1. The image visible optical code is placed on the test/subject/patient; in this case a spine sawbones phantom. A minimum of 3 tags is required. If only skin codes are used, five are recommended. They can also be placed on a plastic tag holder attached to a bone pin. To get the best depth accuracy having one or more partially to the side of the patient can be helpful.

2. The subject is then imaged with 3D CT (PET, or an operative CT scanner such as an O arm or a cone beam CT).

3. The Novarad PACS software is then launched and the relevant series opened into the 3D viewer.

4. This will show three orthogonal multiplanar reformatted images along with a 3D image.
5. A preoperative planning tool is then launched which allows the system to automatically identify the tags. If for some reason the system fails to identify a tag, the user can manually drag the tag position so the image visible tag matches with the optically visible tag.

With the preoperative planning system, the user can create virtual tracts, pedicle screw holes, incisions etc. for the preoperative planning phase. These can be adjusted in all visible views as desired by the surgeon. In addition, on the preoperative planning tool the user can drop coordinates on anatomic landmarks such as a posterior spinous process or other structure that will be exposed and visible to the surgeon which can then be recognized at surgery.

6. From the study browser, the user right clicks on the series which have been annotated and a QR access code is printed. This optical code has a 300+ bit encrypted string which when viewed by the AR headset will automatically retrieve the images from the Novarad server along with relevant annotations.

In the OR, the data set is retrieved and the VisAR system launched by looking at the optical code or manually retrieving them through the browser.

7. It is critical that calibration be performed prior to using the headset. This consists of both the Microsoft HoloLens eye calibration as well as the Novarad interpupillary distance calibration.
8. Registration of the hologram to the patient is accomplished by simply looking at the optical tags which are affixed to the patient and turning the auto registration on.

The user can also manually register using the 6-axis/drag/rotate functionality of the image set over the patient.

Alternatively, one can register based on coordinate tags or anatomic landmarks that have been placed in the data set during the preoperative and then using the Optical Wand to touch these points and register them to the patient. The Optical Wand consists of a needle with optical codes that will precisely localize the point desired on the patient into the virtual space.

9. A test of the calibration and accuracy review of the system is then performed by looking at the optical codes. Surgeons can receive details on how tightly the system is calibrated by using the command phrase “turn rays on.” If all of these projected registration points pass through a single point in the center of the optical code they know that the camera and eye-calibration are adequate. Error is shown by the size of the dots.

Once registration is accomplished, the surgeon can then launch the patient images viewing these in real-time reconstruction in any orthogonal or 3D view.

10. By turning the annotations on, the user can see the preoperative planning tracts, needles, screws or incisions. One can cycle through these one at a time by saying next needle or previous needle.
11. The virtual needle or trocar will have a central targeting area. The larger circle represents the chosen entrance location either on the skin or at the lamina or other exposed area that the surgeon has selected. The smaller circle is the final target of the instrument. By aligning the user’s eye carefully to look down the target the circles will go away leaving only the crosshairs in green. This indicates complete alignment.

The distance of the virtual needle or trocar is shown to the operator adjacent to the virtual line when one is within 15° of the alignment of the target.

A stop is placed on the trocar or needle system which prevents it from going deeper than desired by the surgeon. In the case of pedicle screws, the length of the pedicle screw is determined on the preoperative planning system. This will be displayed in the augmented reality system adjacent to the virtual screw. Alternatively, tool tracking can be used to access z axis depth.

The surgeon places the needle or trocar in the center of the crosshairs and inserts until the appropriate distance of the target is reached. The user can double check the trajectory and angle of the virtual needle by moving orthogonally to the needle 90° in both directions and observing the virtual needle tract superimposed on the real instrument.
12. The system has a continuous registration feature which can be enabled. This feature allows for continuous registration to the optical codes during a procedure.

Optical codes can be attached to instruments allowing them to also be tracked virtually into the target and provide feedback to the operating surgeon.

If the system senses a problem, it will alert the operating surgeon. The problems for which a surgeon would be alerted include:

1) if the system has not been calibrated for interpupillary distance,

2) if the camera is not calibrated,

3) if the patient has moved,

4) if the registration measured by the tightness of the registration rays is below tolerance, or

5) if the system is in a state where the AR device is not accurately tracking the optical codes.

Guidelines for use

1. This has been tested for patients of average BMI. The skin is known to shift in obese patients. Having multiple codes over a large area (20 - 30 cm tag distance) reduces the movement error. However, we recommend using bone pin fixation of the optical codes if significant skin laxity is present.

2. While a physician is achieving experience with the system, we recommend additional confirmatory imaging such as fluoroscopy to check placement during the procedure.