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Improving safety and efficiency during emergent central venous catheter placement with a needleless securing clamp

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ABSTRACT

Objective To compare the needleless securing clamp to the traditional suture-secured clamp for central venous catheters.

Methods Compare the holding strength of each type of clamps by measuring the amount of kinetic energy absorbed, ask 20 physicians to evaluate the clamp placement using sutures or staples, and summarise the clamps effectiveness and complications in 10 patients.

Results Compared to sutured clamp, the needleless clamp was more secure. The needleless clamp was also significantly better with regard to ease of use, safety, perceived strength (p value <0.002), and insertion time was reduced by 63%. No adverse events or skin infections occurred while using the needleless clamps.

Conclusions Without incurring complications or increasing risk to patients, the needleless clamp is secure and improves safety and efficiency for physicians.

INTRODUCTION

Central venous access permits rapid drug delivery to the central circulation during cardiopulmonary resuscitation, as well as an avenue for fluid administration and access for advanced monitoring and therapeutic devices. Central venous catheters (CVCs) must be secured in place to prevent accidental removal; sutures inserted by needles are typically used for this purpose. One drawback of needles is they increase the likelihood of needlestick injuries to healthcare providers. It has been reported that 28% of needlestick injuries occurred during CVC placement.[1] Providing the required function of drug delivery, the recently developed needleless securing clamp (U.S. patent number 7 799 000) can be secured using sutures or staples. Should we use staples exclusively, we eliminate the risk of needlestick injuries. The aim of this study was to compare the needleless securing clamp to the traditional suture-secured clamp based on strength, safety and efficiency.

METHODS

The study was approved by the institutional review board. The traditional clamp shown in figure 1 has to be secured with sutures. The needleless clamp shown in figure 2 is designed to be secured with staples (used exclusively with the needleless clamps in this study) but also provides the suture option.

Compare holding strength

The traditional clamps were secured on a pig cadaver at room temperature by two single loop sutures where each loop was made with a 3.0, black braided, 000 silk, non-absorbable sutures. The needleless clamps were secured to the same pig cadaver using four staples (3M, Precise, DS-5 staples). Note that in order to reduce the influence of the elasticity of the skin, the clamps were isolated to a 4-inch diameter area on the flank of the carcass by holding firm pressure on a wooden plate with a circular hole. To compare the holding strength of each type of clamps, we simulated the situation of a kinetic energy input by a person inadvertently 'jerking' on the catheter by dropping weights connected to the clamps with a an implicitly non-elastic string. The string pulled the clamp in one of three directions: transverse, longitudinal and perpendicular. For each weight drop, we measured how many ft-lbs of energy were needed to dislodge the clamps. A weight of 2.5 lbs was dropped one or two feet to deliver 2.5 or 5 ft-lbs to the clamp.

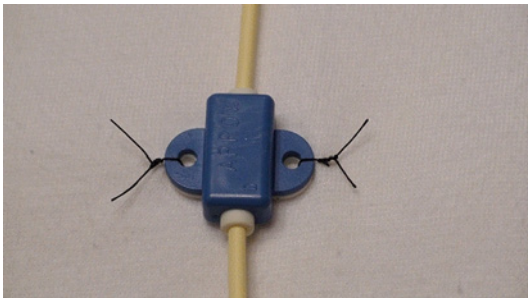

Figure 1 Traditional suture-secured clamp

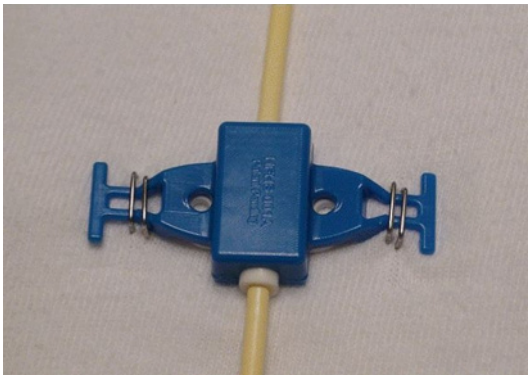

Figure 2 Needleless securing clamp with staples.

