach which should be correlated.

6.2.1. Task completion time

The comparison between the average time to perform the insertion task using PIÑATA and the conventional system is represented

Table 1
Median (Mdn) and interquartile range of the responses to the Likert items and p-value of the one-sample Wilcoxon signed-ranks test comparing their median with the median of the scale (3.5) regarding training with the PIÑATA system.

Statement	Mdn (IQR)	p-value
1. The anatomy of the mannequin is realistic.	5.0 (1)	<0.001
2. The anatomy of the projected vessels is realistic.	4.0 (1)	<0.001
3. Allows to identify the anatomical landmarks.	5.0 (1)	<0.001
4. The possibility to see the internal anatomy (vessels) is useful.	6.0 (1)	0.002
5. The indication of the value of needle's angles is useful.	5.0 (1)	<0.001
6. The indication of the value of needle's depth is useful.	5.0 (0)	<0.001
7. The graphical elements represented to indicate the insertion site are useful.	4.5 (1)	<0.001
8. The graphical elements represented to indicate the orientation of the needle are useful.	4.0 (0)	<0.001
9. It is useful for training the insertion of needles.	5.0 (1)	<0.001

Table 2
Mean and standard deviation (SD) of task completion time (in seconds), correlation coefficient (r_S) and p-value of the Spearman's rank order correlation test comparing the two training methods.

Access site	Training method	Mean (SD)	r_S	p-value
Jugular	PIÑATA	32.76 (19.17)	0.872	<0.001
	Conventional	32.22 (20.45)		
Subclavian	PIÑATA	31.63 (18.98)	0.730	0.001
	Conventional	27.63 (15.35)		

Table 3
Median (Mdn) and interquartile range (IQR) of the number of errors and correlation coefficient (r_S) and p-value of the Spearman's rank order correlation test comparing the two training methods.

Access site	Training method	Mdn (IQR)	r_S	p-value
Jugular	PIÑATA	0 (1)	0.421	0.082
	Conventional	1 (1)		
Subclavian	PIÑATA	1 (1)	0.198	0.431
	Conventional	1 (1)		

in (Fig. 11). The mean and standard deviation (SD) values for each training method and for each access site can be seen in (Table 2).

A Shapiro-Wilk test was used to assess if the samples follow a normal distribution. Since this was not the case, a Spearman's rank order correlation test was performed. The null hypothesis (H_0) was defined as "There is no monotonic relationship between the task completion times for PIÑATA and for conventional training methods". The correlation coefficients and p-values obtained are presented in Table 2.

Based on the descriptive statistics, the efficiency of PIÑATA seems to be comparable to the efficiency of the conventional training method since the task completion times of both training methods are similar. It is observable that the average time is slightly lower in the conventional method, likely because the participants are not used to OST-AR glasses and thus leading to longer completion times. Moreover, the Spearman's correlation test has shown a strong, positive correlation between task completion times($p < 0.05$), thus supporting the concurrent validity of PIÑATA.

6.2.2. *Number of errors*

The comparison between the number of errors (the sum of the number of redirection and arterial puncture errors) during the insertion task using PIÑATA and the conventional system is represented in (Fig. 12).

As the normal distribution condition was not verified by the Shapiro-Wilk test, a Spearman's rank order correlation test was performed. The null hypothesis (H_0) in this case was defined as "There is no monotonic relationship between the number of errors using PIÑATA and using conventional training methods". The median and IQR values of the number of errors and the correlation coefficients and p-values obtained are presented in Table 3.

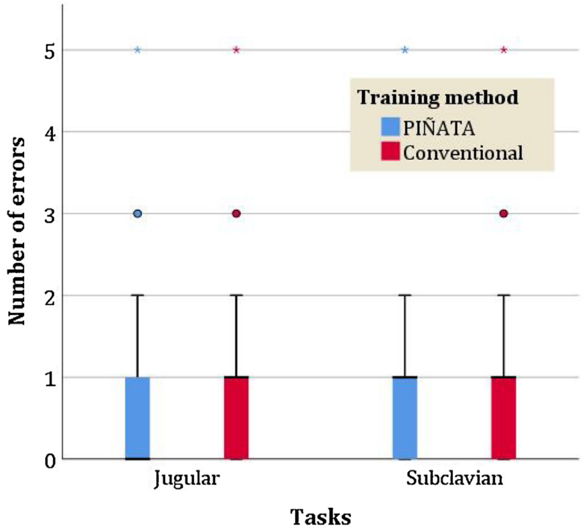

Fig. 12. Comparison of the number of errors in the jugular and subclavian access sites between PIÑATA and the conventional training method.

