

# Thopaz™

“ there is little questions that the  
digital drainage system is our future ”

Dr Robert J. Cerfolio

# A prospective randomized study evaluating a chest tube drainage system – THOPAZ™ – containing a digital air leak meter and self-contained suction

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## Introduction

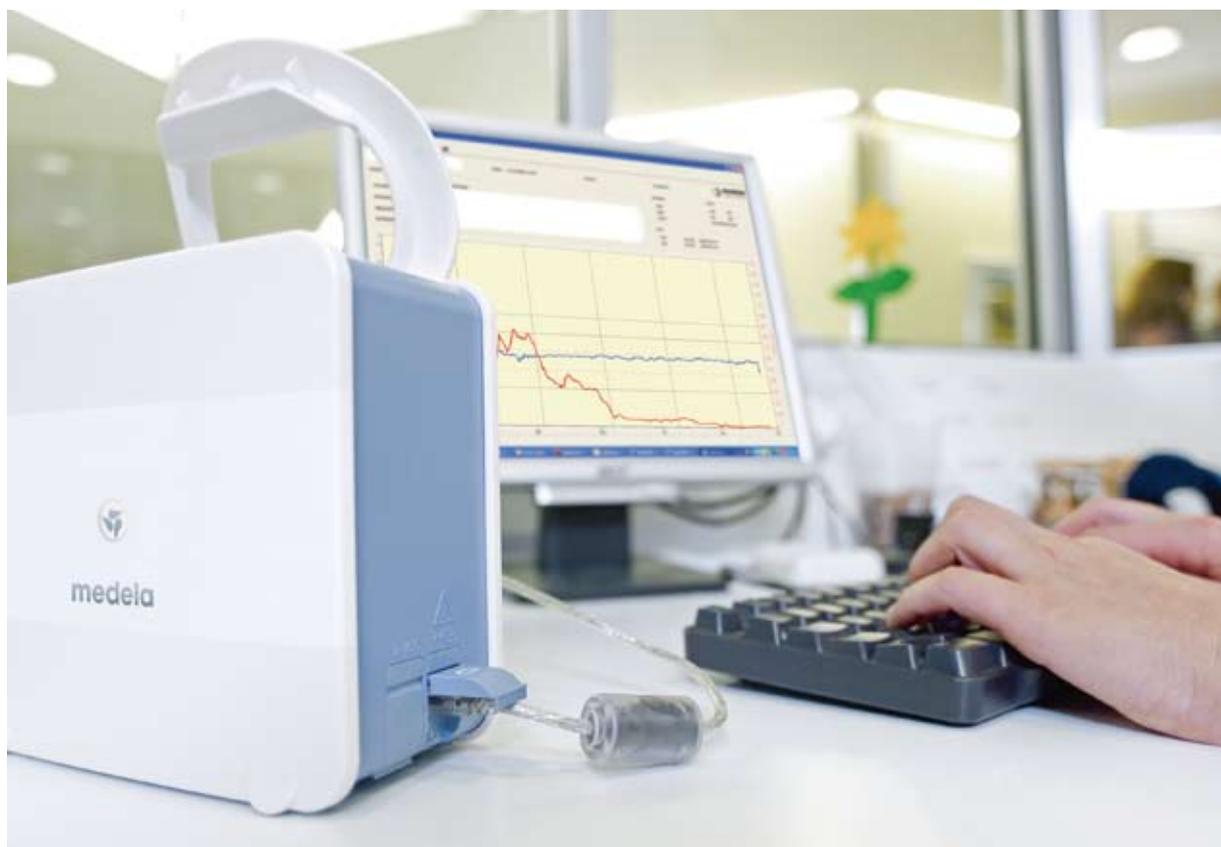
Air leaks remain a common nagging, post-operative complication after pulmonary resection and add to morbidity, mortality and cost. Quick and safe chest tube removal depends on accurate chest tube management and this requires an accurate assessment of air leak size. The analogue measurement or grading of air leaks, despite the development, verification and utilization of an air leak classification system, The Robert David Cerfolio system (RDC)<sup>1</sup>, currently relies on a static analogue measurement of “bubbles in a chamber” and still has observer variability and subjectivity. In this study we have shown the improvement in chest tube management using a digital system.

## Aim

Assessing the use and handling of a digital device to treat patients undergoing elective pulmonary resection.

