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The Adjustable proGAV Shunt: A Prospective Safety and Reliability Multicenter Study

OBJECTIVE: To evaluate the reliability of the gravitation-assisted adjustable proGAV shunt system with a prospective multicenter study conducted in 10 German hospitals.

METHODS: Enrollment for this observational study began in April 2005 and concluded in February 2006. The protocol required re-examinations 3 and 6 months postoperatively and fixed the endpoint of follow-up at 12 months after implantation. Patients with different types of adult, juvenile, and pediatric hydrocephalus were included and 165 patients were enrolled; 9 died and 12 had incomplete follow-up.

RESULTS: Of the assessable 144 patients, 130 completed the protocol after 12 months, whereas 14 failed because of the need to explant the device, mainly because of infection. In 12 patients, components of the shunt, not the valve, were revised. In 65 of the 144 patients, there were 102 readjustments of the valve in 67 incidences because of under-drainage and in 35 because of overdrainage. In 1 case, readjustment was not possible. Determination of pressure level with the verification instrument was safe and corresponded to the required x-ray controls after adjustments. No unintended readjustments were noted.

CONCLUSION: The proGAV is a safe and reliable device.

KEY WORDS: Adjustable valve, Hydrocephalus, Shunt

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