Title: The Thopaz+ portable digital system for the management of chest drains

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Declared interests of the authors

None.

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Rider on responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Contents

ABBREVIATIONS

Term	Definition
ACS	Analogue chest drain system
BTS	British Thoracic Society
CI	Confidence interval
DCS	Digital chest drainage system
EAC	External Assessment Centre
HES	Hospital Episode Statistics
HR	Hazard ratio
HRG	Healthcare Resource Groups
ICU	Intensive care unit
IQR	Interquartile range
ITT	Intention to treat
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines & Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
MTG	NICE medical technology guidance
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
PP	Per protocol
QS	NICE quality standard
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised Controlled Trial
SD	Standard deviation
TS	Traditional suction
VAS	Visual Analogue Scale
VATS	Video-assisted thoracoscopic surgery
vs.	Versus

1 Executive Summary

The company submission contained a total of 3 studies. The EAC carried out its own literature search and identified six RCTs, three observational propensity matched comparative studies and four non-comparative observational studies to give a total of 13 studies relevant to the scope. Eleven of the studies assessed the postoperative use of Thopaz in patients who underwent pulmonary resection and two studies assessed the use of Thopaz in the treatment of pneumothorax.

The EAC considered that on the whole the quality of the evidence was strong with six randomised studies and three studies that used propensity-matched control cohorts. The included evidence contained outcomes relevant to the scope.

The company's economic submission was very simple with no costs considered for the comparator. The company's submission showed Thopaz+ to be cost saving. Due to the simplicity of the model the EAC developed its own based on the structure of the company's submitted model which resulted in Thopaz+ becoming more cost saving. The EAC also carried out scenario and sub-group analyses to consider the effects of purchasing rather than leasing a Thopaz+ device and its use in the treatment of pneumothorax on the model.

On the whole clinical evidence showed a reduction in duration of chest tube drainage, reduced length of hospital stay, and some evidence for patient satisfaction. There was a non-significant reduction in the need for chest tube reinsertion postoperatively in patients undergoing pulmonary resection when Thopaz+ was compared to conventional drainage. Thopaz+ was shown to be cost saving and the main driver for cost savings was a reduction in the length of hospital stay.

2 Background

2.1 Overview and critique of company's description of clinical context

The company presents a thorough description of the clinical context, referencing the British Thoracic Society (BTS) guidelines for pneumothorax, pleural infection in children, and general guidelines on chest drain insertion. They also make use of Hospital Episode Statistics (HES) data to show that there are over 6,000 instances of chest tube insertion per year in the NHS. They specifically reference BTS paediatric tube insertion guidelines to highlight the high demand on staff time in monitoring an underwater seal chest drain, as currently used in standard care. This involves making sure that the drainage system always stays below the level of the patient's chest, and that immediate action is taken if the patient complains of breathlessness or chest pain.

The Thopaz+ system is intended to alleviate this risk by providing regulated negative pressure whilst monitoring air leakage and fluid drainage. The device is compact, battery-powered and self-contained. This allows patients greater mobility than standard care, where suction drainage is provided from a fixed hospital wall unit.

The company claims that the device allows more standardisation across different hospitals and Trusts where standard practice currently varies considerably. However, it does not require any alteration to the care pathway for patients who currently undergo chest drain insertion. Other claimed benefits include reduced duration of chest drain insertion, reduced length of hospital stay, reduced complications and higher patient satisfaction.

The claimed system benefits include reduced hospital costs, enhanced patient recovery, increased convenience for clinical staff, and standardisation of chest drain management.

The company's description of the clinical context is appropriate and relevant to the decision problem under consideration.

2.2 Critique of company's definition of the decision problem

Table 1| EAC's critique of the company's definition of the decision problem.

Decision problem	Company submission	Matches decision problem? (Y/N/partially)	EAC comment
Population	All people requiring a chest drain.	Y	Chest drains are used in a wide range of indications, and the company submitted one paper on pulmonary resection, one on pneumothorax and a clinician/patient survey study.
Intervention	Thopaz+	Y	All of the submitted studies assess the original Thopaz device, rather than Thopaz+. However, the main method of action of the device has not changed (confirmed by the company), so the evidence is transferrable and applicable.
Comparator(s)	Underwater seal drain, chest drains involving a flutter valve and any other recognised mechanism or valve.	Y	Only one of the submitted studies was comparative in nature (Pompili et al. 2014) and used a traditional "water seal" drainage system.
Outcomes	Duration of chest drain placement. Incidence of chest drain re-insertions. Fluid loss measurement. Length of hospital stay. Rate of complications and device related adverse events. Staff time. Patient satisfaction (including measures of patient discomfort).	Y	The company's submission covers most of these outcomes. Patient satisfaction is only mentioned by Rathinam et al. (2011), and comprises one short paragraph which is general in nature. Staff time is not covered by any of the studies included by the manufacturer. This is a limit of the available evidence rather than the company's submission, as the EAC did not find any staff time data in our additional searches.

