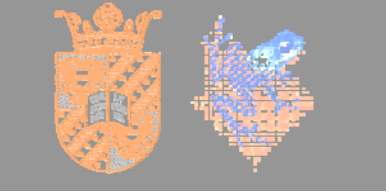

# Development and test of the iValve. A new speech valve approach.


EB (Ward) van der Houwen*

T.A. van Kalkeren, J.G.M. Burgerhof, B.F.A.M. van der Laan and G.J. Verkerke

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*Universitair Medisch Centrum Groningen, Rijksuniversiteit Groningen.*
*A. Deusinglaan 1, 9713AV, Groningen,*
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# University Medical Center Groningen

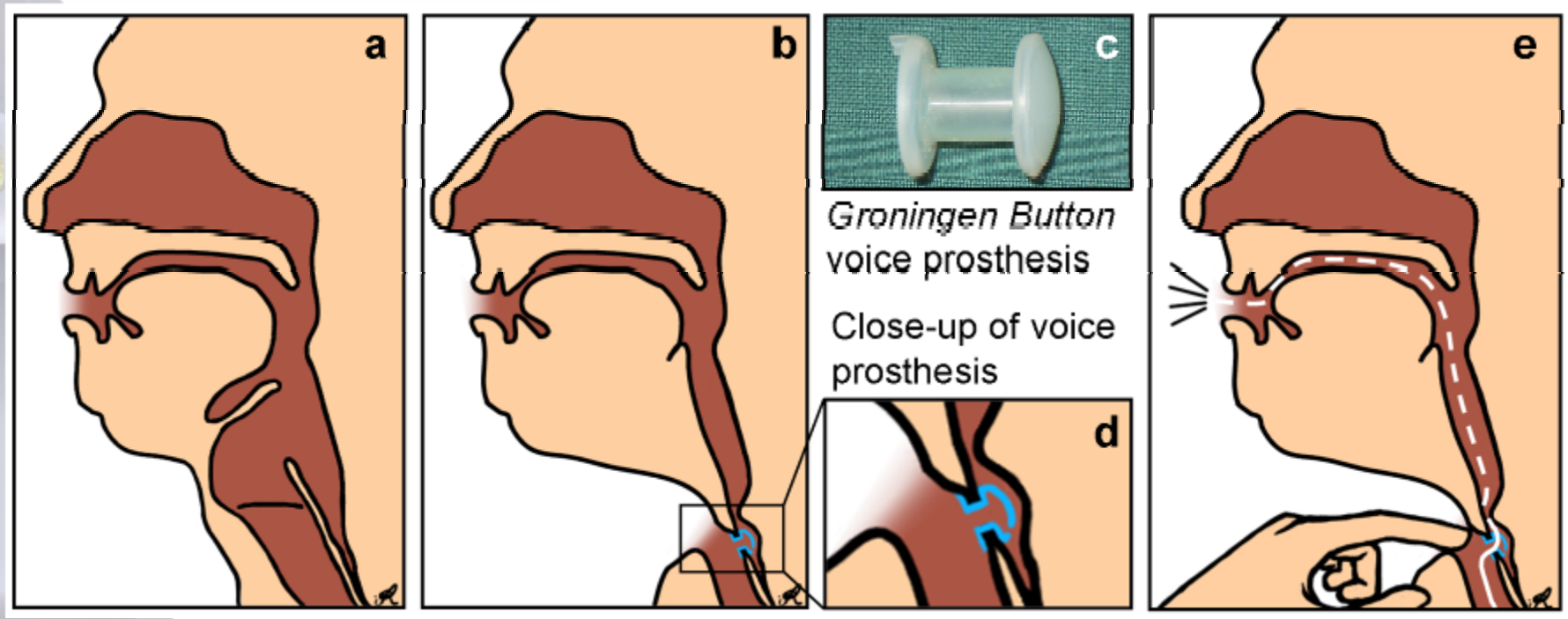

Groningen (GRQ): 187700 inhabitants.
UMCG: 1339 Beds. >10000 employees

# The laryngectomized patient

Removal of the larynx after cancer:
breathing through a stoma.

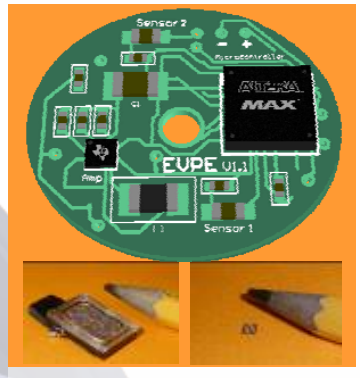
# reroute air through the pharynx for speech

reroute air through the pharynx for speech

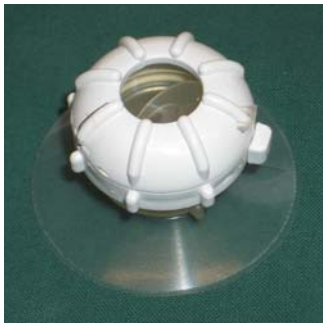


# Speaking laryngectomee

# Speech restoration

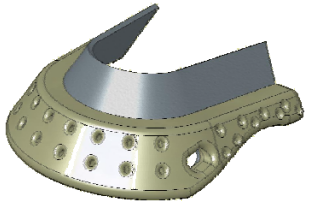



EVPE: EB van der Houwen, BFAM van der Laan, GJ Verkerke



Adeva hands-free valve: AA Geertsema, GJ Verkerke

Groningen Button: Medin/Atos

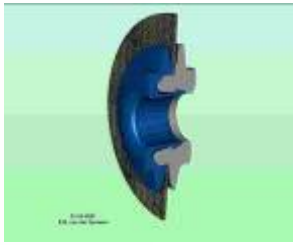


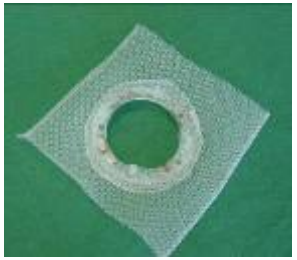
Artificial Hyoid Bone: EB van der Houwen, IF Herrmann, GJ Verkerke

iValve hands free inhalation valve

## Dept of BioMedical Engineering

VPE: JW Tack, EB van der Houwen, GJ Verkerke





Tissue connector: EJO ten Hallers, EB van der Houwen, HAM Marres, GJ Verkerke

iPatch anatomically shaped stoma patch

# Use of patches and valves




Literature

- 78% of patients use stoma patches (Hilgers, 1991)
- 70% of patients use a HME-filter (Bień, 2009)
- 15-25% of Automatic Speech Valve use (Hilgers, 1991, Lorenz, 2007, Op de Coul, 2005)
- All studies show benefits of HME-use

Some clinical observations:

- Patients prefer hands-free speech
- ASV exert considerable stress on stoma patches
- Deepest stoma patches are ±7mm deep
- Most patients' stomas are considerably deeper

# Existing Automatic speech valves

Adeva Window

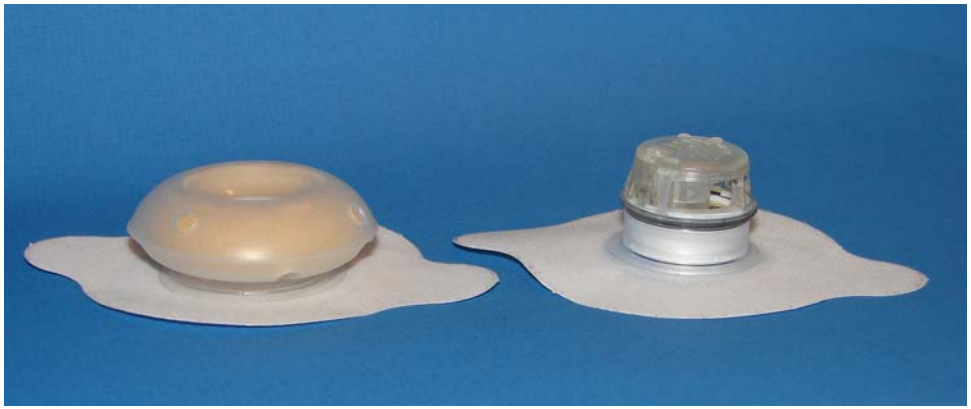
InHealth hands-free valve

Atos FreeHands

Valve characteristics

- All based upon closing on *ex*halation
- Momentary speech mode only
- Patches release because of pressure
- Air lost at closure: short sentences
- Small speech dynamics
- Unnatural speech (no pauses)
- Learning curve