Table 1 Comparison scale for staples versus sutures

−5 Extremely*	−4 Moderately	−3	−2 Slightly	−1	0 No difference	1 Slightly	2	3 Moderately	4	5 Extremely†
Difficult					At Baseline	Easy				
Not safe						Safe				
Not secure						Secure				

*Extensive training or experience needed.
†Minimum training or experience needed.

Evaluate and grade the clamp placement

Twenty emergency department (ED) attending and resident physicians experienced with the use of traditional suture-secured clamps were educated for the new needleless clamp. They were then equally and randomly partitioned into two groups and were asked to secure and remove each clamp to a store bought, room temperature, pig's ham hock. In one group, 10 physicians were first asked to secure and remove the traditional suture-secured clamps with two sutures. Next they did the same with the needleless clamps and four staples. The other group of 10 physicians secured and removed the needleless clamps first and the traditional suture-secured clamps second. When physicians proceeded to secure and remove clamps, we recorded the time of insertion and removal where time was defined as the duration between picking up the first piece of required equipment and completing the procedure. After they finished insertion and removal of the clamps, we asked them to compare these two types of clamps based on ease of use, safety and perceived strength. We asked them to provide the difference in score between the two types of clamps by defining the first insertion/removal process as their baseline. The difference in score is the score of the second insertion/removal process relative to this baseline. The grading scale is from -5 to 5 as shown in table 1.

Record adverse event

A convenience sample of 10 ED patients (with consent) had their CVC secured with the needleless clamps using staples. The locations of the clamps were recorded. Patients were asked to evaluate whether the stapled clamps were comfortable. The physicians who attached the needleless clamps were asked for their opinions about level of difficulty. The 10 patients were followed up for any procedural complications, accidental dislodgements or skin infections until the clamp and catheter were removed.

Statistical analysis

The scores of ease of use, safety, time of insertion and removal were summarised using mean and SD. To compare the scores of difference between needleless clamp and suture-secured clamp, one-sample *t*-test was used. All p values were based on two-sided tests and significance level was set at 0.05. All statistical analyses were conducted using SAS V.9.2 (SAS Institute).

RESULTS

The studied needleless CVC clamp held with staples had equal or greater holding strength than those held with sutures. The energy required to dislodge both needleless and staple clamps in three perpendicular directions are shown in figure 3. All of the dislodgements were due to breaking of the sutures or release of the staples. There was no tearing of skin tissue or equipment failure.

Compared to suture-secured clamps, the needleless CVC clamps evaluated by 20 ED physicians were significantly better