Cost analysis	The population, intervention and comparator for the cost analysis are described in the sections above. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters.	Partially	The company's economic submission contains a table based on a single node decision tree. with data inputs from Pompili et al. (2014). Therefore the model focused on chest drainage in patients in undergoing pulmonary resection only. The perspective and time horizon match the scope. Sensitivity analysis has also been carried out.
Subgroups	Use in adults: any clinical situation in which a chest drain is indicated. Use in children. Specific indications: • pneumothorax (differentiating spontaneous and other air leaks) • post-operative use after cardiac or thoracic surgery • patients with pleural disease, thoracic trauma or injury	Partially	The company did not include any paediatric studies, which is not in agreement with the scope of this assessment. However, the EAC only found one small paediatric study on this device (Costa Jr et al 2016), so this may be a limitation of the available evidence.

Special considerations, including issues related to equality
The EAC did not find any specific equality issues that were not already covered in the provided scope.

3 Clinical evidence

3.1 Critique of and revisions to the company's search strategy

The company carried out searches in Medline, Medline In Process, Embase and The Cochrane Library. However, it was unclear if all Cochrane Library databases were searched. The search strategy used was simplistic, an English language restriction was used and date of publication was restricted to 2008-2017. In light of the simplistic search strategy it is likely that relevant studies may not have been identified. Therefore, the EAC conducted its own literature search using a comprehensive search strategy. The search made use of free text terms and medical subject headings and was used across databases identified in the MTEP sponsor submission template and other databases. The company made an effort to identify unpublished studies but did not appear to search trial registers. Both the company's and EAC's search strategies have been presented in the Appendix A.

3.2 Critique of the company's study selection

The company submitted a total 3 studies. One of the submitted studies (Rathinam et al. 2011), in the view of the EAC, is not applicable to the scope. The EAC felt that the company's selection criteria did not match the scope. For interventions the company focused on procedures carried out on the lung (e.g. thoracic surgery, video-assisted thoracoscopic surgery (VATS) and chest drain insertion) when the intervention in question should have been Thopaz+. In addition, the company focused on the requirement for chest drain placement or insertion as an outcome instead of the outcomes identified in the scope. The company decided to include studies only if they were freely available, excluding three studies they needed to pay for. The EAC did not feel this was a valid reason to exclude a study as the cost is very low. The company excluded non-comparative studies but included individual case studies with no comparator. The EAC felt this was not appropriate and considered all non-comparatives studies in its assessment of outcomes

identified in the scope. PRISMA diagrams for both the EAC's and company's literature search are provided in Appendix A.

3.3 Included and excluded studies

The company assessed a total of 15 records at full text for eligibility to the submission. The company excluded a total of 9 studies as they were conference abstracts with insufficient data. The company also excluded 3 studies due to a "publisher paywall". The EAC did not feel this was a valid reason to exclude these studies and therefore requested citations for the 3 studies. All three of the studies were conference abstracts with insufficient data and therefore the EAC concluded that these should be excluded.

In total the EAC identified 13 studies relevant to the scope of this assessment. The EAC's relevant studies included two studies identified by the manufacturer (Pompili et al. 2014 and Tunnicliffe and Draper. 2014). However, the EAC excluded a study identified by the manufacturer (Rathinam et al. 2011) as the study was outside of scope. A summary of the papers included by the EAC and company has been provided (Table 2| Studies included/excluded by the company and the EAC.

Table 2| Studies included/excluded by the company and the EAC.

Study	Included/excluded by the company?	Included/excluded by the EAC?
Brunelli et al. (2013)	-	✓
Costa Jr et al. (2016)	-	✓
Gilbert et al. (2015)	-	✓
Jablonski et al. (2013)	-	✓
Lijkendijk et al. (2015)	-	✓
Linder et al. (2012)	-	✓
Marjanski et al. (2013)	-	✓
Mier et al. (2010)	-	✓
Miller et al. (2016)	-	✓

Pompili et al. (2011)	-	✓
Pompili et al. (2014)	✓	✓
Rathinam et al. (2011)	✓	×
Shoji et al. (2016)	-	✓
Tunnicliffe and Draper. (2014)	✓	✓
✓ = included; × = excluded; - not identified.		