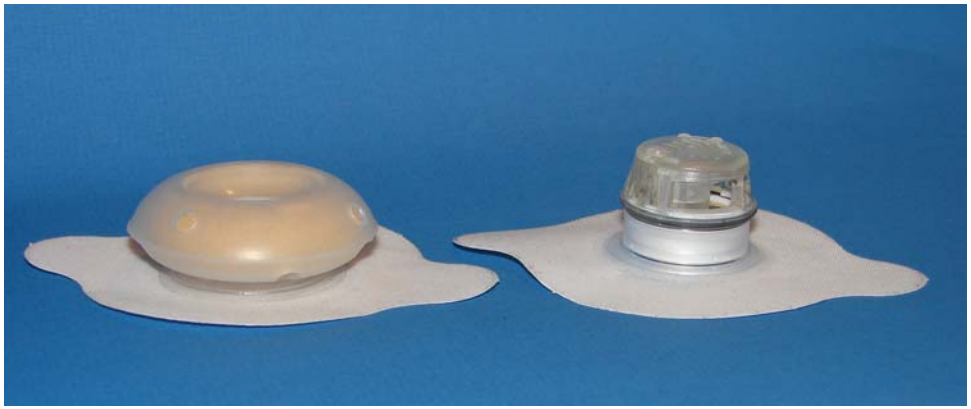
# The iValve Automatic speech valve



Valve characteristics

- Based upon closing on *in*halation
- Toggle switch to speech mode and back
- Lower pressure during speech
- No air lost at closure: long sentences
- Greater speech dynamics
- More natural speech (pauses allowed)
- Shorter learning curve

# The iValve Automatic speech valve



Additional requirements

- Better speech quality
- Less parts than current
- Cheaper to manufacture
- Disposability
- Comfortable to skin
- Comparable size/weight

Valve characteristics

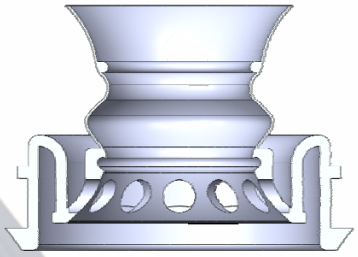
- Based upon closing on *in*halation
- Toggle switch to speech mode and back
- Lower pressure during speech
- No air lost at closure: long sentences
- Greater speech dynamics
- More natural speech (pauses allowed)
- Shorter learning curve

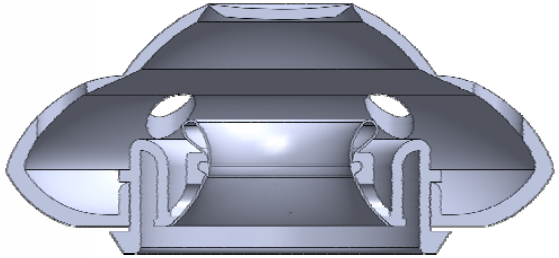
# Speaking with the iValve

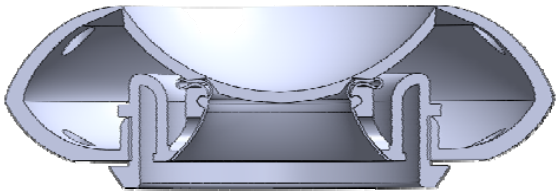
# Overview

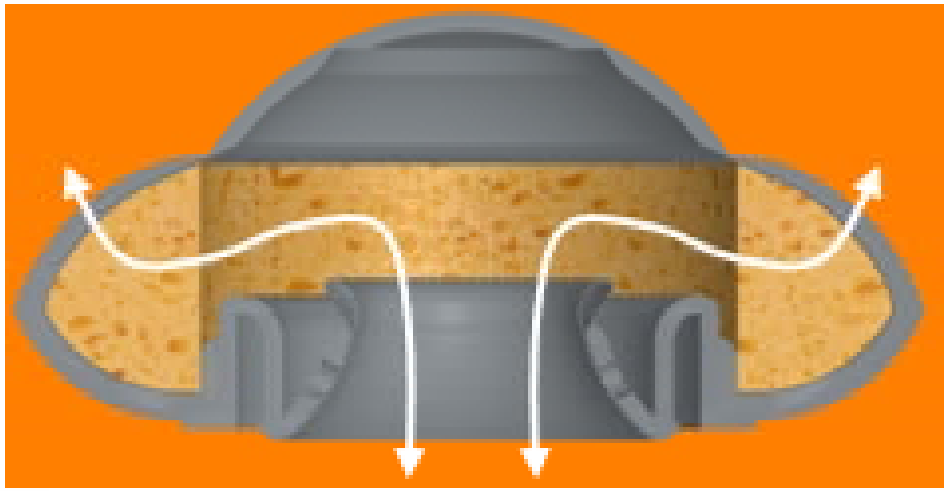
- iValve workings
- *In vitro* validation
- *In vivo* validation
- Conclusions and future development

