



TubaVent[®]

The first causative therapy for tube dysfunction



TubaVent®

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SPIGGLE & THEIS Medizintechnik



New therapy concept in the treatment of chronic tube ventilation disorders

Obstructive tube dysfunction is, a common chronic disorder, in which the usual ventilation and the cleaning capability of the middle ear is restricted. Among other things, the consequences of this disorder is the development of chronic otitis media, that in the worst case can result in destruction of the middle ear (structures) and thus in hearing loss.

Prevalence of obstructive tube dysfunction is approximately 1% of the adult population¹. TubaVent®, the first causative therapy concept for the treatment of any obstructive dysfunction of the tuba Eustachii (Eustachian tube) was developed in 2009.



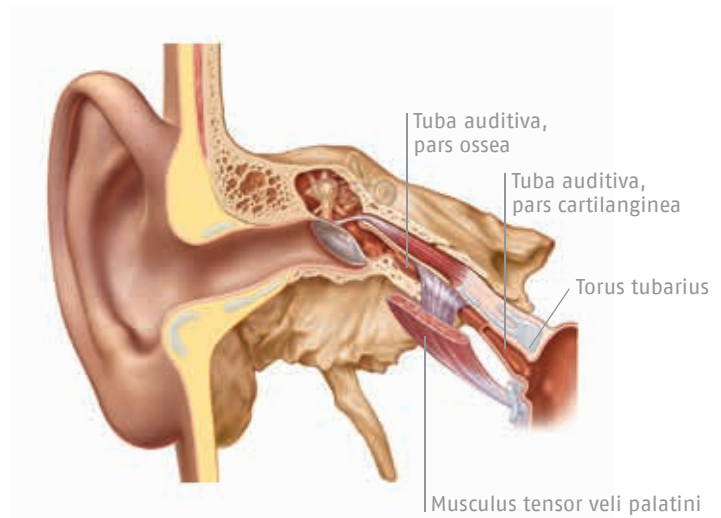
"The use of microscopic and endoscopic technologies has revolutionised medicine and is state of the art today. With the development of balloon catheters, for example for the dilatation of heart coronaries, previously inconceivable revolutionary treatment concepts emerged. The transfer of this technology to the dilatation of the auditory tube provides the possibility for the first time to treat the cause of many chronic middle ear infections. Particularly for chronic tube dysfunctions or middle ear pathologies, there is now the opportunity to therapeutically approach the black box of otolaryngology. The new treatment concept provides the possibility for the first time to successfully treat chronic tube dysfunction and to provide our patients with a new treatment possibility for this previously untreatable condition."

Prof. Dr. med. Holger Sudhoff,
FRCS (Lon), FRCPath
Senior consultant of the Klinikum
Bielefeld (Ear, nose and throat,
head and neck surgery clinic, Bie-
lefeld medical centre)

1) Browning G, et al. The prevalence of middle ear disease in the adult British population. Clin Otolaryngol Allied Sci. 1992 Aug; 17(4):317-21

Anatomy of the tuba auditiva (auditory tube)

- Total length: 31– 38 mm
- Cartilaginous part: 20–25 mm



Cause of tube ventilation disorders

- Chronic recurring infections
- Allergies
- Laryngopharyngeal reflux
- Inflammatory disorder of the mucosa
- Anatomically caused obstruction
- Adenoid vegetations, e.g. "polyps"
- Glue tube

Possible consequences of not treating tube ventilation disorders

- Otitis media chronica
- Possible destruction in middle ear
- Hearing loss
- Cholesteatoma



Pre-operative diagnostics

- Thorough medical history examination
- Valsalva
- Inspection and endoscopy of the nasopharynx
- CT/DVT of the petrous bone, if necessary
- Tympanometry
- Audiometry
- Tubomanometry, according to Estève