In the following study summary table (Table 3| Summary of studies included by the EAC ordered by reason for requiring drainage and study design. the intervention, comparator (if applicable), participants and outcomes have been coded as follows:

G	Fully included within the scope
A	Partially included within the scope
R	Not consistent with the scope

None of the included studies fully meet this assessment's broad scope. Therefore, a green coding signifies that the intervention, comparator, participants or outcomes are included in the scope.

Table 3| Summary of studies included by the EAC ordered by reason for requiring drainage and study design.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
Pulmonary resection (including lobectomy, segementectomy and wedge resection)						
Brunelli et al. (2013).	RCT comparing Thopaz in regulated suction mode and in regulated seal mode individualised to the type of lobectomy carried out. Intervention: Thopaz regulated individualised suction mode. ● Comparator: Thopaz regulated seal mode. ●	100 patients randomised (Group 1, Thopaz regulated suction mode n=50; Group 2, Thopaz regulated seal mode n=50). Group 1: Mean age 66.1 years (SD 11.3), male n=28 (56%) Groups 2: Mean age 68.4 years (SD 9.8), male n=42 (84%). Single-centre (Italy), general thoracic surgery ward All patients underwent pulmonary lobectomy. ●	**Relevant to scope:** Length of hospital stay, duration of chest tube drainage and complications. ● **Not relevant to scope:** Air leak duration, incidence of air leak lasting longer than 7 days and incidence of air leak lasting longer than 5 days. ●	No significant difference in the duration of chest tube placement or length of hospital stay was observed between the two groups. No significant difference in the number of cardiopulmonary complications was observed between the two groups.	None.	This paper compares Thopaz in two different modes. One of the authors has a consultancy agreement with Medela.
Gilbert et al. (2015).	Open label RCT comparing	172 patients stratified (Group 1, no air leak	**Relevant to scope:**	No significant difference in median length of	N=6 (post-operative	Device blinding was not