# the iValve: three parts only



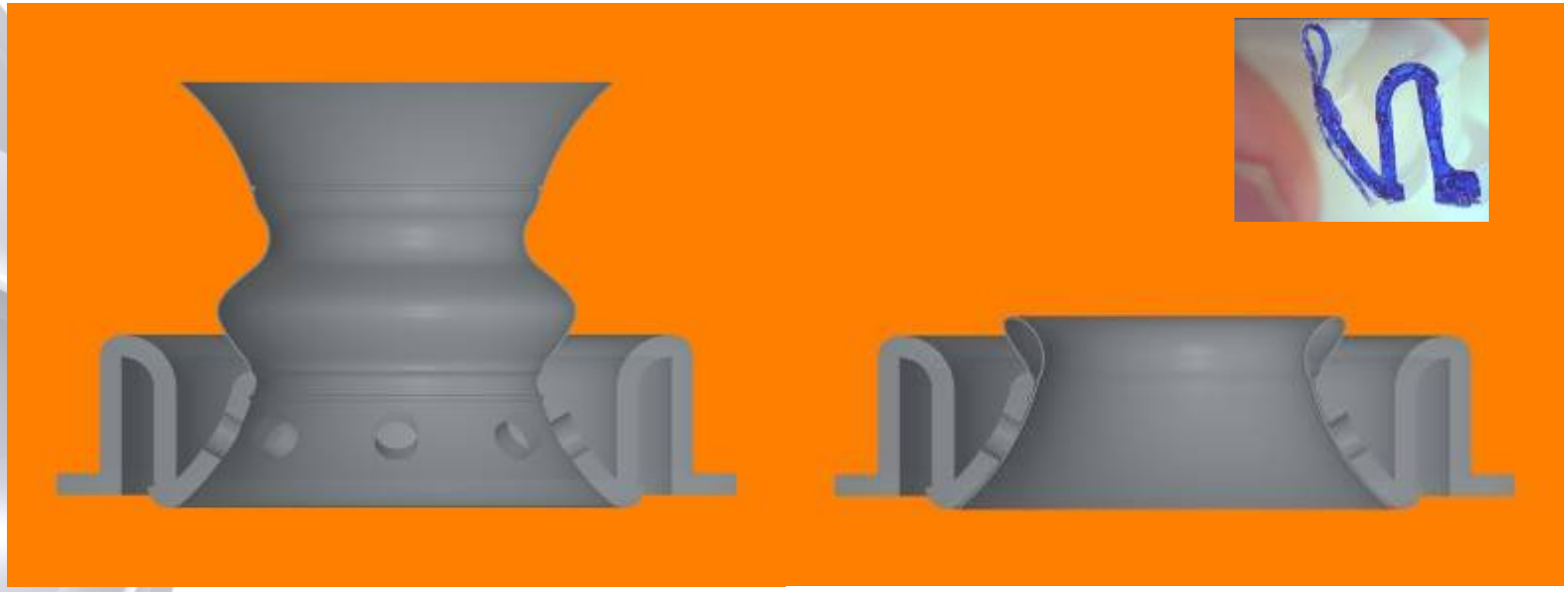






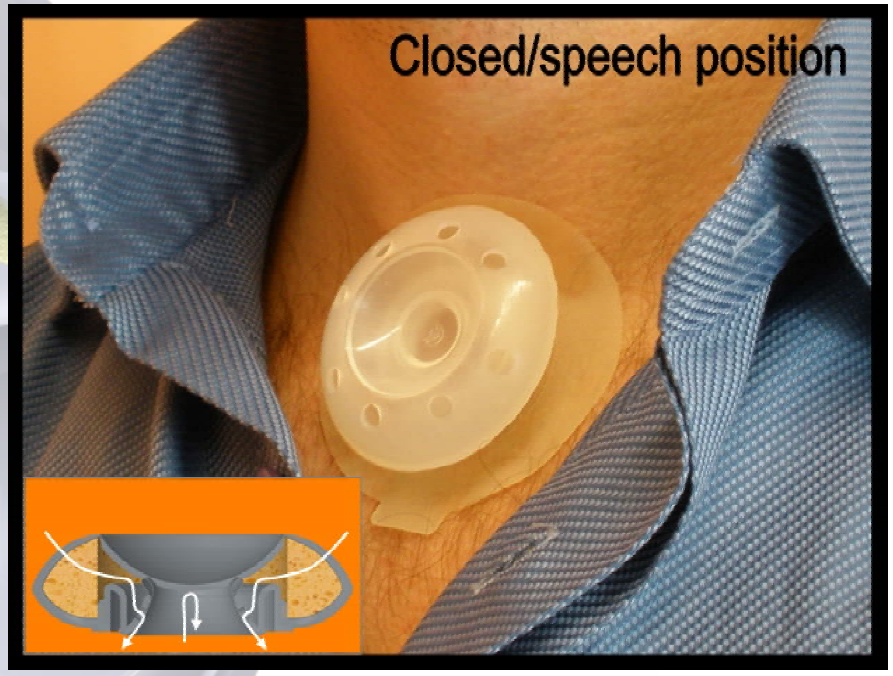
Soft silicone rubber

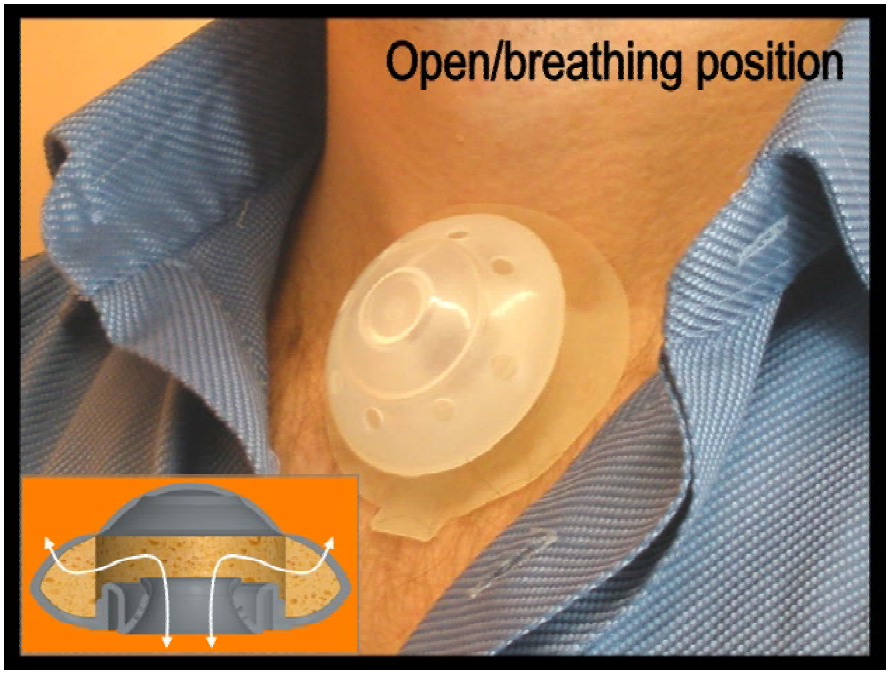
# Moulded inside-out



Unique technology

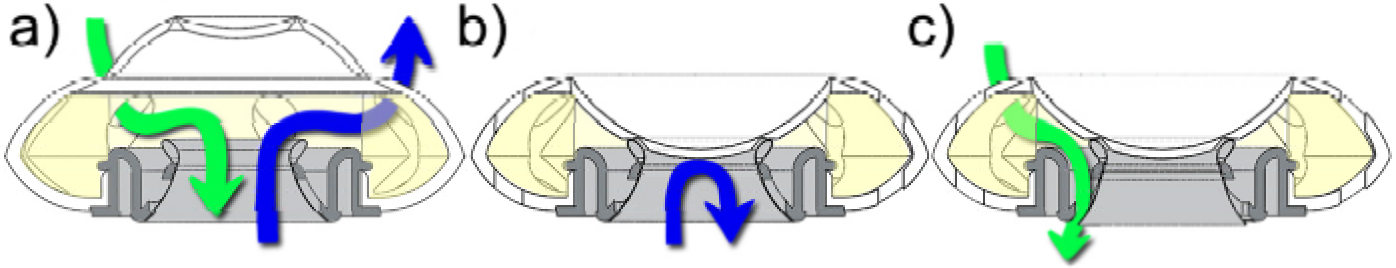
# The iValve



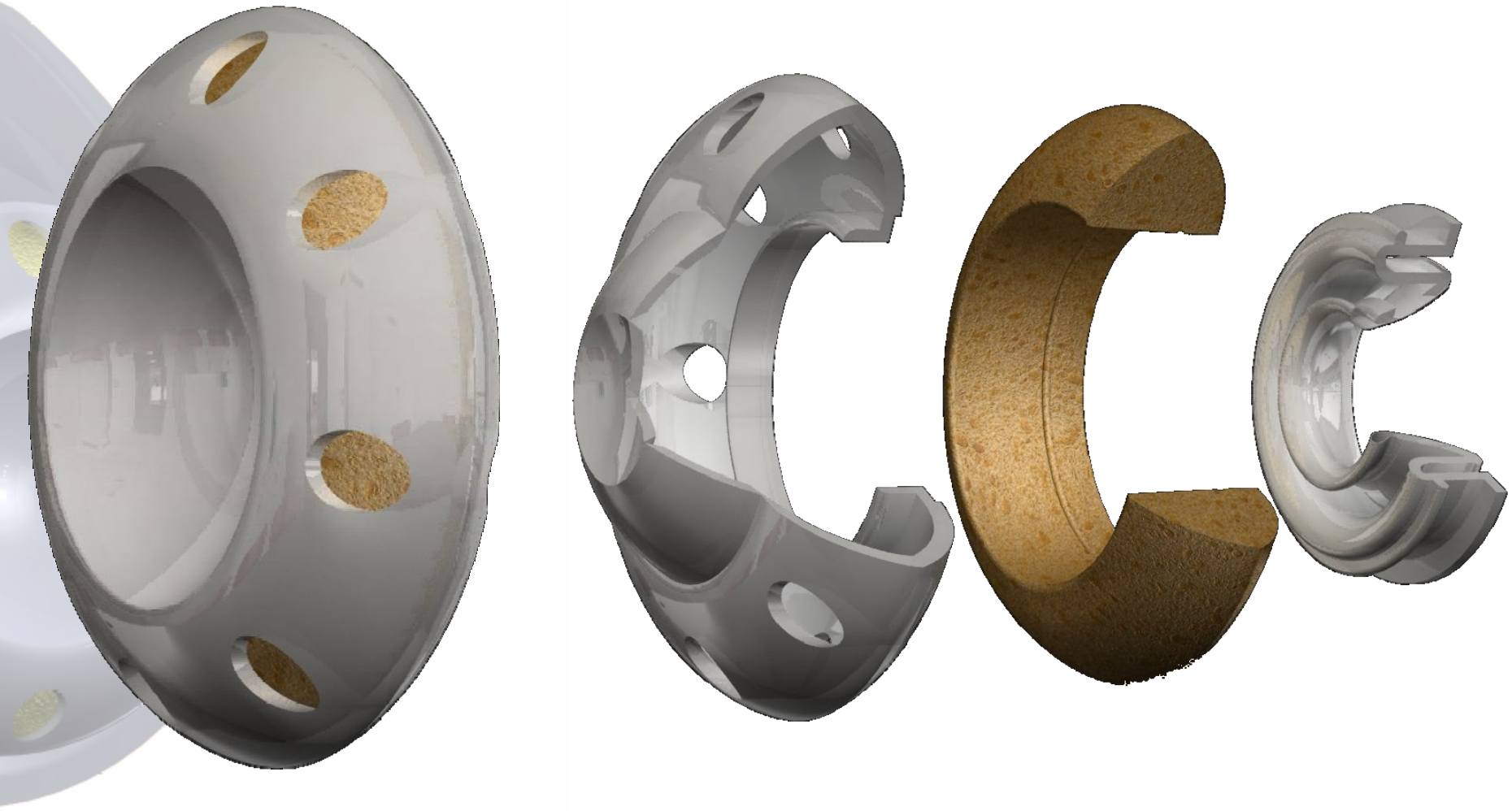
