

used as a cerclage and as a local buckling element, and a silicone sponge can be used as a local buckling element.

In enucleated eyes, it was found out that a mild local inflammatory reaction surrounded the material but despite this reaction, they were well tolerated (Vogel 1978). In another study, the tissue reaction around silicone sponge buckle consisted of a thin fibrous capsule after 1 month, but also a foreign body granulomatous inflammatory reaction was seen in 5 cases of 13 patients with silicone sponge and in 3 cases with solid silicone (Wilson & Green 1987). In some specimens, proteinaceous fluid and old blood was also present in the implant cavity (Wilson & Green 1987). In human samples with 6 removed implants, calcium deposits were found in the implant surface after long-term follow-up periods. Five of these patients experienced bacterial infections, but one had pain and calcium deposits even without any signs of infection (Brockhurst *et al.* 1993). In a study on patients intended for reoperations, it was found that the capsule around the silicone sponge or solid silicone consisted of dense fibrous layer with a smooth regular surface with the capsule containing a few vessels, some mononuclear cells and occasional fibroadipose tissue (D'Hermies *et al.* 1998). In another study, there was only a capsule layer with no inflammatory cells detected around the silicone implants 18–204 months after implantation (D'Hermies *et al.* 1999a).

With silicone and silicone sponge, all of the above mentioned common long-term complications of permanent implants (i.e. infections, scleral thinning under implant, extrusion through the tissues (conjunctiva and/or eyelid), intrusion to the vitreous cavity, diplopia, persisting pain, increase in ocular pressure, disturbance of ocular blood circulation and necrosis of ocular tissues) are possible. In fact, in studies concerning early and late complications requiring reoperations, most patients have been implanted with solid silicone or silicone sponge materials (Deutch *et al.* 1992, Kreissig *et al.* 1992, Foster & Meyers 2002, Deokule *et al.* 2003).

Hydrogels

Hydrogels are semisolid hydrophilic materials with the ability to absorb water. Three types of hydrogels have been tested, polyglyceryl methacrylate (PGMA), poly(2-hydroxyethyl acrylate) (PHEA), co-poly(methylacrylate-2-hydroxyethyl acrylate) (MAI) but only MAI has been commercially available (Refojo *et al.* 1980, Tolentino *et al.* 1981, Shepens *et al.* 1991). An MAI implant has been used

both episclerally and intrasclerally (Tolentino *et al.* 1981). It was in clinical use for several years but was abandoned due to long-term complications (Shepens *et al.* 1991, Marin *et al.* 1992, Hwang & Lim 1997, Roldán-Pallarés *et al.* 1999). The swelling of hydrogels has been reported to occur to a remarkable degree in a relative volume, i.e. one study reported that the cross-sectional area of hydrogel implants had increased on average by 185% in a group of 28 patients (Oshitari *et al.* 2003). The reasons for implant removal were sensation of foreign body, subconjunctival bulge, ocular motility problems and pain (Oshitari *et al.* 2003, Le Rouic *et al.* 2003). A histological follow-up from 3 weeks to 3 months in rabbits noted that the material was surrounded by a capsule of connective tissue. In three weeks there was a mild inflammatory reaction but in 3 months there were almost no inflammatory cells (Refojo *et al.* 1980). Later in experimental studies in rabbits with a longer follow-up it was found that the material became surrounded by a capsule of connective tissue, but the inner surface of the capsule contained deposits of material (indicating material fragmentation) surrounded by foreign body giant cells (D'Hermies *et al.* 1995, D'Hermies *et al.* 1999b). Findings of irregular inner surface of capsule and foreign body giant cell granulomas have also been found in human samples (D'Hermies *et al.* 1998, D'Hermies *et al.* 1999a).

e-PTFE and silicone band coated with e-PTFE

Expanded polytetrafluoroethylene (e-PTFE, also known as Gore-Tex™) has been studied with various pore sizes (Lobes *et al.* 1981, Tawakol *et al.* 1989, Korobelnik *et al.* 1999, Korobelnik *et al.* 2000, Sheu *et al.* 2001). In an evaluation of enroled thin layer of porous e-PTFE, it was found out that there was colonisation of material with fibrocellular tissues and adhesions to surrounding conjunctival tissue (Lobes *et al.* 1981, Tawakol *et al.* 1989, Korobelnik *et al.* 1999, Sheu *et al.* 2001). This kind of colonisation by fibrovascular tissue may be good for preventing migration or exposure, but may also represent an extra challenge if removal is required. In these studies, the tissue reaction was rated to be minimal or only a mild inflammatory reaction. The material was described in most studies as being well tolerated or to display good biocompatibility, except for the study of Sheu *et al.*, who discovered massive adhesions (Lobes *et al.* 1981, Tawakol *et al.* 1989, Korobelnik *et al.* 1999, Sheu *et al.* 2001).

Three weeks after insertion of an implant made of a silicone band, coated with e-PTFE (S/e-PTFE), massive adhesions from material to the surrounding