White paper

PhysioAssist

The Simeox device

Research team

SCRCM Hôpital Nord

Pr. M. REYNAUD-GAUBERT
MK. P. GIOVANNETTI

CNRS – M2P2 UMR 7340

PhD. J. FAVIER
Ing. O. LAFFORGUE
PhD. S. PONCET
PhD. I. SEYSSIECQ

Physio-Assist

Ing. A. MITHALAL

Research program
Airway Clearance by Rheology

The Physio-Assist research program was formed from a postulate: the ability to treat specific diseases by modelling tangible elements such as materials, and study them accordingly.

This program was devoted to the study of bronchial mucus. Modification of the mucus rheology allows, in conditions that make it abundant and viscous, improvement of bronchial decongestion.

This program is conducted in three phases:

- 1. Specification of the physical structure of bronchial mucus in vitro
- 2. Modelling a lung to perform numerical simulations by inserting into this model the mucus specified in Phase 1
- 3. Validation of the numerical results through a clinical study in our target patients.

This research program has developed the ACT technology used in the Simeox device

Abstract

The vibration technology - Airways Clearance Technology - developed by Physio-Assist in partnership with the CNRS and the North of Marseille Hospital, is available in its medical device Simeox, CE marked.

The vibration technology - Airways Clearance Technology - developed by Physio-Assist in partnership with the CNRS and the North of Marseille Hospital, is available in its medical device Simeox, CE marked. This patented technology offers a solution to patients with obstructive respiratory diseases and health professionals when performing their daily decongestions.

Our fundamental research on bronchial mucus rheology and its transport by low pressure waves enabled the development of a device to help mucociliary clearance: Simeox.
Simeox uses passive expiration technology. It mobilises mucus in the distal tracts to change its rheology and transport it to the proximal tract for expectoration.

It generates a vibratory pneumatic signal when the patient expires and allows a direct intrapulmonary action on the dynamic viscosity of the bronchial mucus. The viscosity decreases sharply by the rheofluidifiant properties and thixotropy of the mucus...
The amplitudes and optimal frequencies have been determined numerically and confirmed by laboratory experiments
The Simeox medical device has been evaluated in clinical practice in 15 patients hospitalised in the pulmonology department with chronic bronchorrhea (cystic fibrosis or other bronchiectasis disease) to evaluate its safety and performance on bronchial decongestion.

The results have shown a satisfaction rate of use of the device in 73% of patients, especially when used in addition to conventional respiratory physiotherapy, thereby increasing its effectiveness.

Physio-Assist Technology

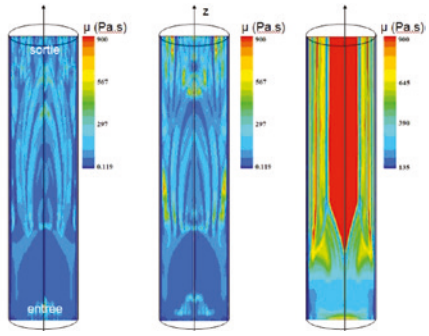
CNRS - Rheology Laboratory - M2P2

Our fundamental research on the study of mucus rheology in vitro and numerical simulations was used to characterise the physical structure of bronchial mucus. In particular, we characterised the special properties of the thixotropic nature of mucus. Indeed, under the effect of a specific stimulus, mucus is destructured and its viscosity drops.

The numerical modelling performed by the specialist rheology laboratory of the CNRS has determined the performance criteria to liquefy and adequately transport bronchial mucus.

The specifications of the optimal vibratory pneumatic signal in successive low pressure points are the core of the unique technology of Simeox medical device. Within seconds, a very significant drop in viscosity is measured on output of the optimum vibratory signal.

To promote the transport and disposal of secretions, it is necessary to impose this signal in the expiratory phase to transport the mucus from the distal tract to the proximal tract.