# exhalation vs inhalation

Atos Freehands: “restart” device after each breath

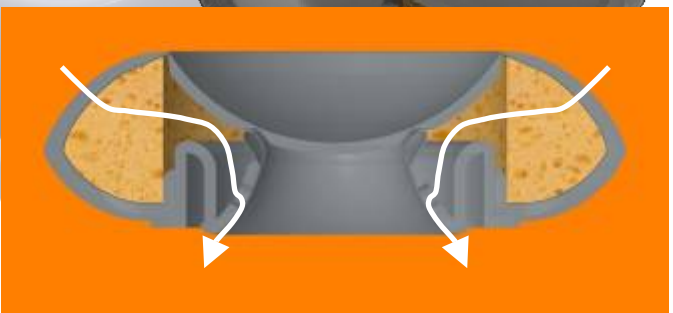


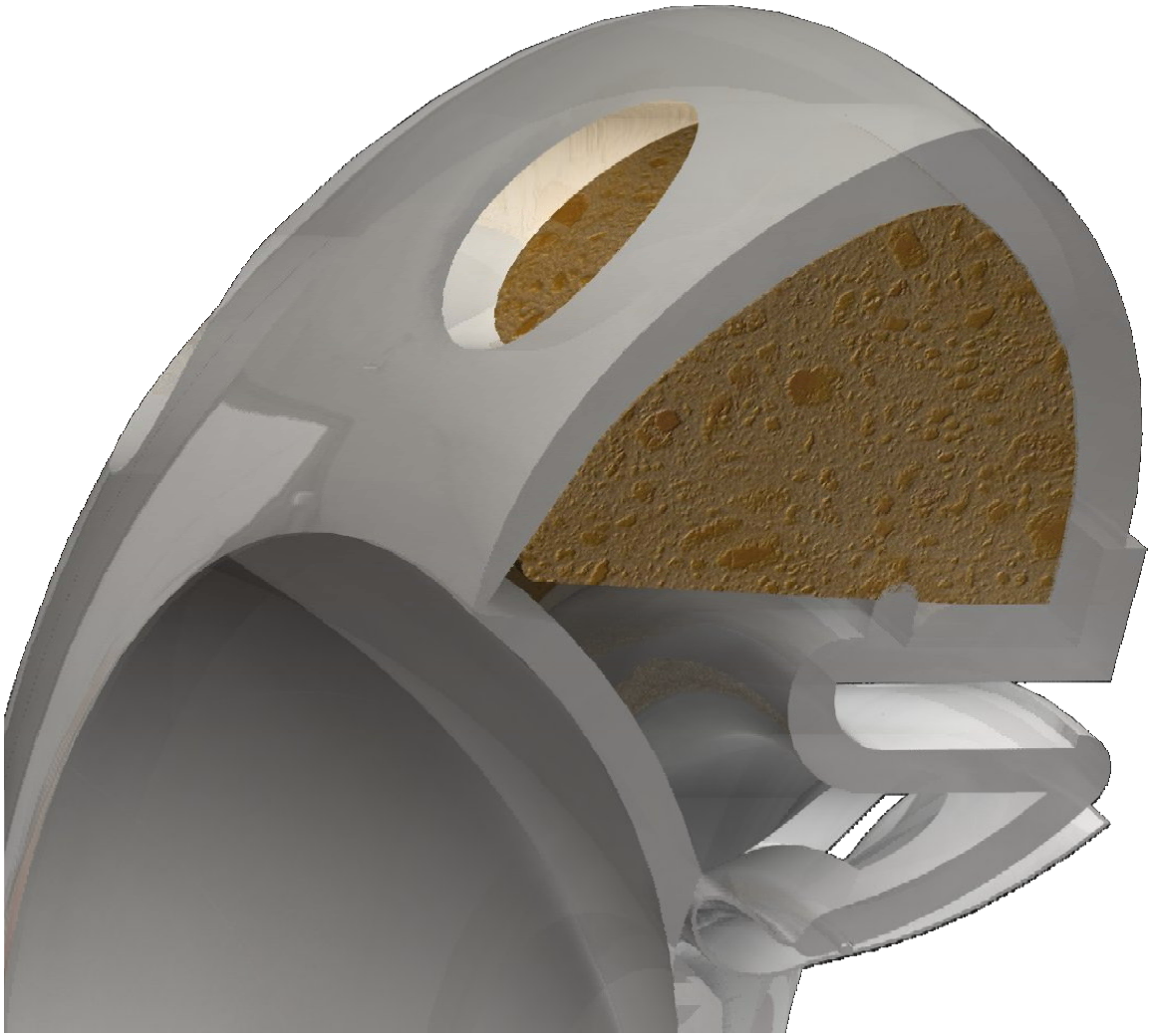

The iValve: inhalation during speech

# the iValve: three parts only

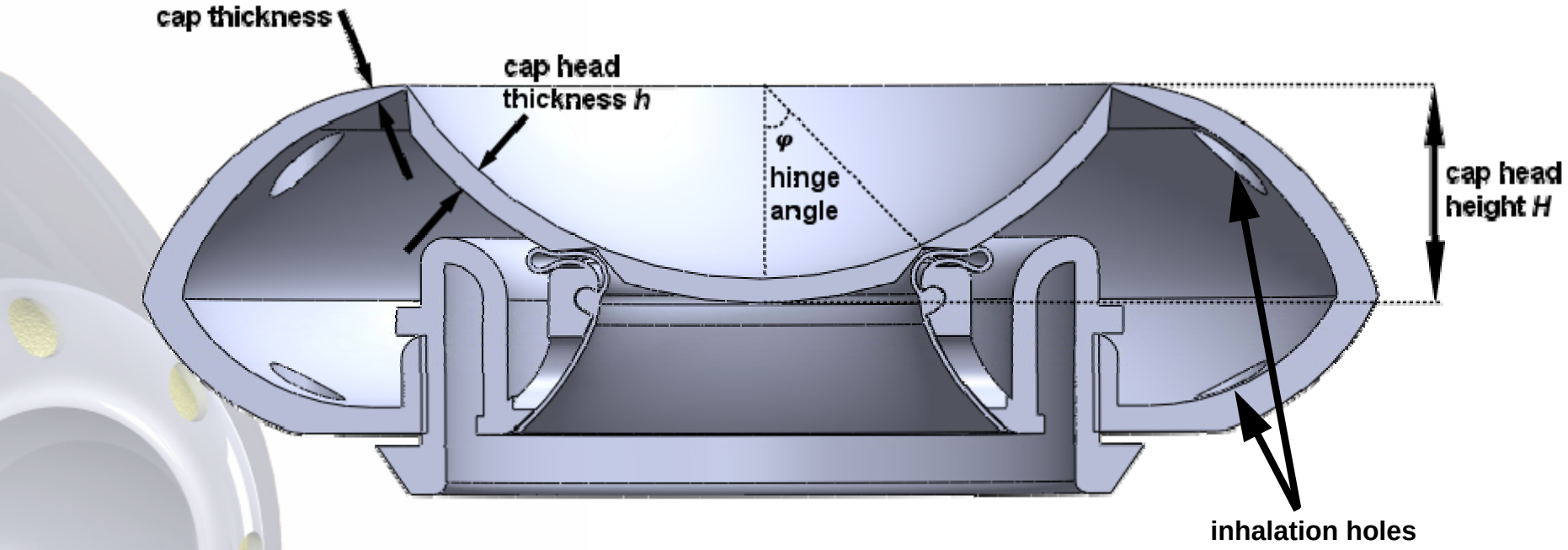


# the iValve: inhaling





# Optimization




Investigate relation between

