

VAS 2023–Porto

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Vascular Access Society

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CERTA ACCESS SYSTEM AUTOMATED CENTRAL VENOUS ACCESS DEVICE PERFORMANCE IN ANIMAL MODEL.

Introduction:

Central venous catheter (CVC) placement is often necessary to provide an appropriate level of care for the critically ill. However, extensive training and experience are necessary to place these catheters. Even so, placement complication rates are 4 – 7 %. Automation of the catheter placement may allow safer, more reliable placement with far less training. We present here the results of experiments to test the reliability, safety and efficiency of an automated CVC placement system.

Materials and Methods:

The CERTA Access System from Obvious Robotics was tested for efficacy in gaining central venous access (CVA) in experiments on two separate domestic sheep. A graphic illustration of the device is shown in figure 1. The animal was used in accordance with THI IACUC policy. The procedure protocol for gaining central access, in brief, was that the central venous access sites of the sheep was prepped in the usual fashion for CVC catheter placement in humans. The CERTA Access system was applied to various central venous access sites. The system targeted the central vein through ultrasound imaging, and the access needle was deployed automatically to the target. When vessel access was confirmed by blood return, a guidewire was placed into the vessel through the access needle. Confirmation of the guidewire position within the vessel was confirmed by ultrasound.

Results:

The overall success rate for central venous access attempts by the CERTA system was 96 % (54/56). The vessels accessed had diameters of 6 – 7 mm. There were no complications of the procedure defined as notable bleeding, hematoma, or vessel disruption. The mean time to vessel entry, from placement of the device in the groin area of the animal to placement of the guide wire was 61 seconds (hi 180, low 16 seconds).

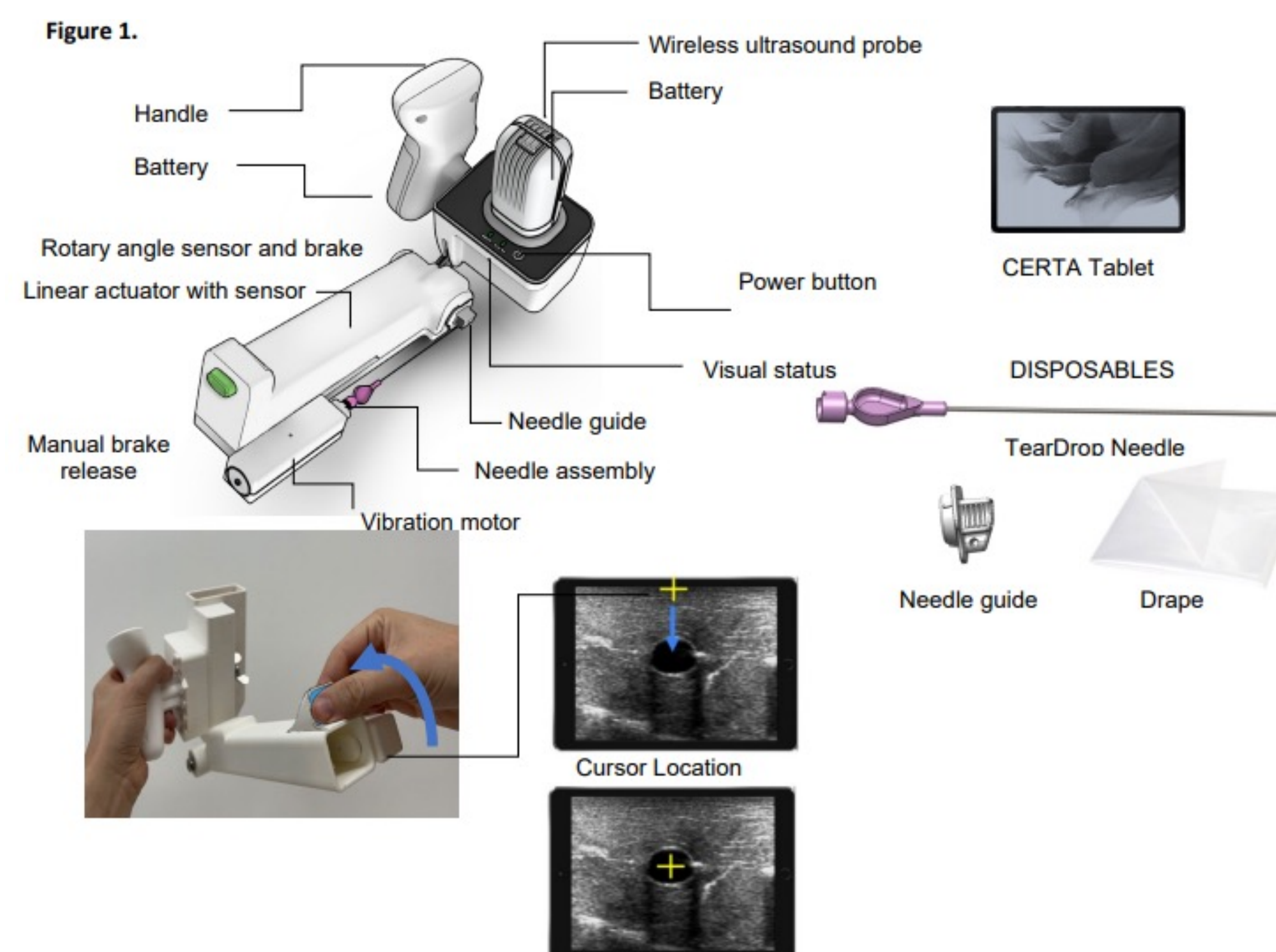
Conclusion:

These experiments demonstrate the potential for a safe, reliably effective, efficient device for CVA that does not require advanced training and experience to perform.

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Animal Lab(s)

Lab 1 July 8, 2022
Sex/Age: F/14mo
Weight: 72Kg
Vessel Size: 3-6mm
of Attempts: 26
Avg time of Access: 69s
Users: Cohn, Herlihy

Attempts	Success	%
1	20	77%
2	3	12%
3	2*	8%
Overall		97%

*One failure due to spasm/Clot

Notes:
• 100% (14/14) 1st time success in femoral vein and artery.
• 55% (6/11) 1st time success in jugular vein.
• Specific technique identified for jugular access in sheep model due to tissue density.

Lab 2 Aug 10, 2022
Sex/Age: F/14mo
Weight: 47Kg
Vessel Size: 6-7mm
of Attempts: 30
Avg time of Access: 55s
Users: Cohn, Herlihy, Mortus*, Gluck*, Rennicks*

Attempts	Success	%
1	25*	83%
2	2	7%
3	2^	7%
Overall		97%

*Device failure
^First time users w limited or no experience

Notes:
• First time user 1st attempt success rate of 64% (7/11)
• Experienced user 1st attempt success rate of 96% (26/27)
• Sterile sleeve used on all cases

Summary
Total Animals: N=2
Total Attempts: 56
Avg time of Access: 61s
of Users: 5
Expert users: 2
Novice users: 2
No experience: 1