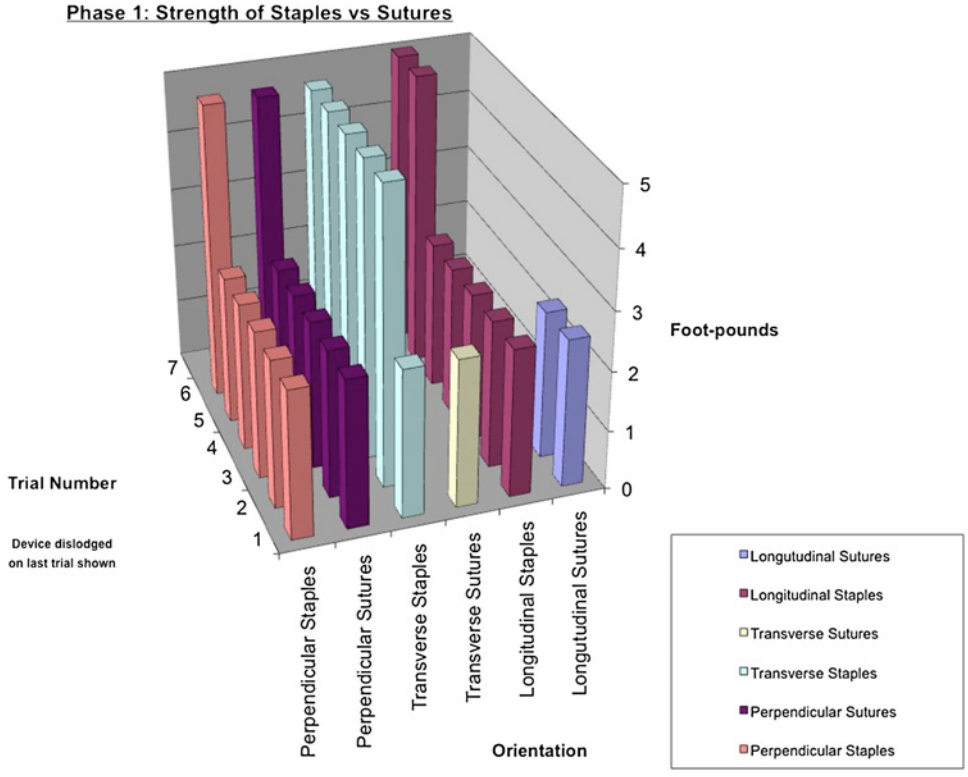

Figure 3 Strength of staple versus suture.

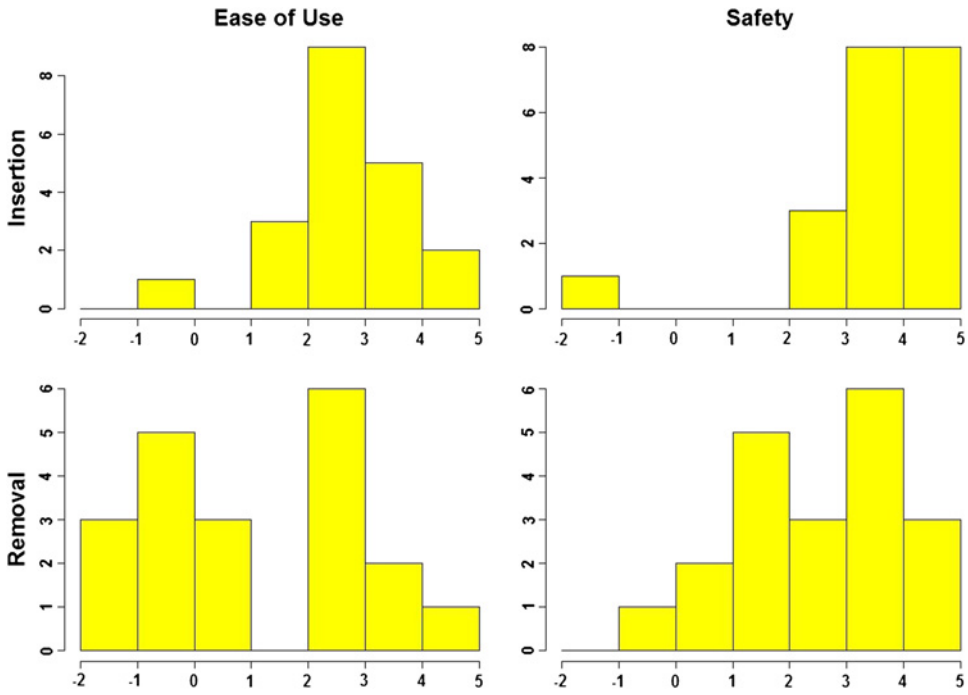

Figure 4 The histograms of relative score, the scores of staples minus the scores of sutures, with respect to ease of use and safety for insertion and removal

with regard to ease of use and safety. Using the *relative score* defined as the physicians' scores in staples minus those in sutures, figure 4 showed that the needleless clamps on average had large positive values. In addition to graphical comparison, statistical analysis showed that the scores of the needleless clamp were higher than the ones of the traditional clamp ($p<0.004$). Figure 5 showed the time distribution to insert and remove each clamp. On average, insertion took 127.4 s using sutures and 47.5 s using staples. The insertion time was reduced by 63% using staples ($p<0.001$). The average removal times were 12.5 s using sutures and 19.9 s using staples. The difference in removal time is negligible in practical situations.

