

AN OPTICAL DEVICE FOR DETECTING INTRAVENOUS INFILTRATION

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ABSTRACT

Intravenous infiltration is a serious problem associated with infusion therapy. It is usually accompanied by pain, erythema, and swelling at the needle insertion site. Severe infiltration may lead to necrosis requiring skin debridement, skin grafting, and/or amputation. Early detection of infiltration prevents the occurrence of serious incidents. A new device, ivWatch™, was developed to monitor the intravenous infusion site for infiltration. The results of validation studies on animal and human subjects are presented. A clinical trial on 800 patients is currently underway to investigate safety and efficacy of the ivWatch™.

BACKGROUND

There are 150 million peripheral IV infusions per year in the US. The incidence of IV infiltration reported in the literature varies widely. Table 1 lists the IV infiltration incidences, fractions of infiltrations to total infusions in the study, and the respective reference.

Table 1. Infiltration Incidences

Incidence	Reference
11% of IVs in children (1800/16380)	Brown et al., Plast. Reconstr. Surg. 64, 145-150, 1979.
18% of patients with teflon needles (84/468) 40% of patients with steel needles (194/486)	Tully et al., Am. J. Med. 70, 702-706, 1981.
57% of patients with teflon needles (17/30) 100% of patients with steel needles (28/28)	Batton et al., Pediatrics 70, 487-490, 1982
58% of infusion in 78 infants (88/151)	Phelps et al., J. Pediatr. 111, 384-389, 1987.
20% of patients (117/598)	Hoffmann et al., Am. J. Infection Contr. 16, 101-106, 1988
63% of IVs in 69 patients (125/199)	Johnson et al., Am. J. Dis. Child 142, 968-971, 1988.
29% of infusions (76/259)	Hecker, Anaesth. Intens. Care 17, 433-439, 1989
28% of IVs in 303 pediatric patients (183/654)	Garland et al., Pediatrics 89, 1145-1150, 1992
12.2% of male patients (50/411)	Catney et al., J. Infusion Nurs. 24, 332-341, 2001

In addition to patient suffering, infiltration events result in serious financial consequences. Recently, Wyeth Pharmaceuticals paid a \$6.7 million out-of-court settlement to a patient who suffered the loss of a limb and permanent nerve damage due to IV infiltration. A report from the Ohio Hospital Association states that IV infiltration is the most frequent allegation in the pediatric patient monitoring category, and multi-million dollar malpractice awards are not uncommon. It was reported that for the cost of one hand infiltration per year, a hospital can hire ten full-time nurses to monitor IV's more often.

METHODOLOGY

Figure 1 illustrates the principle of the ivWatch™ technology. The ivWatch™ consists of two components, a skin contact sensor and an electronic device, connected via two light guides. The first light guide sends input optical radiation to the skin contact sensor whereas the second light guide delivers the collected radiation (output) from the infusion site to the electronic device. As IV fluid infiltrates the interstitial space, the optical density of tissue changes, resulting in a change of the collected optical signals. The presence of infiltrated fluid in subcutaneous layers is inferred from the differences in the measured signal.