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	analogue and digital chest drainage in patients stratified according to presence or absence of air leak. Intervention: Thopaz. ● Comparator: Pleur-Evac (analogue water sealed device). ●	n=87; Group 2, air leak n=85) and then randomised (Group 1 Pleur-Evac n=43 and Thopaz n=44; Group 2 Pleur-Evac n=42 and Thopaz n=43). Group 1: Median age (25th and 75th percentile) Pleur-Evac 67 years (61-71), Thopaz 69 years (59-76; Pleur-Evac male n=10 (23%), Thopaz male n=18 (41%). Group 2: Median age (25th and 75th percentile) Pleur-Evac 68 years (60-75), Thopaz 68 years (60-72); Pleur-Evac male n=21 (50%), Thopaz male n=14 (33%). Single-centre (Canada), post-operative drainage, non-ICU patients. All patients underwent pulmonary resection	Duration of drainage, length of hospital stay, number of chest tube reinsertions and complications. ● **Not relevant to scope:** Number of chest tube clamping trials and the number of postoperative chest radiographs. ●	hospital stay, median duration of chest tube drainage or postoperative complications was observed between Pleur-Evac and Thopaz in both air leak status groups. A non-significant number of chest tube reinsertions were carried out in patients receiving treatment with Pleur-Evac. No Thopaz patients required a chest tube reinsertion.	ICU transfer n=4, returned to operating theatre n=2).	possible due to differences in size and functions of Thopaz and Pleur-Evac. The operating surgeon was blinded to air leak group stratification. The authors obtained device disposable items from Medela at a discounted price, but state Medela were not involved with any part of the study.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		(lobectomy and segmentectomy). ●				
Lijkendijk et al. (2015).	Prospective, single centre unblinded RCT. Intervention: Thopaz. ● Comparator: Thora-Seal (Covidien), traditional drainage system. ●	105 patients were randomised (Electronic: Thopaz n=55; Traditional: Thora-Seal n=50). Electronic: median age (range) 69.5 years (48-87), 21 males, 34 females. Traditional: median age (range) 67 years (46-85). 18 males, 32 females. Thopaz set to -15 cm H_2O, whereas Thora-Seal used gravity pressure only. Single centre (Denmark) All patients had lobectomy by thoracotomy or VATS. ●	**Relevant to scope:** Chest drain duration, length of hospital stay and number of chest tube reinsertions. ● **Not relevant to scope:** None.	Cox proportional hazards regression showed no significant difference between the two groups in: optimal chest tube duration, actual chest tube duration or length of hospital stay on an intention to treat (ITT) basis or per protocol basis.	In the Electronic group four patients had protocol violations due to their drainage system being switched from Thopaz. One patient had a very long (35 day) length of stay due to removal of a large necrotic tumour. Therefore results were analysed using ITT and per-protocol where these	Blinding was not possible as the two systems are different.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
					patients were excluded. No patients needed to be excluded from the Traditional group.	
Marjanski et al. (2013).	RCT comparing digital chest drain to conventional suction drainage. Intervention: Thopaz. ● Comparator: traditional suction drainage using a Sherwood glass bottle with suction provided via a central wall suction system. ●	64 patients were randomised (Group 1: Thopaz n=32; Group 2 had traditional postoperative drainage using Sherwood glass bottles, with suction provided via a central wall suction system. ● Negative pressure set to -15 cm H_2O in each group for the first two days postoperatively, and then reduced to gravitational drainage. Digital: Mean age (range) 63 years (52-79), 16 males.	**Relevant to scope:** Complication rates, number of chest tube reinsertions, drainage duration, and hospitalisation time after lobectomy. ● **Not relevant to scope:** Histology of resections and stages of resected non-	Mean drainage and duration of hospital stay were not significantly different between Thopaz and conventional groups. Complication rates were significantly lower in the Thopaz group than conventional group. A non-significant number of chest drain re-insertions were required in the conventional drainage group. No drain re-insertions were required in the Thopaz group.	None.	The study was not blinded.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		Analogue: Mean age (range) 63 years (44-75), 22 males. Single centre (Poland). Patients recovering from pulmonary lobectomy. ●	small cell carcinomas. ●			
Pompili et al. (2014).	RCT comparing digital and traditional drainage devices. Intervention: Thopaz. ● Comparator: traditional "water seal" suction drainage. ●	325 patients were randomised (Digital: Thopaz n=191; Traditional n=190). Digital: Mean age (SD) 66.5 years (±12.1), 94 males (49%). Traditional: Mean age (SD) 65.9 (±10.2), 105 males (55%). Both systems were set at -20 cm H_2O until the morning of post-operative day one. After this period, Thopaz was set to -8 cm H_2O during the day, and the traditional system had no suction.	**Relevant to scope:** Duration of chest tube placement, length of hospital stay and patient satisfaction survey. ● **Not relevant to scope:** Air leak duration. ●	Mean duration of chest drainage and postoperative hospital stay was significantly shorter in the Thopaz (Digital) group than the traditional group. In a satisfaction survey the Thopaz group reported a significantly improved ability to arise from bed, a perceived improved system convenience and felt more comfortable being discharged home with the device if needed than those in the traditional group. Fewer Thopaz patients felt that they would prefer	A total of 6 patients did not receive their intervention (Thopaz n=2; Traditional n=4) due to ICU admission. 3 patients were lost to follow-up due to death (Thopaz n=1; Traditional n=2). The final study number was 325 patients.	Three of the authors have financial relationship with Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		Multi-centre (Italy, UK, USA, China). Pulmonary lobectomy (n=320), segmentectomy (n=56) and bi-lobectomy (n=5). ●		to change the system with another one observed in another patient. A mean difference of 2.6 days from air leak cessation to tube removal was observed and was similar in the two groups.		
Miller et al. (2016).	Two-armed observational comparative study, using propensity matching analysis, comparing digital and analogue chest drainage. Intervention: Thopaz. ● Comparator: Oasis 3600 by Atrium (analogue drainage system). ●	108 patients received chest drainage (Digital: Thopaz n=33; Analogue: Oasis n=75). Patients were propensity matched and analysed (Digital n=20; Analogue n=40). Digital: Median age (range) 63 years (48-77), 55% males. Analogue: Median age (range) 63 years (52-79), 60% males. Single centre (USA). Patients underwent VATS lung resection,	**Relevant to scope:** Duration of chest tube drainage, length of hospital stay, number of chest tube replacement procedures and complications. ● **Not relevant to scope:** Air leak duration and number of	The median total hospital stay and duration of chest tube drainage was significantly shorter in the Thopaz (Digital) group compared to the Oasis (Analogue) group. Significantly fewer complications were observed in the digital group compared to the analogue group. No chest drain reinsertions were required in either group.	None/not reported. However, a subset of patients were propensity matched using a 2:1 ratio (analogue to digital).	Two of the authors declare financial relationship with Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		(85% underwent lobectomy). ●	patients sent home with chest tube. ●			
Pompili et al. (2011).	Observational comparative study, using propensity matching analysis, comparing electronic and traditional chest drain management. Intervention: Thopaz. ● Comparator: traditional suction drainage. ●	286 patients received chest drainage (Electronic: Thopaz n=51; Traditional n=235). Consecutive patients (n=51) received drainage using Thopaz and were propensity matched with 51 historical controls from a pool of 235 patients who received traditional drainage. Both systems were set to -15 cm H_2O during the night. During the day, Thopaz was set to -8 cm H_2O, and the traditional system had no suction. Electronic: Mean age (SD) 68.5 years (±10.6), gender not reported but was used for propensity matching.	**Relevant to scope:** Duration of chest tube drainage, length of hospital stay, complications and chest tube resinsertions. ● **Not relevant to scope:** No outcomes.	Mean duration of chest tube drainage and hospital stay were significantly shorter in the Thopaz (Electronic) group than the traditional group. No complications related to chest tube management were observed in either group. No chest drain reinsertions were required in either group.	None.	One of the paper's authors has a consultant agreement with Medela.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		Traditional: Mean age (SD) 66.7 years (±10.1), gender not reported but was used for propensity matching. Single centre (Italy). Pulmonary lobectomy. ●				
Shoji et al. (2016).	Prospective observational study with propensity score matched controls. Intervention: Thopaz. ● Comparator: Analogue chest drainage system, (ACS) using "water seal". ●	233 patients received chest drainage (DCS: Thopaz n= 112, ACS n=121). DCS patients were matched, by propensity score, with historical ACS controls to give two groups of n=86. Thopaz: Mean age = 67 (range 20-87), 55 males, 31 females. ACS: Mean age 65 (range 19-87), 57 males, 29 females. Thopaz set to -13 cm H_2O in the presence of air leak, and reduced to -	**Relevant to scope:** Chest drain duration and complications. ● **Not relevant to scope:** Air leak incidence. ●	Chest drain duration was significantly shorter in the Thopaz group than ACS group. There was no significant difference in patients requiring re-drainage.	Six Thopaz patients were switched over to ACS due to implausible air leak readings. None had an air leak. This was most likely an operator error in Thopaz setup.	The six DCS patients who were switched to ACS were not part of the propensity score matched cohort.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		8 cm H_2O if there was no air leak present. All ACS set to -5 cm H_2O suction initially, and suction turned off if air leak not present. Single centre (Japan). All patients underwent pulmonary resection. ●				
Mier et al. (2010).	Three-armed prospective, comparative case study comparing two digital and an analogue chest drain systems. Intervention: Thopaz. ● Comparators: Digivent (digital chest drain system). ● Pleur-Evac (analogue water-sealed device). ●	75 patients received chest drainage (Group A: Thopaz n=26; Group B: Digivent n=24; Group C n=25). Group A: age 65.6 years, 18 males and 8 females. Group B: age 62.04 years, 17 males, 7 females. Group C: age 66 years, 20 males, 5 females (uncertain whether presented ages for all groups are medians or means).	**Relevant to scope:** Duration of chest tube therapy. ● **Not relevant to scope:** Air leak at insertion and at drain removal and survey for nursing staff. ●	The mean number of days to chest tube withdrawal was significantly shorter with Thopaz than the comparators. The comparators did not differ significantly to one another.	N=6 (2 from each group due to discharge home with a Heimlich valve).	It was unclear if the withdrawals were reflected in the final study numbers. The authors state that the mean length of stay was presented, but this is missing from the paper. Patients were not randomised to the different