Influence of Simeox on mucus viscosity (maximum viscosity in red, minimum viscosity in blue)

Technology	Clinical value
Development of a numerical simulation pulmonary model	Ability to measure in real time the performance of an intra-pulmonary vibration signal
Thixotropic	Very quick drop in mucus viscosity
Successive low pressure signals	Improvement of the mucus transport

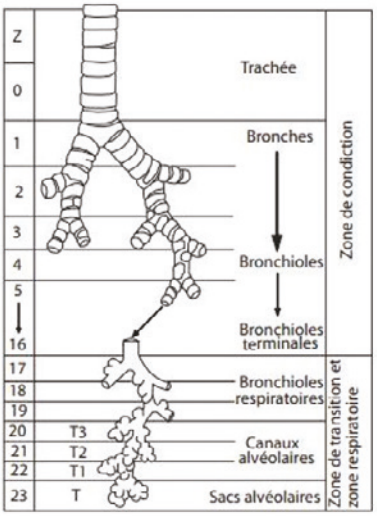
Physio-Assist model

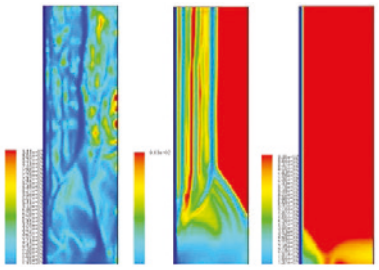
Physio-Assist, after precise work of the characterisation of bronchial mucus, developed a model measuring in real time the impact of a pneumatic stimulus on mucus in the bronchial tree.

Obstructive respiratory diseases require daily decongestion to improve ventilation and reduce stagnation of secretions that cause lung infections. This stagnation is especially hazardous in the distal tract, the first target in bronchial decongestion manoeuvres. Our model takes into account bronchial secretion reductions and allows measurement of the pressure drop to determine the specifications of a powerful signal in areas distant from the bronchi.

We can measure the contribution of the Airways Clearance Technology of the Simeox device in mucus sections in the distal tracts of congested patients.

We demonstrate the impact of our technology on the most difficult mucus to mobilise during the decongestion sessions, and therefore, the most conducive to pulmonary infection due to stagnation.





Clinical study of the Simeox medical device

Cystic Fibrosis Resource and Competence Centre - University Hospital of North Marseille
The Simeox device has a mouthpiece for the ventilation mode, which consists of successive low pressure signals during passive expiration according to the guidelines dictated by the fundamental research.
Our Simetol clinical study was conducted under the direction of Prof. Reynaud-Gaubert and MK Giovanetti at the University Hospital of North Marseille. The study focused on patients hospitalised in pulmonology department with chronic respiratory infection causing bronchorrhea and requiring regular sessions of bronchial decongestion by a physiotherapist. These patients had multiple bronchial decongestion sessions each month (between 8 to 60 / month, median 30 / month). They were divided between sessions of chest physiotherapy and self-drainage in patients that had been trained to use the device.

According to Mr Giovannetti, physiotherapist and consultant at the CRCM of the University Hospital of North Marseille.
"The original principle of Simeox is to combine:

- An expiratory aid, which increases the expiratory time.
- Expiration is ensured by the machine, so it is passive, which prevents physiological airway collapse.
- Simeox has a direct effect on the viscoelastic properties of mucus, which no other physical device offers and which is its most innovative feature.

The duration of a Simeox session allows it to be used:

- As part of a bronchial drainage session;
- Before the physiotherapy session, after the patient has been trained by a physiotherapist or as an autonomous exercise performed by the patient.

The device is ergonomic and simple to use. The touch-screen interface allows visual feedback that facilitates the "effective" learning of the ventilation mode.

Technology	Clinical value
Direct action on mucus viscosity	Improved transport and decongestion
Passive expiration	Decreased physiological collapse Reaches the distal tracts of the lungs
Biofeedback	Allows the patient freedom in his treatment

