578a Is Silicon Suitable for Making Implantable Biomedical Devices

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Silicon has been widely used in the development of implantable biomedical devices, such as neural prostheses, controlled drug delivery systems, chemical/biological sensors, and so on. Many biochips and MEMS devices are also silicon-based. We investigated the short- and long-term biocompatibility and stability of various novel and traditional materials in the central nervous system, which include aluminum nitride, borosilicate glass, sapphire, platinum, silicon and iridium oxide. Wafers (2.5mm dia x 0.25mm thick) of these materials were surgically implanted on the cortical surface of adult rat brain for 10, 28 and 90 days. This study addressed whether the implanted alien materials would cause: (1) deformation of the brain, (2) inflammatory response in the meninges and underlying tissue, and (3) degeneration of the cortical neurons or their efferent and afferent connections. We found that silicon is actually neither biocompatible nor biostable in the central nervous system, while biocompatibility and biostability are two very important criteria in determining the feasibility of implantable medical devices. Silicon caused significantly elevated tissue and glial cell reactions in all groups (10-, 28- and 90-day), compared with borosilicate glass, aluminum nitride and sham control. However, silicon only caused a negligible level of neuron and axon degeneration. The surface of silicon was noticeably corroded while implanted *in vivo* for as short as 10 days, as was observed on 28-day and 90-day samples as well.

In order to prevent the above *in-vivo* reactions, the surface of silicon wafers was modified by depositing a SAM of o**ctadecyltrichlorosilane** (OTS) or **trichloro (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silane** (FAS), and two biopolymers (heparin and hyaluronan) were covalently attached to silicon surface with OTS SAM as the bridging layer by UV-based photo-immobilization. This process has been effective in improving the biocompatibility of implanted sapphire wafers. Although these surface modification techniques enhanced the *in vitro* biocompatibility of silicon, the *in vivo* biocompatibility was only negligibly enhanced or not enhanced at all. Figure 1 shows the GFAP scores of silicon with or without surface modification, together with shams and positive controls for comparison. Astrocytic gliosis (i.e., GFAP reaction) was increased in animals implanted with silicon chips with or without surface modification. All the coatings also had no significant effect on the neuron and axon degeneration in the cortex and white matter, except that heparin coated silicon caused a noticeably more severe neuron degeneration in the cortex. The failure of improvement in biocompatibility was attributed to the poor stability of the surface-modified silicon. *In vitro* stability test with saline solution at 37 °C showed that all the coatings are very stable for up to 30 days, however the harsher physiological environment removed most of the coatings within 28 days. All the coatings on silicon surface were gone after 90 days. Figure 2 shows the AFM images of some extracted silicon wafers. Pits due to corrosion were observed on all silicon wafer surface, regardless of the implantation time and type of coating. Therefore, the SAM coatings and heparin/hyaluronan coatings (of only a few nanometers in thickness) failed to protect silicon against corrosion under physiological conditions. If silicon is to be suitable for implantable medical devices, other effective protective and biocompatible coatings must be developed.

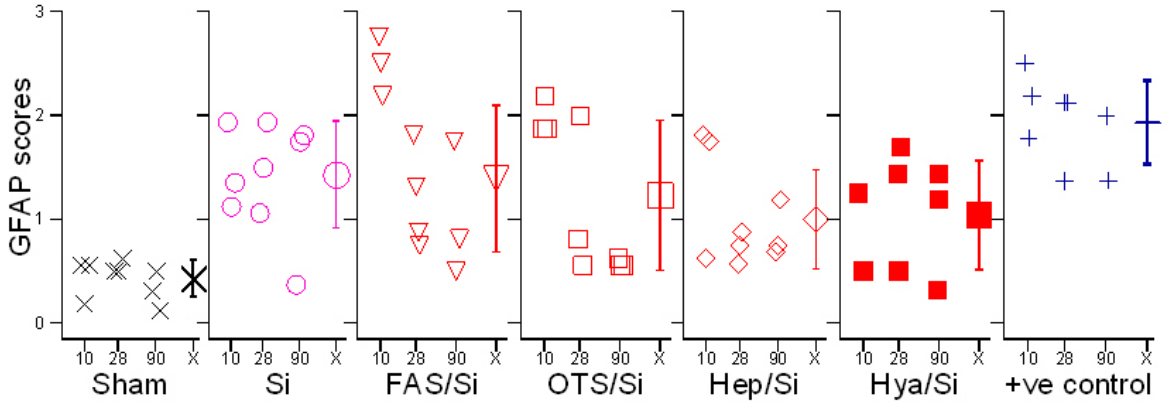

Figure 1. Comparison of astrocytic gliosis (GFAP reaction) in sham-operated animals (Sham), positive control animals and animals implanted with silicon wafers with or without surface coatings. The data is plotted as a function of days implanted (10, 28 and 90 days; individual points are offset to illustrate all points), and as a grand mean (x) with standard deviation (S.D.) of all animals in each group.

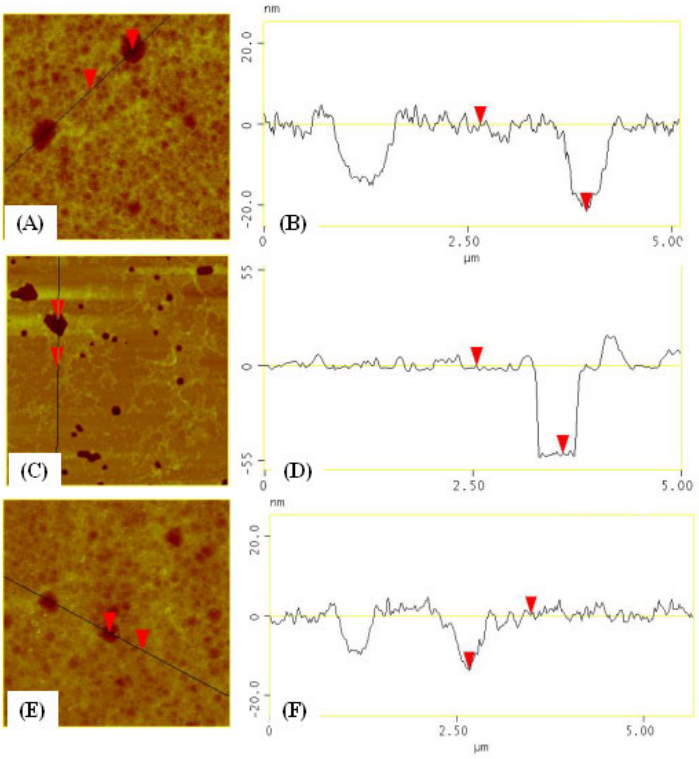

Figure 2. AFM images of representative extracted wafers of (A) silicon (10-day), (C) OTS SAM/Si (10-day) and (E) FAS SAM/Si (28-day). (B), (D) and (F) are the depth profiles along the lines shown in (A), (C) and (E), respectively. The scan area is 5 mm x 5 mm for all images. Pits due to corrosion could be found on all extracted silicon wafer surfaces regardless of the implantation time, which was also seen on the extracted heparin and hyaluronan coated silicon wafer surfaces.