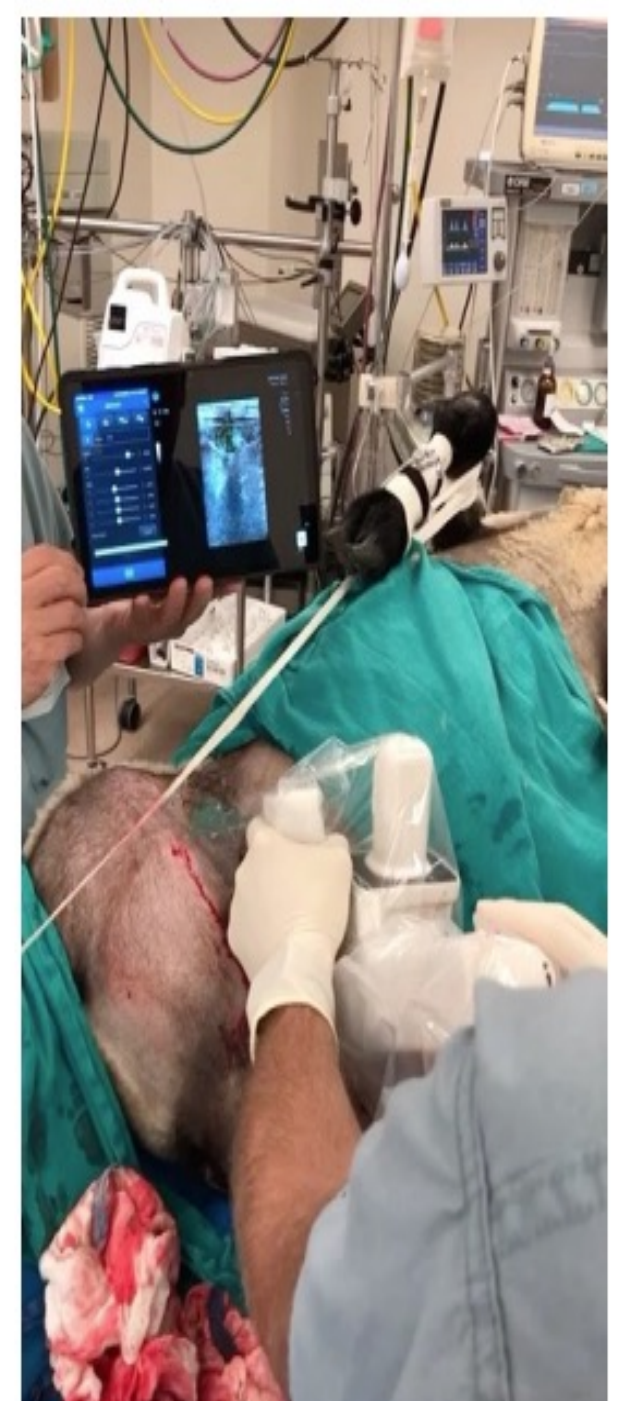
Attempts	Success	%
1	45	80%
2	5	9%
3	4*	7%
Overall		96%

Notes:
• Average 1.2 attempts to access required.
• Average Target, Access, Place Guidewire time of 61 seconds

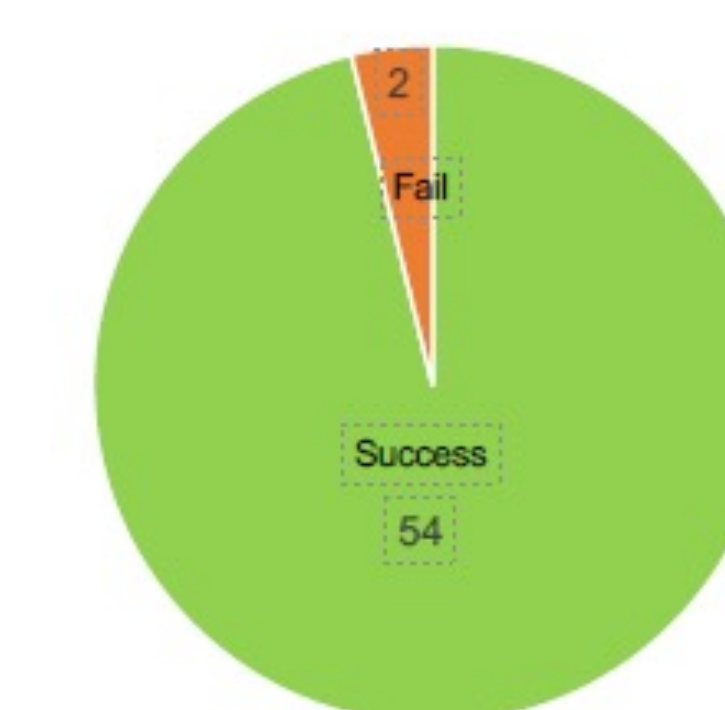
CERTA Animal Lab Example

Case #25 - L Femoral Vein
Procedure time: 45 sec

CERTA Access Tablet
(Will be stand mounted in commercial version)
Bluetooth enabled
CERTA Ultrasound
Connected to tablet
CERTA handle



CERTA Animal Lab Summary



96%
Success*
54/56

Successful Vessel Access
• 45/54 First time femoral access (80%)
• Two failures:
• Spasm/Clot in IJ unable to advance guidewire
• Device power failure



61
Seconds
Average time to access
Hi: 180 sec
Lo: 16 sec



1.2
Attempts
required
for access
67/54
Hi: 3

* Success defined as placement of needle and advancement of .035" guidewire