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		Single centre (Spain). Patients underwent pulmonary resection for non-small cell lung cancer. ●				treatment groups.
Linder et al. (2012).	Prospective, multicentre case series of patients undergoing postoperative chest tube management. Intervention: Thopaz ● No comparator.	80 patients received chest tube therapy (Thopaz). Mean age 64.0 years (SD ±10.3); 67% male. Multi-centre (four centres in Germany). Patients undergoing pulmonary wedge resection, anatomic segmentectomy or lobectomy. ●	**Relevant to scope:** Duration of chest tube therapy and post-operative hospital stay ● **Not relevant to scope:** Air leak duration, lag of chest tube therapy and lag of discharge. ●	Average length of chest tube therapy differed significantly across centres with an average of 4.9 days. Length of hospital stay did not differ significantly across centres with and average of 7.7 days.	One patient excluded due to damage of the respective Thopaz log file.	Study funded by Medela. Four centres have different standard protocols for chest tube management.
Costa Jr et al. (2016).	Prospective observational, non-comparative study of Thopaz in paediatric patients.	11 paediatric patients received chest drainage using Thopaz. Mean age 5.9 (SD ±3.3), male n=4 (36%).	**Relevant to scope:** Duration of drainage, length of hospital stay	The mean length of stay was 4.9 days, mean duration of drainage was 2.5 days and mean drainage volume was 270.4 mL. Postoperative	No withdrawals.	Although non-comparative this paper shows the use of Thopaz in a paediatric population and

