

Sekiguchi Y¹, Yao Y Y¹, Ohko Y², Ishizaki A³, Tanaka K⁴, Ishido T⁴, Fujisima A⁵, Kubota Y¹
 1. Department of Urology, Yokohama City University, Graduate School of Medicine, 2. Science and Technology Promotion Project Party, PRESTO　JAPAN, 3. Toshiba Lightec Inc., 4. Department of Urology, Kanagawa Rehabilitation Center , 5. Kanagawa Academy of Science and Technology

SELF-STERILIZING CATHETERS WITH TiO₂ PHOTOCATALYST THIN FILMS FOR CLEAN INTERMITTENT CATHETERIZATION : CLINICAL USE

Hypothesis / Aims of Study

Titanium dioxide (TiO₂) as photocatalyst is chemically activated only by light energy. It can safely decompose materials of our choice, e.g., dirt, grime, bacteria, etc by powerful oxidizing action under lighting. The materials coated TiO₂ have been already used in practice for tiles, mirrors, tents and so on. Additionally, TiO₂ is chemically and physically stable and safe materials enough to be used an additive for food and cosmetics. We have developed successfully the technology of coating TiO₂ on silicone rubber. And we have made the TiO₂ coated catheters for clean intermittent catheterization using this technique. We, then, reported the photocatalytic anti-bacterial effect in vitro and the safety of them by the experiments on animals in ICS 2002¹⁾. Here we show the results of the examination on the photocatalytic anti-bacterial effect in clinical use and the safety of them by using cultured cells.

Study Design, Materials and Methods

[TiO₂-coated catheters]:

We made TiO₂-coated silicone catheters after the pretreatment of silicone surface with a sulfuric acid solution.²⁾ The TiO₂ film adhered to the silicone substrate strongly against tensile and bending stresses.

[Antibacterial quality in clinical use]:

The subjects were 18 persons. (Male 6, Female 12) The average age was 36.6. (Maximum is 63. Minimum is 18.) All patients were outpatients of Kanagawa Rehabilitation Center. They had neurogenic bladders caused by spinal injuries or spinal diseases. And they had carried on with clean intermittent catheterization more than 1 year.

They used self-sterilizing catheters with TiO₂ film for 4 weeks. In the investigation period, the self-sterilizing catheters with TiO₂ film were rinsed out with clean water and were sterilized in the portable boxes with black lights radiating small amount of 360nm ultraviolet rays inside for 1 hour every time they were used.

After 4 weeks, we cultured the tip of the self-sterilizing catheters with TiO₂ film.

After that, the same patients used control catheters for 4 weeks. The control catheters were rinsed out with clean water and were preserved in disinfectants. And the tip of the catheters were cultured after the investigation period. Moreover all urine cultures of patients before and after investigations were performed.

[Symptomatic change of patients]:

We examined lower urinary tract symptoms of patients by questionnaire in the guideline of neurogenic bladder published by the Japanese Urological Association and investigated the number of clean intermittent catheterization before and after using the self-sterilizing catheters with TiO₂ film.

[Safety study of TiO₂ coated catheter]:

For cell toxicity test of TiO₂ coated catheter, we used early passaged V79 JCRB0603 cells as test cell. And we used polyurethane films contained 0.1% zinc diethyldithiocarbamate (ZDEC) as positive control materials (A) and polyurethane films contained 0.25% Zinc dibutyldithiocarbamate (ZDBC) as positive control materials (B) and high density polyethylene film as negative control materials (C). We preserved these control materials and the tips of catheters with TiO₂ film in M05 medium and extracted samples from them. Afterwards these samples were diluted with culture medium. We estimated cell toxicity from the numbers of V79 colonies in these dilutions. The criteria of cell toxicity are as follows. (1) The formation rate of V79 colonies in (C) was estimated 100% safety. (2) The concentration which reduced 50% colonies (IC50) in (A) was estimated cell toxicity below 7% (3) IC50 of colonies in (B) was estimated cell toxicity below 70%.

Results

- 1) All urine cultures from patients before and after investigations were positive. But the rate of positive cultures of the tips of catheters with TiO₂ film was 20%. (Positive cultures 3, Negative cultures 12). On the other hand, the rate of positive cultures of the tips of control catheters was 60% (Positive cultures 6, Negative cultures 4) By χ^2 examination, the difference of these rates were significant. (p=0.04)
- 2) In 15 patients, the degree of LUTS and the numbers of CIC did not change between before and after using catheters with TiO₂ film.
- 3) About cytotoxicity of catheters, the formation rate of V79 colonies with the samples of catheters with TiO₂ film was over 100%. Thus, catheters with TiO₂ film did not show cell toxicity.

Concluding message

Self-sterilizing catheters with TiO₂ photocatalyst thin films for clean intermittent catheterization is useful and safe as a catheter.

Reference

- 1) Unstructured Poster Sessions 459, ICS 2002, Heidelberg
- 2) .J. Biomed Mater Res 58:97-101, 2001