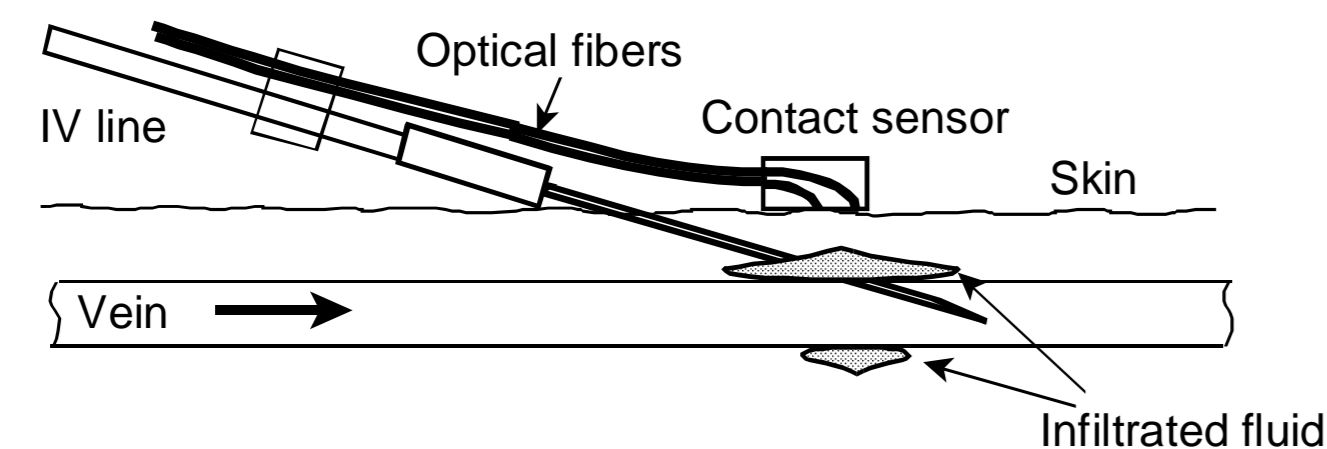


Fig. 1. Schematic diagram of ivWatch™.

ivWatch™ INFILTRATION DETECTION SYSTEM

The ivWatch™ system is a self-contained bedside unit consisting of an electronic device and a disposable skin sensor, as shown in Fig. 2. The system operator (nurse) communicates with the electronic device using a handheld PDA running proprietary software.



Fig. 2. ivWatch™ electronic device and disposable sensor.

Disposable Skin Sensor

The disposable skin sensor consists of a clear base for providing optical coupling to the skin and two light guides for delivering the input optical signal from the electronic device to the infusion site, and the output signal from the infusion site to the electronic device. The base is fabricated from Lexan and biocompatible epoxy.

Electronic Device

The electronic device contains a microprocessor, memory, an LCD display, a serial port, a light emitting diode (LED), and a detector. Housing the LED in the electronic unit eliminates the possibility of thermal burns as seen in some pulse oximeter sensors and reduces the cost of the disposable skin sensor. A near-infrared LED was chosen for its deeper photon penetration depth than the visible-wavelength LEDs. The electronic device stores and analyzes the collected data. When an infiltration is detected by the device, it alerts the nurses via audio and/or visual alarms. The alarm notification can be sent via wired and/or wireless communication protocols.

SYSTEM VALIDATION MEASUREMENTS

The ivWatch™ system was tested in an animal study (pig) and a human study conducted at Eastern Virginia Medical School and the University of Virginia Health System, respectively.

Animal Study

Both simulated and induced infiltrations were conducted. The simulated infiltration was performed by infusing saline into tissue whereas the induced infiltration was performed by either pushing the IV needle through the vein or by pulling the needle out of the vein. Using a mixture of saline and fluorescein as IV fluid, infiltration can be confirmed spectroscopically by detecting the presence of fluorescein in tissue near the infusion site. PICU nurses were recruited as expert observers to detect infiltrations visually. In all 17 experiments, the ivWatch™ detected infiltration long before the expert observers did.

Human Study

A Non-Significant Risk (NSR) device study designation (Q030041) of the ivWatch™ was obtained from the FDA. A total of 51 healthy volunteers completed the study. An IV-team nurse was responsible for infusing and infiltrating the subject. Another nurse blinded to the experimental procedures was responsible for observing and reporting. Dorsal metacarpal hand veins were used as infusion sites. Normal saline was infused into the vein at 60 ml/hr, using an infusion pump. The skin sensor was positioned about 1 cm from the needle insertion site, approximating the location above the needle tip. After the initiation of IV infusion, the subject was asked to remain still for 10 to 20 min. The collected signal was steady to within 1% during this period. The subject was then asked to move around to simulate movements of daily activities. The IV nurse then intentionally induced infiltration by advancing through or withdrawing back the needle tip from the lumen of the vein. The time of infiltration was recorded and correlated with optical data. The observation of the IV nurse was recorded and correlated with the measured optical signals.

Figure 3 shows a typical signal vs. time curve of the changes in optical signal due to subject movement and IV infiltration. The ivWatch™ detected 50 out of 51 infiltrations. The missing infiltration was attributed to difficulty in inducing infiltration of that particular subject. Both sensitivity and specificity of ivWatch™ are higher than 97%. In all events, the ivWatch™ detected infiltration before the IV nurse did, even as the IV nurse checked the infusion site every 10-15 min.