Pre-operative preparation / equipment

- Nose drops
- Endoscopic work, using a monitor with a camera and documentation system
- Optics, with xenon light source (0°, 30°, 45°, 70°)
- Rinsing and sterilisation basket for combination insertion instrument
- Combination insertion instrument
- Extensions (30°, 45°, 70°) or tapered extensions (30°, 45°, 70°)
- Inflation pump with extension tube
- *TubaVent*® – balloon catheter (Bielefeld balloon catheter)
- Water bowl
- Nasal speculum
- Extractor
- Bayonet forceps
- Mouth gag, if necessary, for pharyngeal access
- Catheter, if necessary, for velotraction for pharyngeal access



Instrument preparation

- Screw the relevant extension (30°, 45° or 70°) onto the combination insertion instrument
- Fill (aspiration) the inflation pump with physiological saline solution
- Lock the inflation pump
- Remove protection tube, stabilisation wire and distal protective cap of the *TubaVent*® balloon catheter
- Completely insert the catheter into the combination insertion instrument
- Connect the inflation pump (pre- or intra- operative) to the *TubaVent*® balloon catheter

Paths of access

Contralateral access

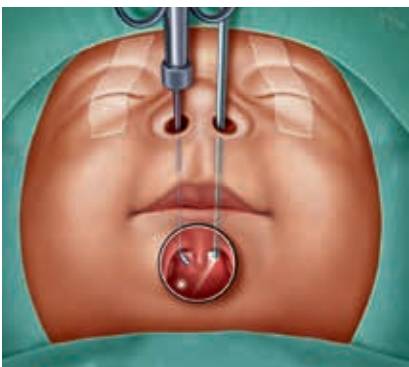
- Insert Hopkins optic on the contralateral side, a 70° for example
- Localise the tubal ostium
- Insert the *TubaVent*® balloon catheter, with the combination insertion instrument and place at the tubal ostium
 - Cave:** Avoid penetrating the Rosenmüller recess (recessus pharyngeus); this is in the direct vicinity of the tubal ostium
 - Cave:** Do not insert the distal instrument too far into the ostium, in order to prevent any dilatation of the boney part.
- Advance the catheter without resistance
- Connect the inflation pump
- Inflate the balloon to 10 bar
- Maintain pressure for 2 minutes
- Release pump lock and evacuate balloon
- Carefully remove the deflated catheter with the combination insertion instrument

Ipsilateral access

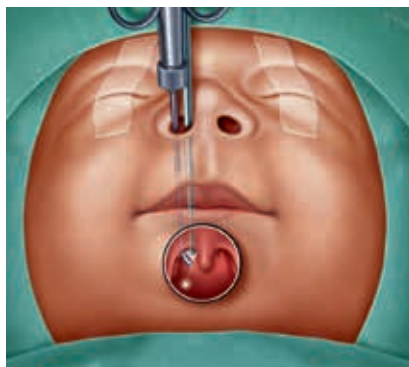
- Insert Hopkins optic, a 30° for example
- Carefully insert the *TubaVent*® balloon catheter with the combination insertion instrument, parallel to the optic, through the same nostril
- The further procedure is as for contralateral access
- This method may not be possible in narrow anatomical conditions

Pharyngeal access

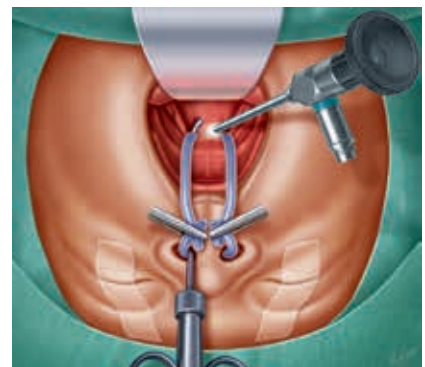
- Insert Hopkins optic, a 70° for example, through the oral cavity; both tube openings are clearly visible
- The further procedure is as for contralateral access
- Advantageous for difficult anatomical conditions