- closing flow/opening pressure

and

- cap thickness (different versions)
- number of holes (adjustable)

# Overview

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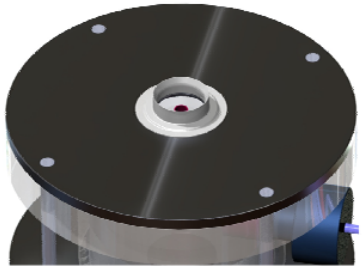
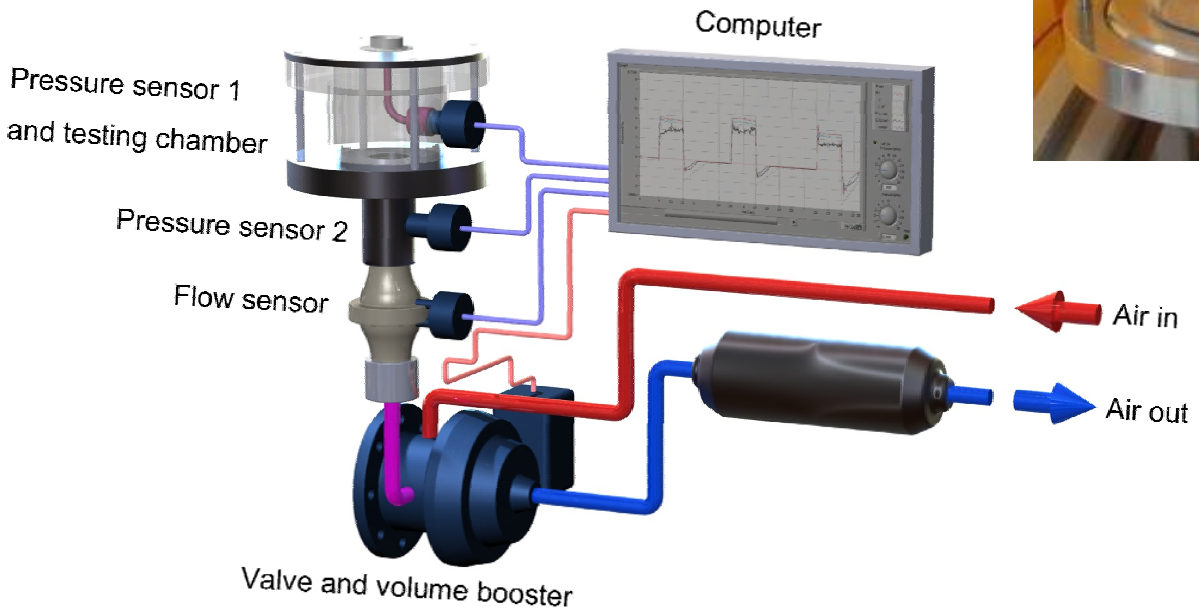
# Optimization: the Pneumatics Simulator

