Causative therapy for tube dysfunction
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 population. \textit{TubaVent®}, the first causative therapy concept for the treatment of any obstructive dysfunction of the tuba Eustachii (Eustachian tube) was developed in 2009.

\begin{quote}
\textit{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.}\\
\end{quote}

Anatomy of the Tuba Eustachii

- Total length: ca. 31–38 mm
- Diameter: between ca. 2,9 und 3,5 mm
- Cartilaginous part: 20–25 mm

Consequences of not treating tube ventilation disorders

- Otitis media chronica
- Possible destruction in middle ear
- Hearing loss
**TubaVent®** – Balloon catheter for the Tuba Eustachii

- Optimum length guarantees the complete dilatation of the cartilaginous part
- Controlled dilatation to 3.28 mm Ø prevents overexpanding of the tube
- A rounded catheter tip and the special catheter surface (shaft & balloon) allow atraumatic advance of the catheter
**TubaVent® combined insertion instrument**

- Defined advance prevents penetrating into the bony part of the Tuba Eustachii

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**Attachments, tapered**

- For insertion of the catheter to the Tuba Eustachii
- Three distal angled tapered attachments: 30°, 45°, 70°

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**80–806–90 – Set inclusive combined insertion instrument**

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**80–806–91 – Set inclusive combined insertion instrument**
System Screen Basket for combined insertion instrument
- For combined insertion instrument and attachments
- 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
Paths of access

Contralateral access

- Insert Hopkins optic on the contralateral side, a 70° for example
- Localise the tubal ostium
- Insert the TubaVent® with the combined insertion instrument and place at the tubal ostium
  - Avoid penetrating the Rosenmüller recess (recessus pharyngeus); this is in the direct vicinity of the tubal ostium
  - Do not insert the distal instrument too far into the ostium, in order to prevent any dilatation of the bony 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 combined insertion instrument

Ipsilateral access

- Insert Hopkins optic, a 30° for example
- Carefully insert the TubaVent® with the combined insertion instrument, parallel to the optic, through the same nostril
- 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 combined insertion instrument
- 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
- 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 combined insertion instrument
- Advantageous for difficult anatomical conditions
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°)
- System Screen Basket for combination insertion instrument and attachments
- Combined insertion instrument
- Attachments (30°, 45°, 70°) or tapered attachments (30°, 45°, 70°)
- Inflation pump with extension tube
- TubaVent®
- Water bowl
- Nasal speculum
- Frazier suction tube
- Bayonet forceps
- ENT-Patties
- Mouth gag, if necessary, for pharyngeal access
- Catheter, if necessary, for velotraction for pharyngeal access

Instrument preparation

- Screw the relevant attachment (30°, 45° or 70°) onto the combined 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®
- Completely insert the catheter into the combined insertion instrument
- Connect the inflation pump (pre- or intra-operative) to the TubaVent®
Selected publications

M. Tisch, H. Maier, H. Sudhoff, ACTA Otorhinolaryngologica Italica 2017
Clinical experience in the management of children.
Treatment of Eustachian tube dysfunction.

Subjects: 126 children, range 28 months to 13 years.
Preoperative Examination: Clinical Examination, Tympanometry
For the first time worldwide, this procedure was assessed in regard to the treatment of children
with Eustachian tube dysfunction, who had previously not responded to other treatments.
No intra- or postoperative complications.

Result: clinical symptoms improved in more than 80% of patients. No patient reported a deterioration.
81.3% of the participating parents were either very satisfied or satisfied with the outcome of the treatment.

Williams, B. et al., Balloon dilation of the eustachian tube: a tympanometric outcomes analysis;

Documentation of 18 patients, 25 tubes
Period: February 2010 to February 2014
Pre-operative examination: Tympanometry
Post-operative checks after: 2-3, 6-9, 12-15 months

Result: Overall 36 % of ears had improvement in tympanogram type, and 32 % had normalization of tympanogram post–ope-
ratevily. The Jerger tympanogram type improved significantly following the procedure (p = 0.04). Patients also had statistically
significant improvement in measured middle ear pressure post–operatively (P = 0.003). Eustachian tube balloon dilation is a safe
procedure, and produces significant improvement in tympanogram values up to 15 months post–operatively.