Contralateral access



Ipsilateral access



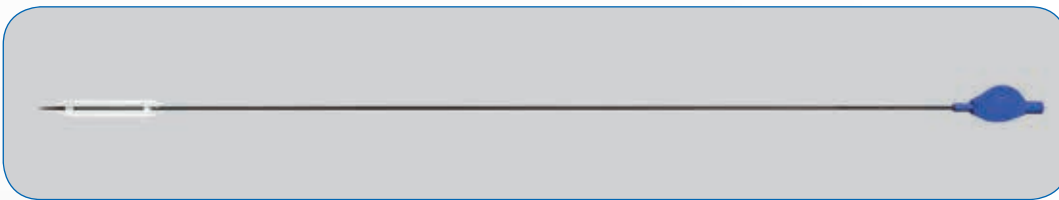
Pharyngeal access



TubaVent® balloon catheter

- Optimum length guarantees the complete dilatation of the cartilaginous part
- Controlled dilatation to 3.28 cm Ø prevents extending of the tube
- A rounded catheter tip and the special catheter surface (shaft & balloon) allow atraumatic advance of the catheter

Balloon catheter



2080-1300320



TubaVent® combination insertion instrument

- Defined advance prevents penetrating into the bony part of the Eustachian Tube



Extensions, tapered

- For insertion of the catheter to the Tuba Eustachii (Eustachian tube)
- Three distal, angled **tapered** extensions: 30°, 45°, 70°



80-806-91

Extensions

- For insertion of the catheter to the Tuba Eustachii (Eustachian tube)
- Three distal, angled extensions: 30°, 45°, 70°



80-806-90



Rinsing and sterilisation basket for combination insertion instrument

- For combination insertion instrument and extensions
- With cover, retaining strap and silicone strips
- Rinsing module for cleaning the inner lumen
- Material: Stainless steel
- Dimensions: 24.4 cm x 24.4 cm

80-850-10



Inflation pump

- Inflation pump with extension tube for inflating balloon catheters
- Single-use
- 20 ml syringe with detachable plunger using command switch, twist grip, pressure gauge and high-pressure connection using Luer Lock rotary adapter
- Division from 0 to 30 atm, PSI scale
- Includes 100 cm - extension tube

2080-9030020



Selected publications

Ockermann, Th. et al., *The Laryngoscope* 2010

Clinical study with 8 patients, 13 tubes

Pre-operative examination: clinical examination, among other matters tubomanometry according to Estève (TMM) assessment of the post-operative tube function: TMM, Valsalva, tube function score according to Prof. Sudhoff, subjective assessment of the patient

Post-operative check after 1 and 2 and 8 weeks

Result: Subjective reduction of the complaints and measurable improvement of the tube function for all 8 patients

Schröder, S. et al., *HNO* 2012

Documentation of 120 patients, 209 tubes

Period: February 2009 to August 2011

Pre-operative examination: clinical examination, audiometry, tympanometry, TMM, computer tomography (CT) of the petrous bones

Assessment of the pre- and post-operative tube function: TMM, Valsalva manoeuvre, tube function score according to Prof. Sudhoff, subjective assessment of the patient

Post-operative checks after 2 weeks, 2 months and 12 months

Result: Subjective reduction of the complaints and measurable improvement of the tube function for approximately 80% of the patients after 2 months

Tisch, M. et al., *HNO* 2013

Documentation of 120 patients, 209 tubes

Period: October 2010 to February 2013

Pre-operative examination: clinical examination

Assessment of the pre and post-operative tube function: Valsalva manoeuvre, Toynbee test, tympanogram, ear microscopy, subjective assessment of the patient

Result: post-operative Valsalva positive with 70.4% in comparison with pre-operative only 7.2% of the patients; subjective reduction of the complaint up to complete absence of the complaint for 71.4% of the patients

Schröder, S. et al., *Clinical Otolaryngology* 2015

Documentation of 622 patients, 1076 tubes

Period: February 2009 to February 2014

Pre-operative examination: clinical examination, audiometry, tympanometry, Valsalva manoeuvre, Toynbee test, TMM, ETDQ score, ETS score

Post-surgery ETS score measurement after 1,2,3,4 and 5 years

Result: 1 year after treatment, the ETS score improved from 3.13 (± 2.47) to 5.75 (± 2.75).

After two years, the ETS score improved for 82% of the patients from 2.65 (± 2.89) to 6.26 (± 3.07).

The ETS score significantly improved after 5 years.

Subjective patient satisfaction is approximately 80%.





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