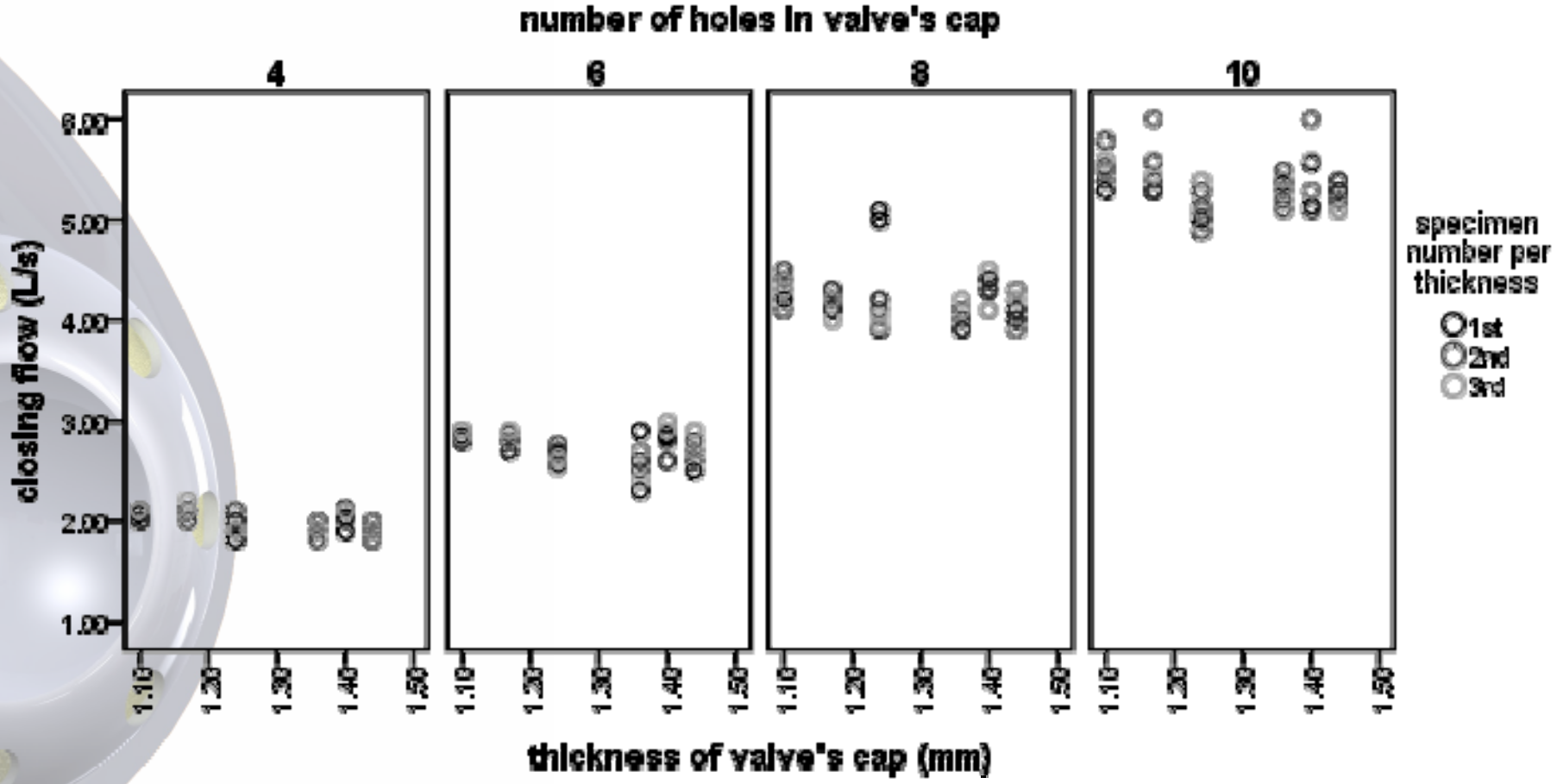


Close up of testing table with Atos connector




simulate exhalation/inhalation in any pattern

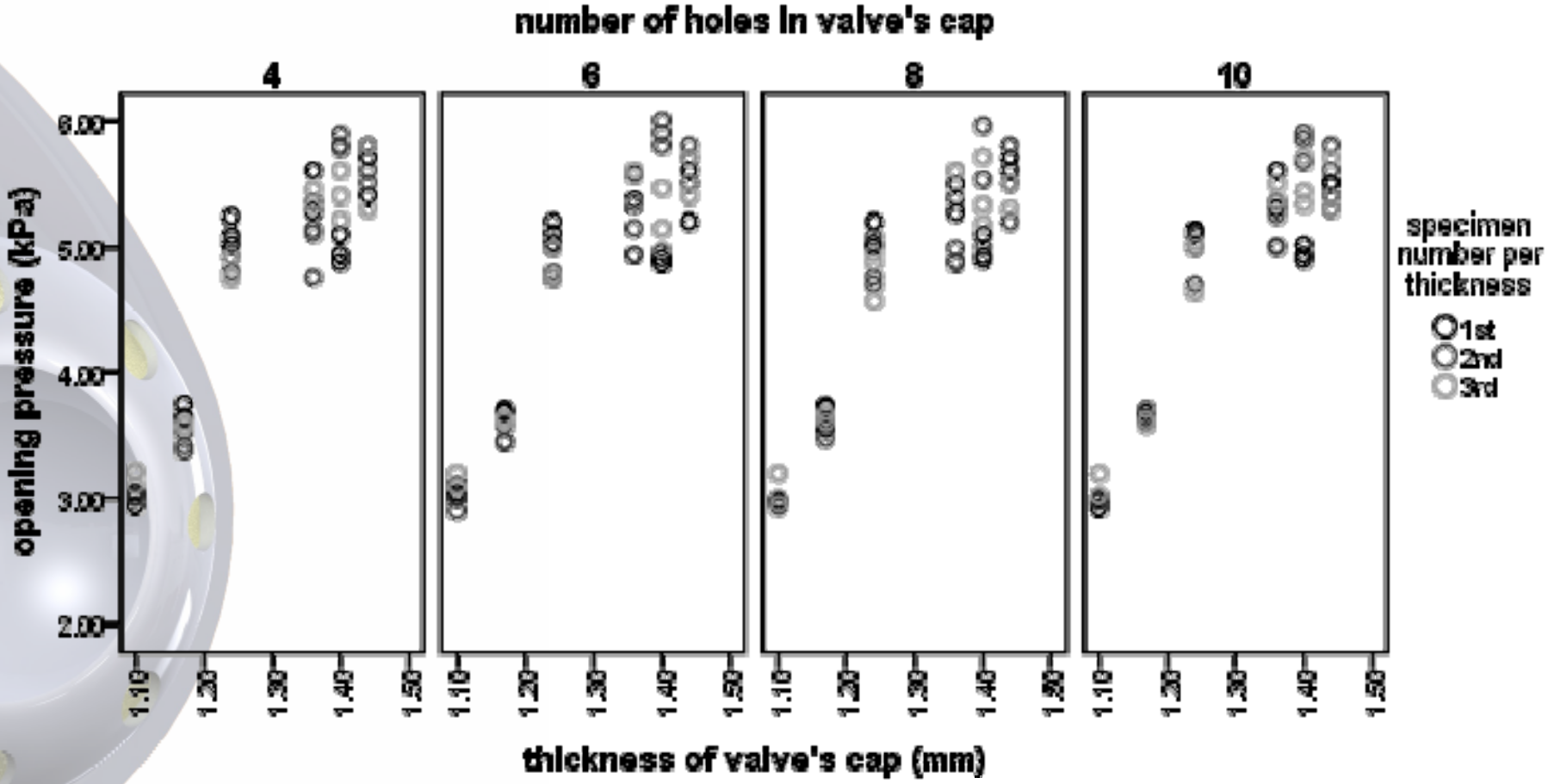
# Optimization




closing flow vs cap thickness and holes

mixed effect analysis: relation significant in linear model

# Optimization

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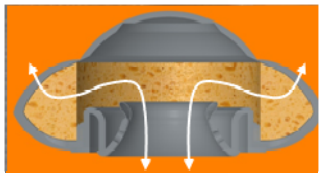
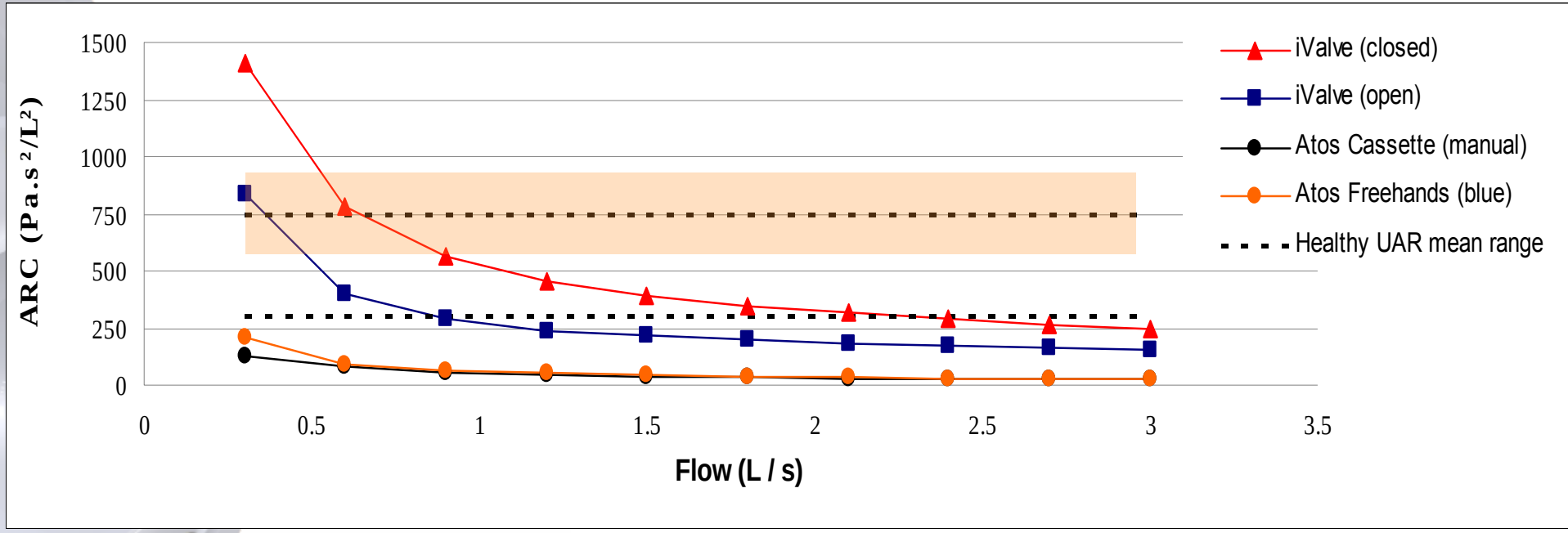
# Optimization