## Methods and Results

Patients (98) who underwent lobectomy, bi-lobectomy or segmentectomy were eligible for this study. After surgery patients were randomly assigned to either the digital device, Thopaz (Medela, Switzerland) or the analog system Sahara S-11000 (Teleflex, Research Triangle Plus, NC, USA). Chest tubes were removed when the output was < 450 cc/day and the air leak was 20 cc/min or less on the digital system or non-discernable on the analog system. Three patients on the Thopaz unit were successfully discharged home on POD 4 with their chest tubes in place, five in the control group. A similar aggressive fast-tracking, post-operative and chest tube algorithm was used for all study patients. Accuracy and reliability of both systems was investigated. Statistical analysis was conducted using SAS software 9.1 (SAS, Cary, NC). Fisher’s Exact test or Pearson’s chi-square test was used to assess categorical data and the Wilcoxon test to evaluate continuous variables. Significance is defined as  $p \leq 0.05$ .

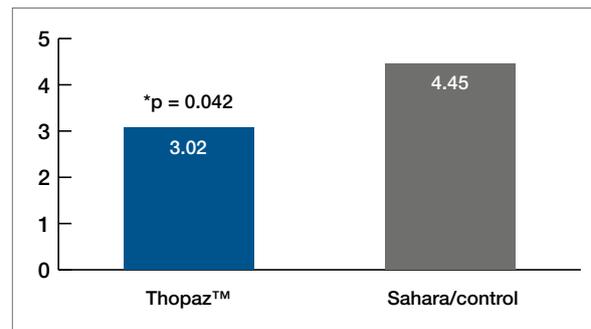


<sup>1</sup>Cerfolio, Advances in thoracostomy tube management, *Surg Clin N Am* **82** (2002), pp. 833–848.

### Figure 1: Chest tube duration

Chest tube duration was significantly shorter with the digital drainage system ( $p=0.042$ ).

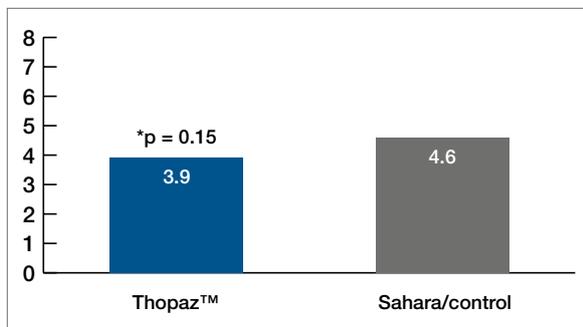
Days (median) of chest tube removal



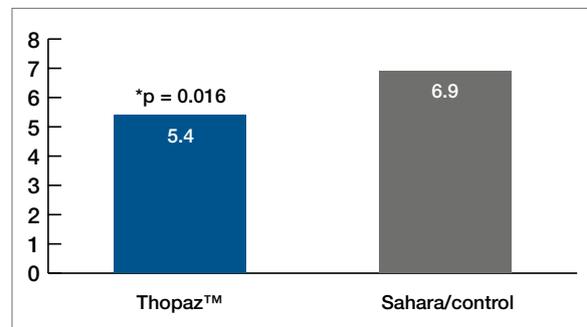
### Figure 2 a, b: Length of stay

Length of stay was assessed for all patients as well as a subgroup of patients with a special need for suction, such as patients with a clinically symptomatic pneumothorax. Patients in the digital Thopaz group showed a shorter duration of hospital stay, and the subgroup of patients with pneumothorax had a significantly shorter hospitalization as well as less days of subcutaneous emphysema.

a) Length of hospital stay



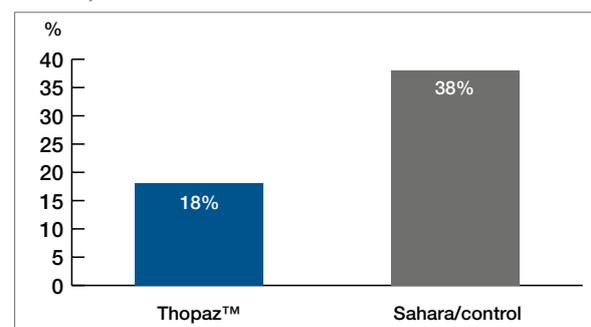
b) Median hospital stay (subgroup of patients)



### Figure 3: Degree of variability

Variability was defined as scores differing by more than 40ml/min for the digital system and one grade on the analogue score scale when read by two different clinicians concurrently. The Thopaz digital system was found to be more accurate and consistent, contributing to a reduction in variability and subjectivity, presumably due to decreased observer subjectivity.

Variability of air leak score



### Conclusions

- In this study the Thopaz™ digital system was found to be more accurate and consistent than the analogue RDC system.
- Shorter chest tube duration was found when using Thopaz™ and this was achieved with statistical significance.
- Patients were sent home on the Thopaz™ who otherwise would not have been able to leave the hospital.
- A consequence of this study was that any technology that improves the ability to treat alveolar pleural fistulas (air leaks) in a scientific, objective manner is an important clinical accomplishment and will translate into better care for patients and into cost savings for the hospital.



Thopaz™ is the future!

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