The median number of errors is similar in both methods, suggesting that the effectiveness of training with PIÑATA is similar to the effectiveness of the conventional training method. The results of the test were not statistically significant ($p > 0.05$), not allowing us to conclude anything about the concurrent validity via number of errors. A possible reason for this is the fact that the number of errors is an ordinal variable and in the majority of the analysed cases took only the values 0 or 1, being the rest of the cases considered outliers as represented in (Fig. 12). As the Spearman's rank order correlation test is not very sensitive to outliers (Spearman's rank-order correlation using spss statistics, 2020), this can explain our result.

6.3. *Construct validity*

To attribute construct validity to PIÑATA, one should prove that there is an inherent difference in training outcomes between experts (attending specialist) and novices (medical residents).

6.3.1. *Task completion time*

The comparison between the average time between experts and novices for the insertion task using PIÑATA is represented in (Fig. 13). The mean and SD values for each group of participants and for each access site are listed in Table 4. As expected, the difference between the two groups is evident (Fig. 13): the group of experts needed much less time to complete the tasks in comparison to the group of novices. As these are independent groups, a Mann-Whitney *U* test was used. The null hypothesis (H_0) considered was "The population distributions of the task completion times

Table 4
Mean and standard deviation (SD) of the task completion time (in seconds) using PIÑATA and p-value of the Mann-Whitney *U* test comparing the two groups of participants.

Access site	Level of expertise	Mean (SD)	p-value	Z-score
Jugular	Attending specialist Medical resident	22.66 (9.02) 42.86 (21.68)	0.040	−2.075
Subclavian	Attending specialist Medical resident	23.86 (13.60) 39.40 (21.10)	0.094	−1.722

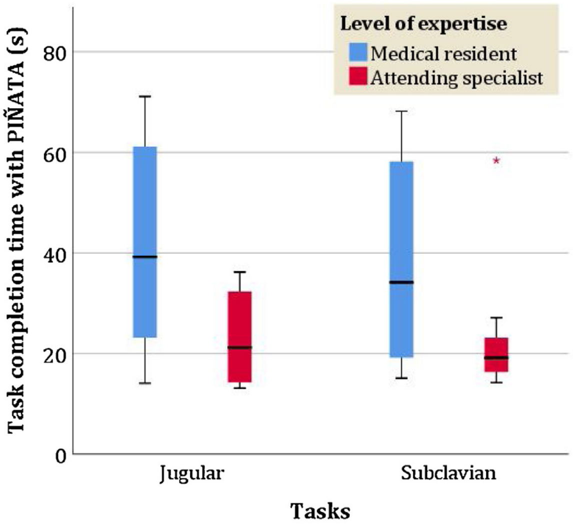

Fig. 13. Comparison of task completion time (in seconds) using PIÑATA for the jugular and subclavian access sites between group of experts (attending specialists) and novices (medical residents).

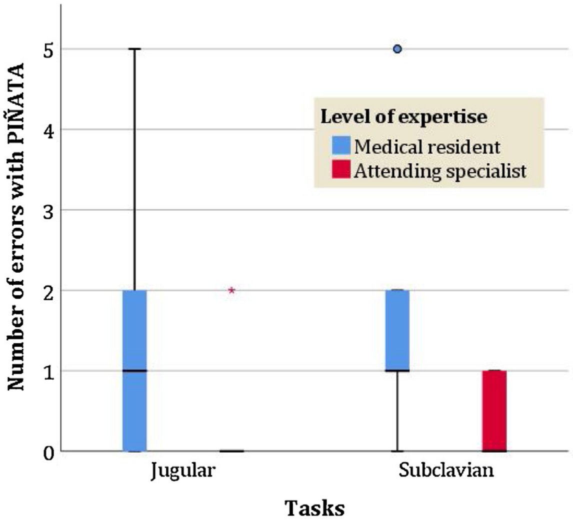

Fig. 14. Comparison of number of errors using PIÑATA for the jugular and subclavian access sites between experts (attending specialists) and novices (medical residents).

using PIÑATA by experts and novices are identical". The p-values and Z-scores obtained are presented in Table 4.