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	Intervention: Thopaz. ● No comparator.	Single-centre (Brazil), post paediatric thoracic surgery. All patients underwent pulmonary resection (lobectomy n=7, segmentectomy n=2, lobectomy and segmentectomy n=2). ●	and complications. ● **Not relevant to scope:** Air leak flow and biosafety. ●	complications were observed in two patients.		matches the intervention and outcomes in the scope.
Pneumothorax (including primary, secondary and spontaneous pneumothorax)						
Jablonski et al. (2013).	RCT comparing digital chest drainage to a traditional suction drainage system Intervention: Thopaz. ● Comparator: traditional suction (TS) drainage. ●	60 patients randomized (Group A: Thopaz n=30, air leak monitored digitally; Group B TS system connected to wall port n = 30, air leak monitored subjectively by bubble observation in the water-seal column). Pressure set to -15 cm H_2O in each group Group A: mean age 41.1 years (SD ±16.57), 23 males and 7 females.	**Relevant to scope:** Duration of drainage and length of hospital stay. ● **Not relevant to scope:** Size of air leak in mL/min, delay of surgery. ●	The mean duration of drainage was significantly shorter with Thopaz than a traditional suction drainage system. Patients receiving Thopaz chest drains were hospitalized for significantly fewer days than those receiving traditional suction drainage.	None.	All patients had air leaks assessed by Thopaz prior to randomisation.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
		Group B: mean age 40.3 years (SD ±15.74), 22 males, 8 females. Single centre (Poland) All patients had spontaneous pneumothorax with air leak. ●				
Tunnicliffe and Draper (2014).	Non-comparative observational case series (pilot study). Intervention: Thopaz ● No comparator.	13 patients received chest drainage with Thopaz. Four primary and nine secondary pneumothoraces with one patient treated in a community setting. Single centre (UK). Patients with pneumothorax (primary pneumothorax n=4, secondary n=9). ● One patient was treated in a community setting. ●	**Relevant to scope:** Length of hospital stay, length of time device was in situ, complications and patient satisfaction of the device. ● **Not relevant to scope:** Nurse and clinician experience of using the device and data	Median length of stay was 3.5 days and duration of chest tube drainage was 4 days. Patient satisfaction with Thopaz was high. One patient was positive with regards to flexibility and mobility. However, one patient was anxious about the device and another asked to be treated with a traditional water-sealed device instead.	None.	Patient comments are not quantifiable. Nurse and clinician comments are not part of the scope. The patient being treated in the community is out of scope. One of the authors received payment from Medela to

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
			gathered from the device. ●			present data at a company training day.
Company included studies excluded by EAC.	**Design and intervention(s)**	**Participants**	**Outcomes**	**Results**	**Rationale for exclusion by the EAC**	**Comments (including EAC view of exclusion)**
Rathinam et al. (2011).	End user assessment and feedback study from a single-armed retrospective case series. Intervention: Thopaz. ● No comparator.	120 patients received chest drainage No patient baseline characteristics stated. Single centre (UK). Patients underwent elective bullectomy/pleurectomy, lung resection, or VATS lung biopsy or mastectomy. ●	**Relevant to scope:** Patient feedback on the device. ● **Not relevant to scope:** Staff feedback: overall device assessment, device assembly, ease of management and satisfaction. ●	Staff feedback on Thopaz, median scores (range), where 1 = excellent, 6 = poor: Overall: 2 (2-3) Efficacy: 2 (2-3) Vacuum adjustment: 2 (1-4) Flow Readings: 3 (1-5) Display: 3 (2-4) Alarm System: 3 (1-5) Setup: 2 (1-3) Canister Change: 2 (1-3) Opinion feedback: Doctors: drain management was more	This study is out of scope. The main focus of the paper is staff feedback on Thopaz. There is patient-focused feedback (in scope), but this is represented by a single paragraph in the paper.	The patient feedback is narrative and contains no quantifiable evidence. In addition, the number of patients that the narrative summary is based on has not been noted.

