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A MULTIDIMENSIONAL STUDY ON MATERIAL AND PRESERVATION METHODS FOR LONG-TERM SAFE INTERMITTENT SELF-CATHETERIZATION

Hypothesis / aims of study
We study various aspects of the optimum catheter material and preservation methods for safe intermittent self-catheterization for the period of 9 weeks (2 months).

Study design, materials and methods
Two types of silicone catheters (SI-1, 2), five types of specimen of polyvinyl chloride (PVC), hydrophilic-coated polyurethane (PU) and Latex (La), and eight types of disinfectant solutions including benzalkonium chloride were used. The specimen underwent sliding load, artificial urine exposure and immersion in disinfectant for nine weeks, and disparities of remaining bacterial amounts were investigated following longitudinal changes (appearance, surface texture observation, bending resistance, coefficient of static friction, tensile strength, flow rate per unit time), bacterial adhesion, preservation requirements (desiccation, tap water, benzalkonium chloride), as well as V79 cellular cytotoxicity test using 0.05% benzalkonium chloride after the above load.

Results
SI-1, 2 and PVC showed stability for longitudinal changes, and for bacterial adhesion testing, both showed excellent bacteriological properties; neither of the specimens allowing increases in bacteria levels for neutralizer treated specimens (non-use of disinfectant solution model), and allowing increases of only *P.aeruginsoa* bacteria levels in the neutralizer treatment specimens (immersion in disinfectant solution model). For preservation methods, the bacteria level following desiccation preservation and benzalkonium chloride preservation was 0, but for tap water preservation many strains remained, and for the immersion in disinfectant solution model all strains except *C.albicans* remained. In cytotoxicity testing, neither SI-1, 2, PVC nor PU showed toxicity, and for La, moderate cytotoxicity was observed and there are concerns about the risk of mucosal irritation for reoccurring catheterization operations. Further, high cytotoxicity (IC50=2.2%) was observed for benzalkonium chloride preservation which raises concerns about the long term toxicity exposure of the disinfectant on urinary mucosal epithelium.

Interpretation of results
The recommended catheter materials for a 9-week period safe intermittent self-catheterization are SI, PVC, and the safest preservation method is desiccation. If in Japan we take into overall consideration the usage situation of PVC for urinary use, the usage of plasticizers and environmental considerations, and then SI is superior.

Concluding message
The appropriate procedure for intermittent self-catheterization is the preservation method of desiccation using silicon, and the catheter can be used safely for 2 months.

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What were the subjects in the study?	**NONE**