Air Flow Resistance Coefficient ($ARC^2$)

# Conclusions

The iValve can be optimally adjusted:

- Opening pressure and closing flow are independent
- Opening pressure: 3-6 kPa (cap thickness versions)
- Closing flow: 2-6 L/s (close/open holes)

this is within physiological ranges

- ARC higer than Atos but closer to natural Healthy UAR

# Overview

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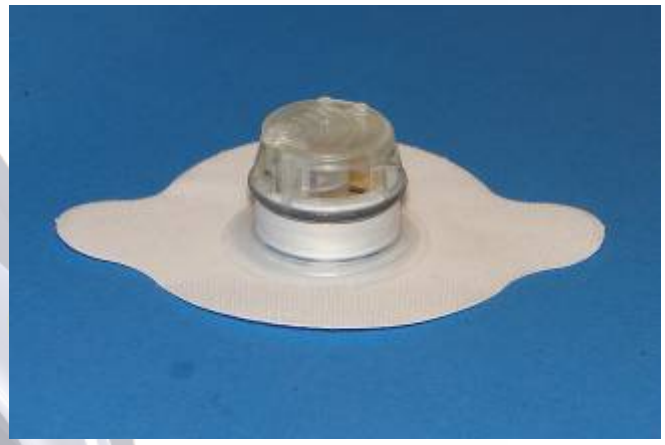
# In vivo comparitive test

TJ van Kalkeren, WAME Schrijver, EB van der Houwen



Versus

Atos FreeHands

iValve

$N_{total}$= 14 patients

7pts first Atos then iValve

7pts first iValve then Atos

# In vivo comparitive test

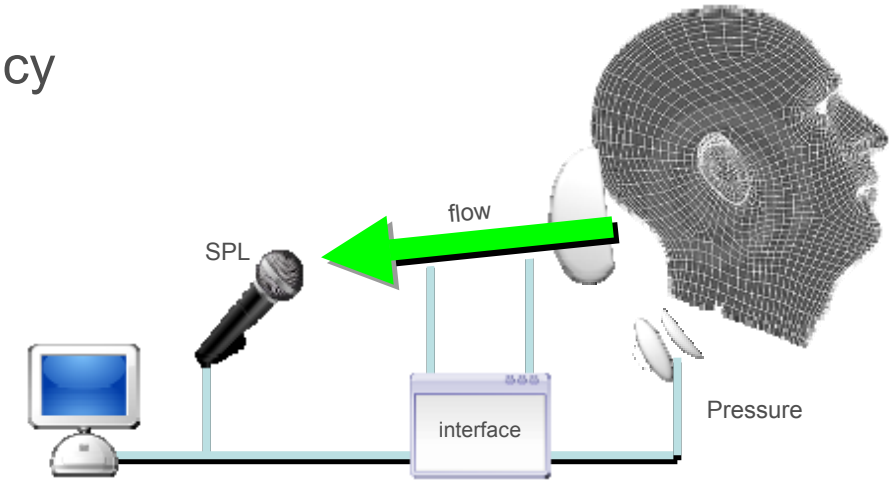
TJ van Kalkeren, WAME Schrijver, EB van der Houwen

Measured variables:

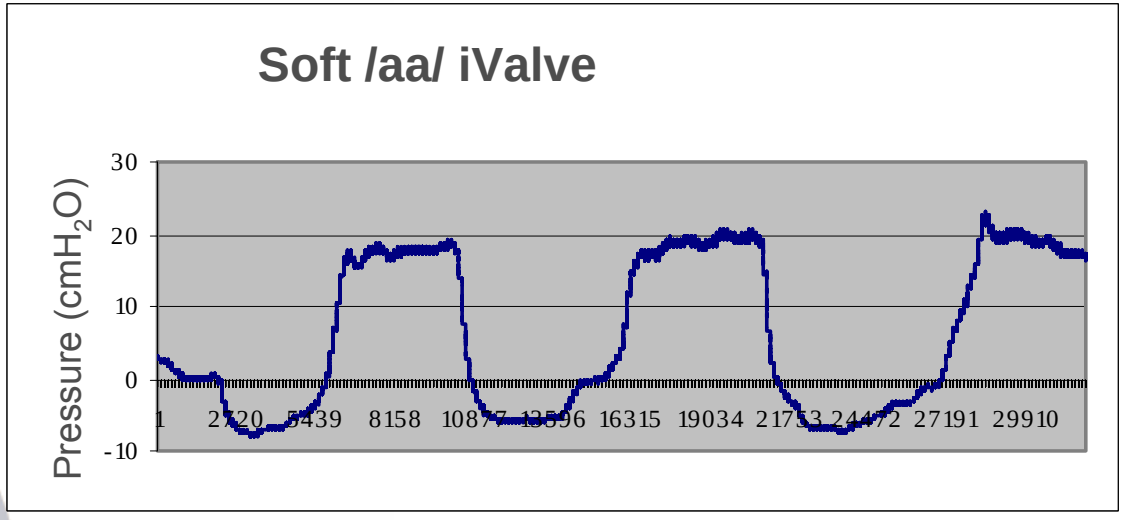
- Pressures and flow
- SPL and fundamental frequency
- Phonation time
- Questionnaire/observations

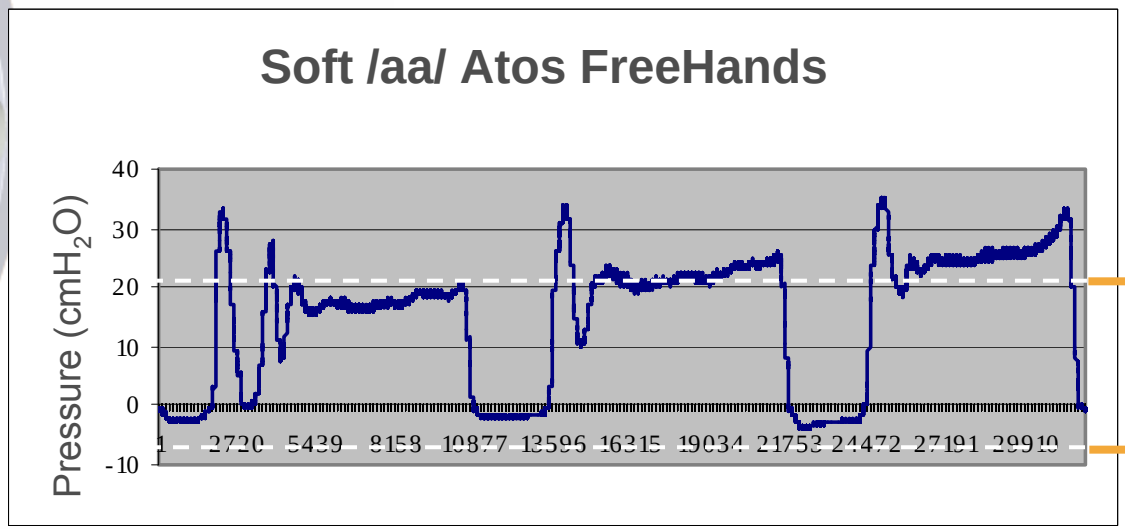
Hypotheses: iValve provides,

- Louder and longer phonation
- Lower intratracheal pressure and flow
- Continuous speech