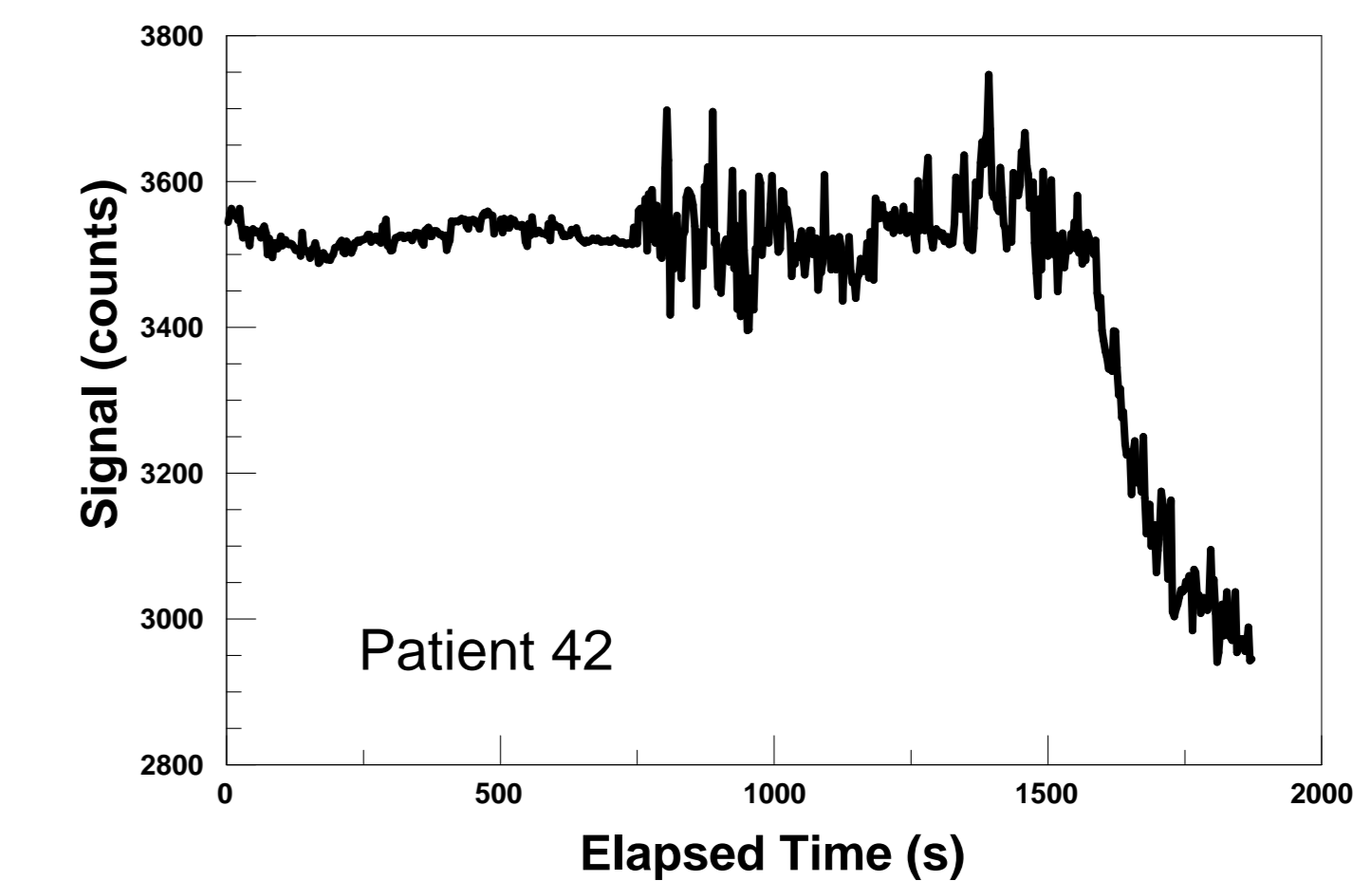


Fig. 3. Optical signal obtained from Patient #42. At around 800 s, the patient was asked to move the hand that was being infused. Infiltration was observed at around 1500 s.

CONCLUSION

ivWatch™ provides early detection of IV infiltration with high sensitivity and specificity.

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