



Opening pressure and airflow characteristics

Atos Medical has been developing voice prostheses since 1990. From the start, our goal has been to develop voice prostheses with high voice quality and low speaking effort. We also have a long-standing tradition of clinical evidence demonstrating that our products perform well and are safe to use. Over the years, many studies have been carried out on our products, and we are proud to say our voice prostheses are supported by more studies and stronger evidence than any of our competitors.¹

A prospective randomized cross-over trial was conducted in 31 patients comparing two indwelling voice prostheses; the Provox Vega vs competitor's device. Patients reported better overall voice and

speech with the Provox Vega (72 % Provox Vega, 14 % competitor) particularly for better clarity of speech, fluency, volume, and less speaking effort.^{2,3}

One study reported on the perception of voice quality from both clinicians and patients. Results showed that both patients and clinicians perceived voice to be better with Provox Vega compared to the competitor's device. Perceptual judgments by clinicians rated speech with the Provox Vega to be less strained, easier to understand, less effortful, and better overall.³

Below, we describe opening pressure and airflow characteristics and why both values are important and impact the performance of the voice prosthesis.

What are airflow characteristics and why are they important?

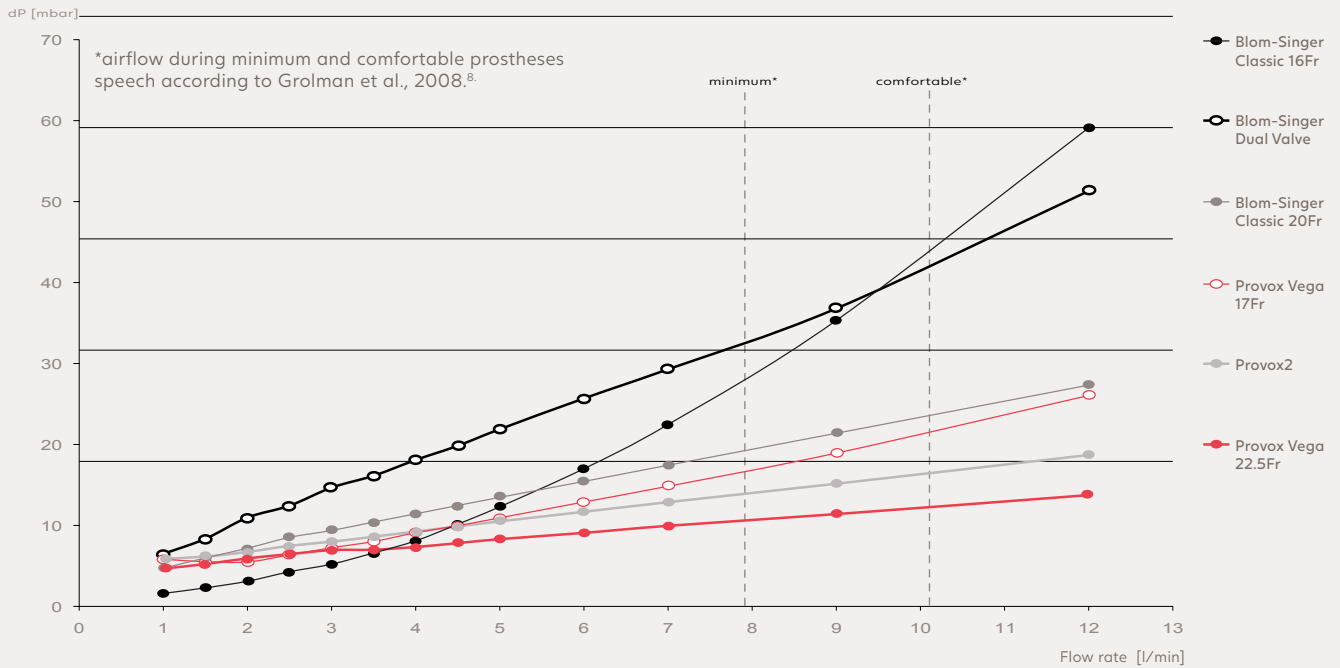
From the patient's point of view, airflow characteristics are the effort needed to maintain a good voice. Depending on the design of the voice prosthesis, such as the diameter of the inner lumen of the voice prosthesis, material properties, where the valve unit is placed in the housing, hinge dimensions and preload of the valve, you may have different outcomes.

A large voice prosthesis inner diameter decreases speaking effort

A larger voice prosthesis inner diameter yields increased airflow and results in less speaking effort and a positive impact on speaking quality.^{3-6,8} If a patient using a smaller diameter voice prosthesis finds that speaking is difficult, consider changing to a voice prosthesis with a larger diameter.

	Provox Vega 17Fr	Blom-Singer Classic 16Fr	Provox Vega 20Fr	Blom-Singer Classic 20Fr	Provox Vega 22.5Fr
Opening area (mm ²)	9.35	7.50	13.66	10.35	17.72
Inner diameter (mm)	3.45	3.09	4.17	3.63	4.75
Outer diameter (mm)	5.7	5.3	6.7	6.7	7.5

Provox Vega 22.5Fr requires the lowest speaking effort due to low voice prosthesis airflow resistance



What is opening pressure and why is it important?

From the patient's point of view, opening pressure is the effort needed to initiate speech.⁷ So, a voice prosthesis with a very high opening pressure would be difficult to start talking with (due to the high effort needed to open the valve flap). On the other hand, a voice prosthesis with very low opening pressure might open unintentionally as the patient is swallowing or inhaling deeply, this may lead to gastric bloating from excess air or allow saliva and fluid to enter the lungs due to poor closure.^{3,5,7}

When the patient is initiating speech, the air pressure rises to a level where the valve flap is forced to open, and a flow of air is generated.

Opening Pressure for Atos Medical Voice Prostheses

Product Name	Target Opening Pressure*
Provox Vega 22,5Fr	4,5 hPa
Provox Vega 20Fr	3,0 hPa
Provox Vega 17Fr	2,0 hPa
Provox Vega XtraSeal 22,5Fr	4,5 hPa
Provox Vega XtraSeal 20Fr	3,0 hPa
Provox Vega XtraSeal 17Fr	2,0 hPa
Provox2	3,1 hPa
Provox ActiValve Light	7 hPa
Provox ActiValve Strong	20 hPa
Provox ActiValve XtraStrong	40 hPa

*hPa (Hecto Pascal)

Above stated opening pressure values are defined as pressure drop over the valve at 0.5±0.1l min. However, voice prosthesis standard ISO21917: 2021 is defining opening pressure as "The peak pressure measured at the time flow is detected through the voice prosthesis."

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