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Are surgical stainless steel wires used for intracranial implantation of PrP^{sc} a good model of iatrogenic transmission from contaminated surgical stainless steel instruments after cleaning?

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Summary Transmissible spongiform encephalopathies are a group of fatal, neurodegenerative diseases commonly known as prion diseases. Prion diseases can resist traditional inactivation strategies and may be iatrogenically transmitted by surgical instruments through the human population. These properties have led to the need for a suitable detection method of the prion infectious agent, and increased pressure regarding the development of anti-prion cleaning methodologies that would ensure the safety of surgical instruments. Although other techniques have been applied, the animal bioassay remains the 'gold standard' method for assessing infectivity. As the vast majority of surgical instruments are made of stainless steel, and in order to test this surface using the animal bioassay, the application of very thin surgical stainless steel wires has been widely adopted. These wires are easily inoculated and may be reimplanted into animals without the requirement for elution of the residual material. However, their comparability to the dimensions, shape and size of surgical instruments is questionable. This article shows how such contaminated wires (residual protein between 6.3 and 16.0 ng/mm^2) can be cleaned more easily than flat metal surfaces (residual protein between 63.9 and 89.3 ng/mm^2) under comparable conditions using recommended cleaning agents. These results indicate that the

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application of wires as a realistic means of assessing the removal or inactivation of the prion infectious agent from surgical instruments should be treated with caution.

Introduction

Transmissible spongiform encephalopathies, or prion diseases, are fatal degenerative brain diseases involving conversion from the normal alpha helical PrP protein to the beta-pleated sheet PrP^{sc} isoform.[1,2] Recent evidence has emerged that the prion disease marker PrP^{sc} can accumulate in peripheral tissue such as appendix and muscle for both the variant and sporadic strains of Creutzfeldt-Jakob disease.[3,4] This evidence and reports linking the transmission of prion disease via blood transfusion has led to increased concern over the possibility of large numbers of subclinical, asymptomatic carriers of the disease being present within the standard population, and the increased risk of iatrogenic transmission that this would produce.[5–9]

The prion infectious agent has been shown to remain viable after traditional inactivation regimes, such as autoclaving (121 °C, 30 min) or exposure to chemical solutions (e.g. formaldehyde), have been implemented.[1,10] This ability of prion infectivity to pass from subject to subject through surgical procedures has been proven in both the laboratory environment and in healthcare institutions.[11–13] Although lengthy, animal bioassay remains the most sensitive method of detecting the presence of the infectious agent.

Bioassay and other detection techniques such as Western blotting or immunocytochemistry cannot be applied directly to an instrument's surface.[14,15] To overcome this shortfall, the application of very thin surgical stainless steel wires that can be inoculated, cleaned and surgical implanted into animals has been developed.[16] The ability of these wires to cross-contaminate animals with prion disease has been well documented,[11,16] and their application to assess the efficacy of novel anti-prion cleaning regimens has become widespread.[17–20]

This study assessed the effect of the substratum configuration on the ability of five commercial cleaning products used routinely in hospital sterile service departments to remove prion-infected contamination from surgical stainless steel.

Methods

Tissue

Prion-infected brain material was obtained from female C57BL/6J mice that had been injected with 1 μL of 10% (w/v) ME7-infected brain homogenate, into the dorsal hippocampal region of the brain, as described elsewhere.[21] All animals were killed 19–21 weeks after inoculation or equivalent age for the naïve group. The tissue was frozen in liquid N_2, and subsequently split into two portions. One portion was made into a 1 mg/mL homogenate and one portion was made into a 10% (w/v) homogenate with phosphate-buffered saline.

Stainless steel tokens and wires

The tokens (10 mm × 25 mm; Advanced Alloys Ltd, Eastleigh, UK) and wires (10 × 0.5 mm; Ormiston Wire Ltd, London, UK) were made from 316L surgical-grade stainless steel, and passed through a two-step cleaning process, described previously, to produce a 'pristine' surface free from any residual soiling prior to artificial contamination.[22]

Evaluation of cleaning products

The test wires were incubated in 10% (w/v) homogenate for 1 h before allowing the protein to adsorb overnight at room temperature. One-microlitre samples of the 1 mg/mL ME7 brain homogenate, comparable to protein adsorbed on to the wire surface (see Figure 1, untreated samples), were applied to the test tokens and allowed to dry on to the surface for 30 min at 37 °C.

Ten millilitres of each cleaning product was placed into soda lime glass vials (Fisher Scientific Ltd, Loughborough, UK, TUL-460-071B). The vials were then placed into a STEM RS900 Reacto-Station (VWR International, Lutterworth, UK), warmed to the required temperature (Table I) and stirred at a constant flow rate of 400 revolutions/min.

The test samples (tokens and wires) were placed into the vials containing the cleaning products and left for 15 min. After cleaning, the test samples