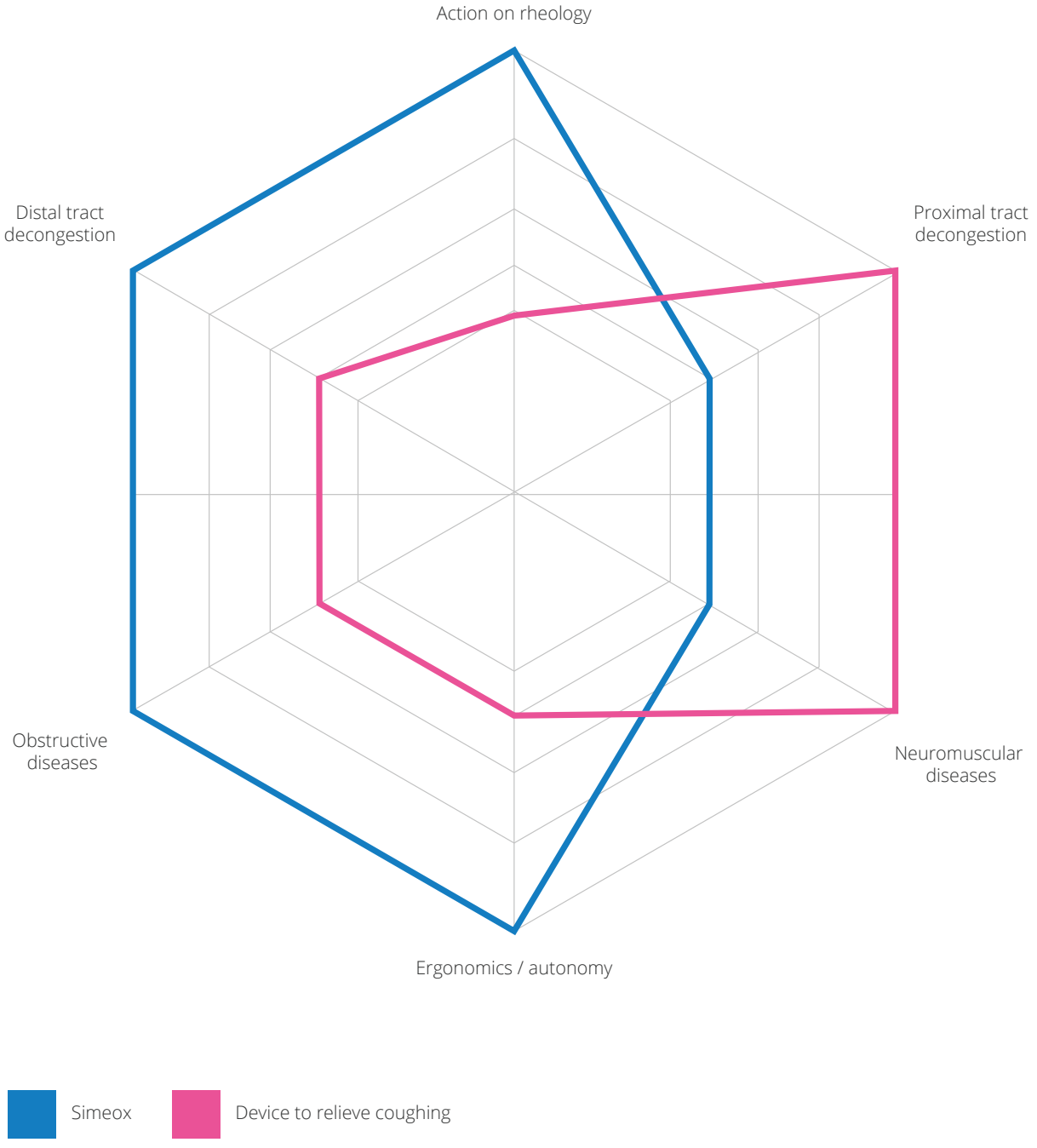
Main clinical outcome

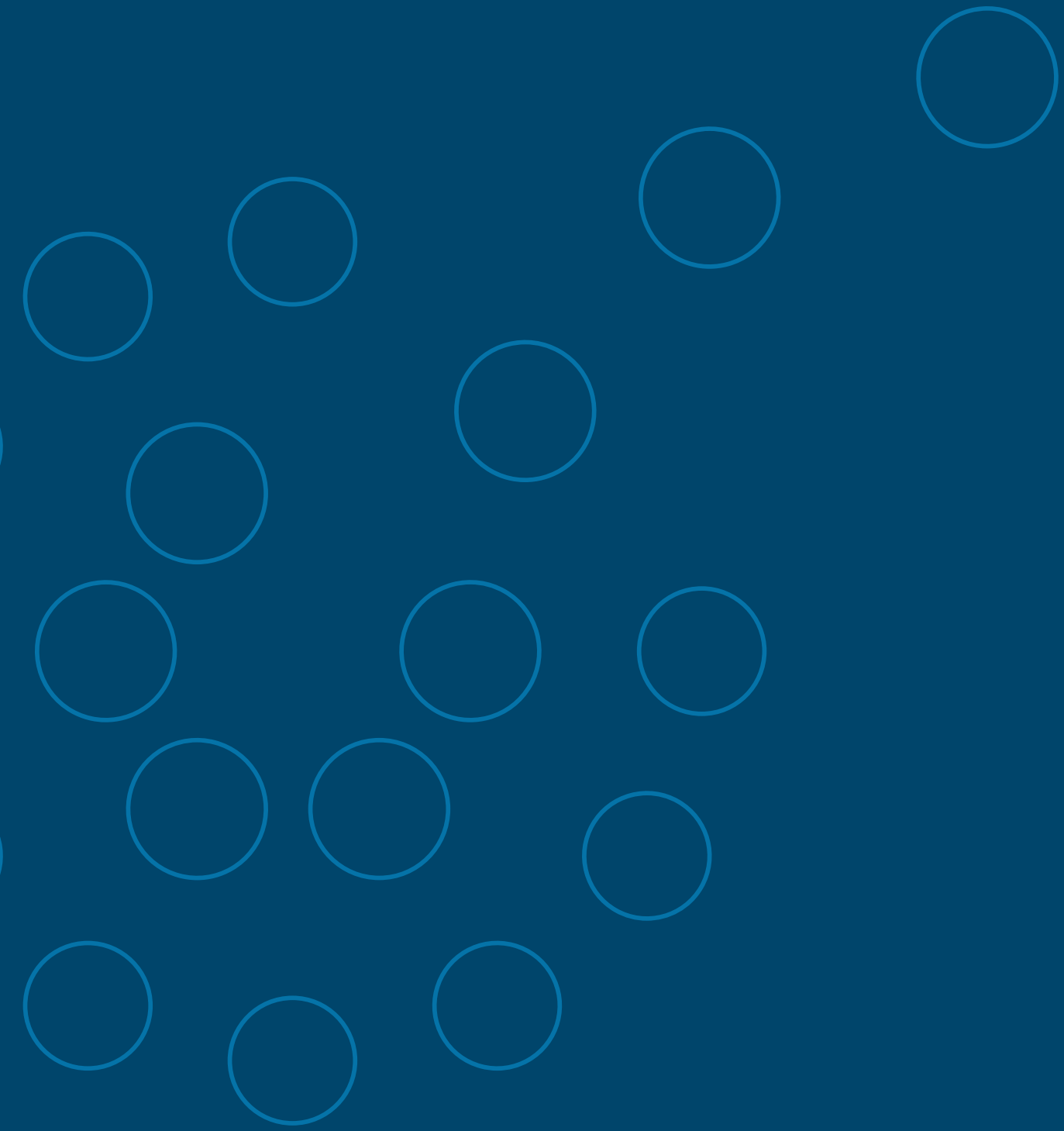
Avantage clinique	Clinical results	Comments
Good tolerance	No patient exclusion	"Not at all stressful" Patient
Good user comfort	Pain: 0.4 / 3	"No pain" "No discomfort or difficulty encountered" "Zero pain" Patient
No specific fatigue	Demanding session: 1.4 / 3	"No perceived fatigue, much less tiring than a conventional session" "No sensation of fatigue" "No fatigue" Patient
Good efficiency perceived by patients	73% of patients satisfied or very satisfied	Sessions generating "significant secretions" "Impression that it mobilises secretions" "Very fast expectoration" "Sputum comes up faster" "More secretion than in a normal session" Patient
Good adoption of the device by patients	73% rate of adoption	
Autonomy		"The device is ergonomic and simple to use. The touch-screen interface allows visual feedback that facilitates the "effective" learning of the ventilation mode. This ease of use allows independent use of the device by the patient initially or in addition to the physiotherapist's intervention" Mr Giovannetti, physiotherapist and consultant at the CRCM of the University Hospital of North Marseille.

Simeox:
Original and innovative use

Simeox is not a device to relieve coughing. The vibration signal generated allows the modification of the mucus structure to make it transportable. Successive low pressure signals during expiration allows its transport from the distal tracts to the proximal tracts.

From current studies, we can compare Simeox claims to devices to relieve coughing.





PhysioAssist

31 Parc du Golf - CS 90519
13593 Aix-en-Provence Cedex 3

Tel : +33 (0)4 67 03 13 92

contact@physio-assist.com
www.physioassist.com

Conception : www.cubedesigners.fr

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