# Intratracheal pressure strain on the patch




iValve $P_{max}$

iValve $P_{min}$

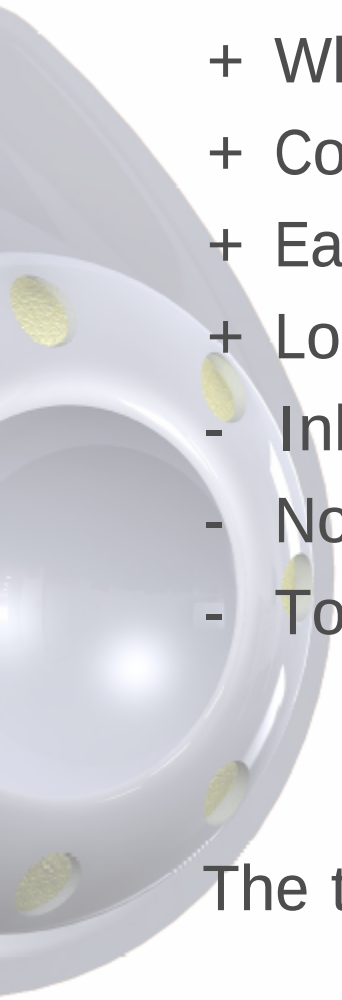
# Results Questionnaire

- 85.7% hands-free speech makes life more easy
- 100% would use handsfree if good
- 33.3% iValve more difficult than manual occlusion

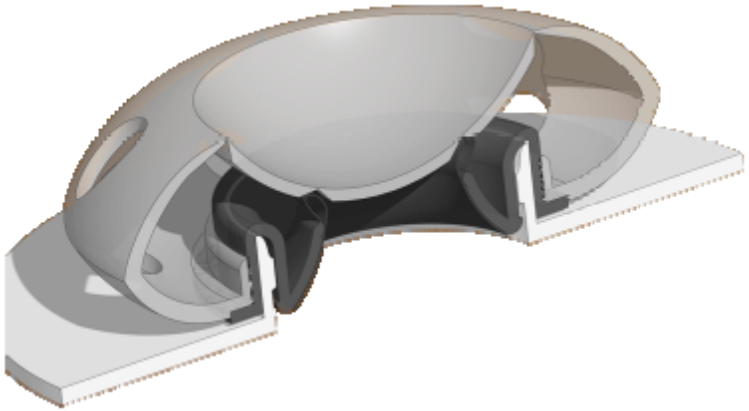
- 57% iValve easier to use than Atos FreeHands
- 23.8% generaly (speech, use) preferred the iValve
- 33.3% generaly preferred the Atos FreeHands

- 81% inhalation iValve still too heavy
- 54.5% iValve still too noisy

# Conclusions



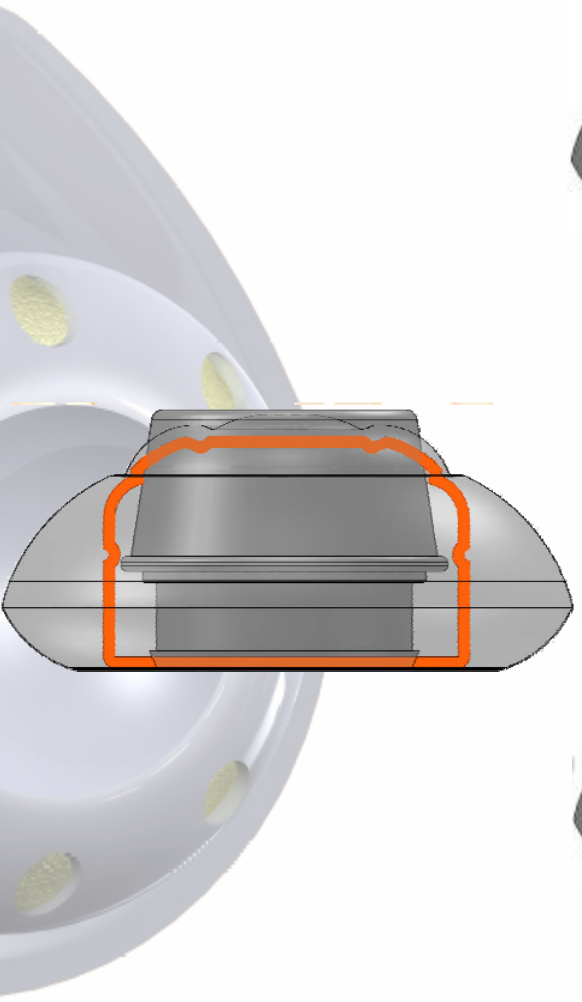
+ Whispering possible
+ Continuous speech possible (inhaling works)
+ Easier to talk
+ Loudness/pressure/time: no significant difference
- Inhalation difficult
- Noisy
- Too big

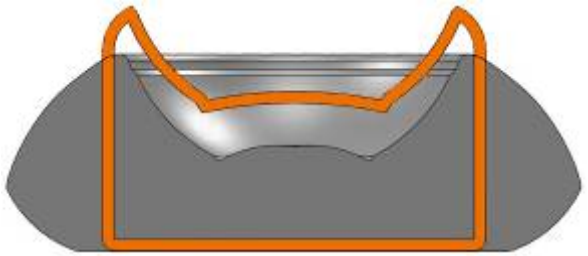


The tested iValve is a prototype!


Tele3C

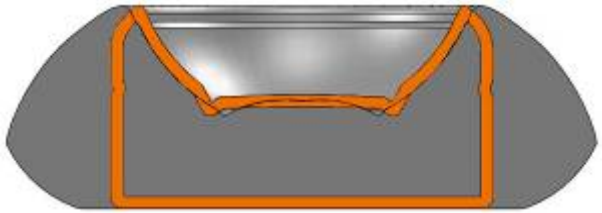
# In development





iValve v2.0. Tested and working.

- Smaller diameter
- Lower ARC at low flows
- Less parts
- “Standard” HME-filter (cassette)



iValve v2.1. In the making

- Even smaller diameter and height

# The iValve prototype works, the patients can't wait!


Teleac 2010 "Het Academisch Ziekenhuis" National Public Broadcasting

For more info: vdhouwen@gmail.com

# Small part of a TEAM!

Current team:

...

Tjouwke van Kalkeren

Tom Oude Hengel

Rolf Eleveld

...

Arpád Szabó
Pablo Serna Sanchez
Dionne Haanstra
Mayke van Dort
Lútzen Kuiper
Derk-Jan Alberts
Lise de Jonge
Agnes Uijttewaal
Hanna Pragt
Arjan Wachtmeester
Robert Kroes
Nienke Krop
Rada Moerman
Sara Panahkhahi
Steffan Sloot
Jan Swartjes
Marcel Timmer
Freerk Venhuizen
Frederik Robijns
Felix Wittemann
Charissa Roossien
Marcel Schouten
Bob Giesberts
Gábor Koska
Jason Pauëlsen
Ward Sikkema
Rolf Eleveld
Tom Oude Hengel