The test indicated that there is statistical evidence to reject H_0 ($p < 0.05$) in the case of the jugular access site, i.e., there are significant differences in task completion times between medical residents and attending specialists. However, for the subclavian access site, the null hypothesis cannot be rejected ($p > 0.05$), probably due to small size of the sample (9 for each group) or to the high variance.

6.3.2. Number of errors

The comparison between the number of errors made by expert and novice groups while performing the insertion task using PIÑATA is illustrated in (Fig. 14). The median and IQR values are also listed in Table 5.

The difference expected between groups can be seen in (Fig. 14): the group of experts made lesser errors during task execution when compared to the group of novices. As before, a Mann-Whitney *U* test was used with the following null hypothesis (H_0): "The population distributions of the number of errors using PIÑATA by experts and novices are identical". The calculated p-values and Z-scores are presented in Table 5.

As for task completion time, the test indicated that there is statistical evidence to reject H_0 ($p < 0.05$) only in the case of the jugular access site. Therefore, there is only statistical evidence to prove the inherent difference of the number of errors between experts and novices, in the case of the jugular access site. One possible explanation for this is the fact that participants, both experts and novices, do not perform CVC training using subclavian access very often, hence, their level of expertise in that specific procedure is not significantly different.

6.4. User satisfaction

The participants were asked to fill a satisfaction questionnaire comparing some aspects of the two training methods for each access site. The median and IQR of the responses are summarized in Table 6. It is important to note that in the way the questionnaires were elaborated, positive answers favour PIÑATA in comparison to the conventional method. A one- sample Wilcoxon signed-ranks test was used to determine the significance of the responses using the null hypothesis (H_0)," the difference between the median of each Likert item and the central value of the scale (3.5) is zero".

The median of all the responses was higher than 3.5, confirming that participants positively evaluated the usability of PIÑATA, considering that it facilitates the training of CVC as beingeasy to use, to learn and to recall. However, not all the results are statistically significant, including the ease of use and learnability ($p > 0.05$). This can be related to the fact that wearing AR glasses can be uncomfortable and requires some training of its own.

For further validation, participants were asked to fill in a SUS questionnaire for assessing the perceived usability of our PIÑATA system (Brooke et al., 1996). The SUS score was calculated for each participant. The mean score was 75.69 (SD = 9.07). To evaluate if this is a statistical significant result, a one-sample Wilcoxon signed-ranks test was run to test the following null hypothesis (H_0):" the difference between the mean of the SUS score and the considered average score of the scale (68) is zero". A p-value of 0.002 indicates that PIÑATA was considered a good user interface with high acceptability rates.

6.5. Perceived workload

To measure the perceived workload we relied on a validated assessment tool, the NASA-TLX. A one-sample Wilcoxon signed-ranks test was used to determine the significance of the responses evaluating the following null hypothesis (H_0)" the difference between the mean score of each parameter and the value from which the workload is considered somewhat high (30) is zero". The associated mean, SD and p-values of these tests are presented in Table 7.

Table 5
Median (Mdn) and interquartile range (IQR) of the number of errors using PIÑATA and p-value of the Mann-Whitney *U* test comparing experts (attending specialists) and novices (medical residents).

Access site	Level of expertise	Mdn (IQR)	p-value	Z-score
Jugular	Attending specialist Medical resident	1 (0) 2 (3)	0.036	−2.217
Subclavian	Attending specialist Medical resident	1 (1) 2 (3)	0.067	−2.021

Table 6
Median (Mdn) and interquartile range (IQR) of the responses to the Likert items and p-value of the Wilcoxon signed-ranks test comparing their median with the centre of the scale (3.5) for both jugular and subclavian access sites.

Access site	Jugular			Subclavian
Statement	Mdn (IQR)	p-value	Mdn (IQR)	p-value
1. Easiness to identify the anatomical landmarks.	4.0 (2)	0.010	4.0 (1)	0.005
2. Easiness to use.	4.0 (1)	0.033	4.0 (1)	0.072
3. Learnability.	4.0 (1)	0.128	4.0 (1)	0.062
4. Usefulness.	5.0 (1)	0.001	4.0 (1)	0.001
5. Recallability.	5.0 (1)	0.001	4.5 (1)	0.002
6. Easiness to debriefing.	5.0 (2)	0.001	5.0 (1)	0.001

Table 7
Mean and standard deviation of the responses to each parameter of the NASA-TLX scale and p-values of the one-sample Wilcoxon signed-ranks test comparing their mean with the value from which the workload is considered somewhat high (30).