Finally, the needleless clamp using staples on 10 ED patients for an average of 2.9 days (SD=2.6) recorded no cases of local infection, catheter dislodgement or evidence of increased risk or harm to patient care. The locations varied with one supraclavicular, two internal jugular, three subclavian and four femoral CVCs.

DISCUSSION

Protecting healthcare providers from the transmission of an infectious disease is a healthcare priority. The National Institute for Occupational Safety and Health has concluded that 'needlestick injuries are an important and continuing cause of exposure to serious and fatal diseases among healthcare workers.[2]' They further state, 'Critical to this effort are the elimination of needle-bearing devices where safe and effective alternatives are available.' It is extremely important to address issues related to needle-bearing devices because 39% of anaesthetists have reported a needle stick injury in a 12-month period.[3] Furthermore, it is estimated that 644 963 needlestick injuries in 2004 cost the healthcare industry $100.7 million to $405.9 million.[4] These numbers equate to about 30 needlestick injuries per 100 hospital beds. Therefore any procedure avoiding the use of a needle will decrease the risk of needlestick injuries to healthcare providers and decrease healthcare costs.

One factor to decrease needlestick injuries is related to CVC placement since 28% of needlestick injuries occurred during CVC placement.[1] Based on the National Institute for Occupational Safety and Health guidance, several studies have looked at alternative CVCs that use staples.[1 5 6] Their findings are varied but previous devices have not led to an elimination or significant reduction in the use of a needle and suture for CVC placement. Examination of these devices reveals they were optimally designed for suture use. Unlike previous clamps, the study clamp is optimally designed for medical staples typically found in a hospital. If healthcare providers must revert to the suturing method, the study clamp also provides this option.

The results of the holding strength tests showed that the four staples were as or more secure than using two single loop 3.0 silk sutures. The 20 physicians' evaluation showed that the new needleless clamp was significantly easier to use, safer, quicker

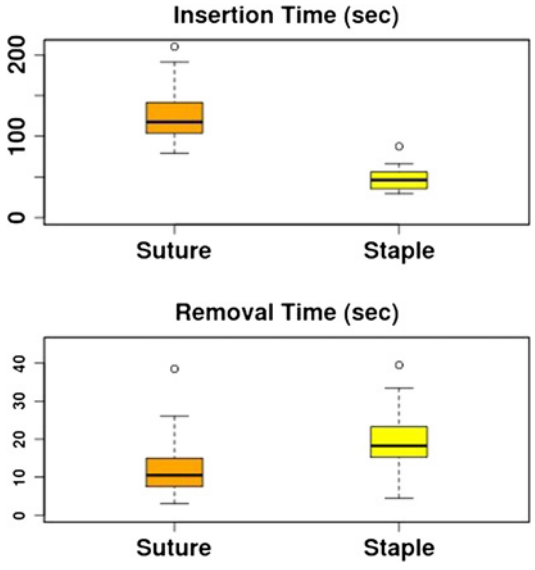

Figure 5 The boxplots of insertion and removal times for sutures and staples

and felt secure. These four features can increase physicians' willingness to adapt and use this new device on actual patients.

Overall, this report shows the needleless clamp with staples is a viable alternative to a suture-secured clamp for use in patient care. This device is easy to use and increases the safety to healthcare providers by eliminating needles.

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Competing interests The Needleless Catheter Clamp is patented by the Henry Ford Health System. Dr Silich is the sole inventor. The Henry Ford Health System and Dr Silich are eligible to receive royalty payments for the commercial use of this device.

Ethics approval Henry Ford Health System Institutional Review Board.

Provenance and peer review Not commissioned; externally peer reviewed.

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