

Oral presentation

23 hydrocephalus valves tested over 367–514 days

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Background

Hydrocephalus valves are potentially life-long implants. In spite of this fact a minority only of the 1400 published in vitro tests had a duration of more than 3 months, maximally 1 year. In addition, in literature tests of susceptibility on external pressures and valve body deformation, elevated CSF protein, simulated gas-sterilizations, pumping volumes and pressures, temperature variations, reflux, syphoning, in adjustable valves the reaction on electromagnetic fields, decentration during adjustment, possibility of emergent adjustment without special apparatus are sporadically available only.

Materials and methods

22 new valves (10 designs, 6 manufacturers) and one specimen explanted after 34 years revision-free function were tested non-stop over 367–513 days with a test-battery of maximum 20 subtests for the open-minded criteria.

Results

15/23 showed mean deviations of >20%, max. 240% related to the specifications. Only 10 have been drift free over the complete period. 17 over-, 2 underdrained; 2 worked physiologically. All specimens were reflux-resistant, all except 5 temperature-stable. 10 showed deviations (max. 53%) by flexion. External diffuse pressure produced variations of 13–82%, directed pressure max. -37%. 18/23 changed their properties after 50× pumping up to 34%. After gas sterilization with 65°C (1 h) 5 specimens only were stable; 5 increased, 8 decreased in resistance; protein let to occlusions of 2 and an increased resistance (max.

52%) of 15 specimens. Medos were adjustable to 21 mm distance; however, a decentration of 2 mm or rotation of 5 degrees can lead to failures. Catheters ruptured between 1.2–4.1 kg.

Conclusion

In spite of the fact that 6/10 valves were designed in the last decade, multiple significant safety or accuracy failures were documented.