Parameter	Mean (SD)	p-value
Mental demand	21.11 (13.56)	0.019
Physical demand	18.06 (12.96)	0.003
Temporal demand	7.78 (7.12)	<0.001
Overall performance	20.83 (15.53)	0.014
Effort	29.17 (15.36)	0.856
Frustration level	14.72 (13.88)	0.001
Overall	19.26 (10.34)	0.002

We noted that the mean score for the majority of parameters lies within the range of a medium workload system. There is statistical evidence to reject H_0 for all parameters except for the level of effort, probably due to the increased effort of wearing AR glasses. Overall, from this analysis, it seems that PIÑATA is not considered to have high demand levels, being a valuable tool for training of CVC.

6.6. Verbal user's feedback

Participants provided detailed feedback during semi-structured interviews, in particular, about the advantages and disadvantages of PIÑATA, their difficulties during task execution and also their suggestions for further improvements. After a thematic analysis, this feedback was summarized in the following themes:

- *Complement to conventional training*

Indeed, almost all the participants (14) considered that PIÑATA can complement the conventional training system, supporting our initial motivation. They stated that" Anything that helps to better understand the correct way of doing the procedures complements the training of inexperienced doctors". Moreover, they agreed that the image overlay is reliable and that the feedback during task execution is useful.

- Content usefulness

When asked about the aspects that they liked the most, the majority of the professionals (10) highlighted the projection of the vessels inside the simulator and several (5) referred that the information about angles and needle depth was very useful. This corroborates the content validity of PIÑATA already supported by the results of the questionnaires.

- Discomfort and unnatural feeling

Regarding the limitations of PIÑATA, 14 participants mentioned that they had issues related to the OST-AR headset, namely, limited FOV and sense of discomfort when wearing the device. Another drawback reported by the participants was a noticeable lack of stability of the virtual elements. This is due to the cheap tracking system ($30) that required an ideal setting to work properly. All these factors combined with the fact that it is the first time that professionals were exposed to this tool contribute to the lack of natural interaction when using PIÑATA.

- High acceptability

When asked if the adoption of this type of OST-AR tool in medical training is possible, almost all the professionals (13) agreed with that assertion. They considered the OST-AR simulation to be the future of medical education. Moreover, they considered that OST.AR is particularly useful during the early stage of training in medical schools.

- Ultrasound (US) integration

Integration of ultrasound (US) imagery in PIÑATA was one of the main suggestions made by the participants interviewed, as it is already common to perform CVC procedures with US guidance.

7. Conclusion and future work

This study compared conventional CVC training with an OST-AR approach. We proposed PIÑATA as an OST-AR prototype that augments not only the simulator space but also the needle space to assist the trainee during CVC practice. The results suggest that PIÑATA fulfils the criteria of validation as a new method for training CVC procedures. Only predictive validity was not assessed in this work since it requires a randomized controlled trial comparing performance performing the procedure in real patients (Barsom et al., 2016). Therefore, the initial hypothesis was confirmed: PIÑATA complements the conventional training system, reducing the dependence of the instructor without affecting the quality of training.

This system leaves room for improvement and further investigation. One of its main limitations is the tracking system that is affected by external factors including light conditions. Further, the

HMD causes some discomfort and has a limited FOV. While these are important limitations, they are described in the state of the art of AR applications showing that it is necessary to keep improving this technology. In the future, other applications for this type of tool can be explored including a collaborative setup for training using handheld devices. A future extension of our work consists of an ablation study to verify the influence of the proposed geometric information (e.g., conical placeholder) and how these graphical components influence the user's experience, performance and satisfaction. Finally, the reasoning behind the new training method proposed here could be applied to more procedures, via a common AR framework to train needle-based interventions, promoting a better medical education and, consequently, improving patient care.

CRediT authorship contribution statement

Helena Catarina Margarido Mendes: Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing - original draft, Writing - review & editing, Visualization. **Cátia Isabel Andrade Botelho Costa:** Conceptualization, Resources, Visualization. **Nuno André da Silva:** Conceptualization, Resources. **Francisca Pais Leite:** Resources, Supervision. **Augusto Esteves:** Writing - original draft, Writing - review & editing. **Daniel Simões Lopes:** Conceptualization, Writing - original draft, Writing - review & editing, Supervision, Project administration, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.compmedimag.2020.101731.

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