Xiong, H. et al., Efficacy of balloon dilation in the treatment of symptomatic Eustachian tube dysfunction:
One year follow-up study; American Journal of Otolaryngology 2016

Documentation of 40 patients, 58 tubes
Period: April 2013 to November 2014
Pre-operative examination: clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS
Post-operative checks after: 1 week, 3 and 12 months

Result: A significant effect of treatment was documented when measuring subjective improvement, impedance audiometry, R-value
in TMM, ETS and the ability to perform a Valsalva maneuver 1 week, 3 months and 12 month postoperatively. Subjective symptoms
were not relieved only in one patient. The overall success rate for all patients was 98%.

Schröder, S. et al., Balloon Eustachian tuboplasty: a retrospective cohort study;
Clinical Otolaryngology 2015

Documentation of 622 patients, 1076 tubes
Period: February 2009 to February 2014
Pre-operative examination: clinical examination, audiometry, tympanometry, Valsalva, Toynbee test, TMM, ETDQ score, ETS
Post-operative checks after: 1 year, 2, 3, 4 and 5 years

Result: One year after treatment, the Eustachian Tube Score (ETS) improved from 3.13 (±2.47) to 5.75 (±2.75). After two years, the
ETS improved for 82% of the patients from 2.65 (±2.89) to 6.26 (±3.07). The ETS significantly improved after 5 years. Subjective
patient satisfaction is approximately 80%. 
Dalchow, C. et al., First results of Endonasal dilatation of the Eustachian tube (EET) in patients with chronic obstructive tube dysfunction; Eur Arch Otorhinolaryngol 2015

Documentation of 217 patients, 342 tubes
Period: September 2010 to April 2013
Pre-operative examination: ear microscopy, clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS
Post-operative checks after: 1 month, 3, 6, 9, 12 months

Result: The Eustachian tube score (ETS) improved after EET from 2.23 (±1.147 SD) preoperatively to 2.68 (±1.011 SD) 12 months after surgery. No complications had been observed. EET was technically easy to perform without any intraoperative difficulties. EET presented itself as a safe and successful procedure. In particular, patients after tympanoplasty showed lower score levels and benefited from tube dilatation shown by higher post-treatment tube scores.

Bast, F. et al., Balloon Dilatation of the Eustachian Tube: Postoperative Validation of Patient Satisfaction; ORL 2014

Documentation of 30 patients, tubes not specified
Period: September 2011 to September 2012
Pre-operative examination: clinical examination, audiometry, tympanometry, CT, Glasgow Benefit Inventory (GBI)
Post-operative checks after: 1 week, 3 months

Result: An analysis of the GBI results shows a significant improvement in the total score and the subscores ‘general health’ and ‘physical health’ following balloon dilatation. This provides evidence that balloon dilatation, with its significant improvement in general and physical health, also leads on the whole to a subjectively improved quality of life.

Gürtler, N. et al., Balloon Dilation of the Eustachian Tube: Early Outcome Analysis; Otology & Neurotology 2014

Documentation of 217 patients, tubes not specified
Period: not specified
Pre-operative examination: ear microscopy, clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS
Post-operative checks after: 1 week, 3 months

Result: The Eustachian Tube Score (ETS) including the R-values, tympanogram, and air-bone gap all showed a statistically positive outcome (p = 0.005) after Eustachian tube balloon dilation. Subjective improvement was seen in 76%. Normal R-values were achieved in 57%. Retraction processes of the tympanic membrane improved in 18% of patients. Only one minor bleeding complication occurred.

Tisch, M. et al., Eustachian tube dilatation using the Bielefeld balloon catheter. Clinical Experience with 320 interventions; HNO 2013

Documentation of 120 patients, 209 tubes
Period: October 2010 to February 2013
Pre-operative examination: clinical examination, Valsalva, Toynbee test, tympanogram, ear microscopy, subjective assessment of patient reported outcomes
Post-operative checks after: not specified

Result: Only 7.2% of the patients were able to perform Valsalva preoperatively. Clinical symptoms improved in 70 % of the patients after balloon dilation and none of the patients reported deterioration of symptoms. 71.4% of the patients reported that the ear symptoms improved or fully regressed.