Included. studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				objective and scientific with Thopaz. Patients: Thopaz portable and light, which improved mobility and independence. They preferred quietness and compactness compared to conventional drains and suction.		

3.4 Overview of methodologies of all included studies

A total of thirteen studies were included. Of these, there were six RCTs, three observational comparative studies that used propensity matching for their analysis and four observational studies with no comparative element. The comparators in almost all of the RCTs and comparative observational studies were traditional analogue chest drainage systems that used wall-mounted suction. One of the RCTs (Brunelli et al. 2013) used Thopaz at two different suction settings, and compared outcomes for these settings.

Eleven of the studies used the device in a patient population that had undergone pulmonary surgery. Two studies used the device in a patient population with pneumothorax.

The EAC considers that the evidence base for this device is quite strong, as there are several randomised studies. Also, three of the case series employ propensity-matched control cohorts, which avoids some biases and can actually match patients more closely than randomisation. Note that none of the RCTs were blinded, as the Thopaz device is significantly different from traditional suction drainage systems. Although this may present a small risk of bias, the EAC considers this to be an unavoidable limitation.

3.5 Overview and critique of the company's critical appraisal

The company submitted critical appraisal checklists for all their included studies, and used the appropriate forms for each study type. The checklists were adapted from the Centre for Reviews and Dissemination (2008).

The only company submitted randomised study (Pompili et al. 2014) is appropriately randomised by a computer-generated randomisation list concealed in sequentially numbered envelopes. The EAC agrees that the concealment of treatment allocation in this study was appropriate, and that blinding was not possible due to the visible differences between Thopaz and the standard care suction system. However, the EAC agrees that this is unlikely to carry a large risk of bias. Baseline demographics are described as well matched for each arm of this study, although the company do not provide details of this, choosing instead to reference the paper. The EAC considers

this appropriate given the range of baseline demographics and limited space in the proforma table. There is no mention of patient dropout or missing data. Therefore, it is assumed that all patients completed full follow-up.

The two observational studies are critically appraised in less detail than the randomised study. In Rathinam et al. (2011), it is not made clear how recruitment was handled, so the EAC agrees that it is “unclear” if enrolment was appropriate. This study is not concerned with clinical outcomes, so the majority of the other checklist fields are not applicable to this paper – it is a subjective staff survey study, so bias, confounding factors, patient follow-up and statistical analyses are not covered in this publication.

In Tunnicliffe and Draper (2014), the company identify that recruitment was consecutive for patients meeting the inclusion criteria. However, only 13 out of 15 eligible patients were invited to participate, and the rationale for excluding the remaining two patients is not detailed. As with Rathinam et al. (2011), this study aims to determine patient, nurse and physician experience with the device. Therefore, several of the checklist fields are not applicable to this paper including bias, confounding factors and statistical analyses. The EAC agree with the company that the patient follow-up appears to be complete where possible, and reoperations, withdrawals and deaths are accounted for by the authors.

The EAC completed its own critical appraisal of the 13 studies included in this assessment (Appendix C).

3.6 Results

Results of all the included studies are summarised below (Table 4**|** Outcomes from included studies.). We have presented scope-specific data only. The studies include those selected by the company and found independently by the EAC. Note that the EAC has excluded Rathinam et al. (2011) for lacking scope-specific data and therefore is not included in the table.

Table 4| Outcomes from included studies.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
Pulmonary resection (including lobectomy, segementectomy and wedge resection)							
Brunelli et al. (2013). - RCT. - Thopaz in two different modes; regulated suction mode (Group 1) and regulated seal mode (Group 2). - Pulmonary lobectomy.	Mean days (SD): Group 1: 4.3 (5.3), Group 2: 4.3 (6.6); p=0.7.	Mean days (SD): Group 1: 5.1 (2.4), Group 2: 6.1 (7); p=0.3.	Not a study outcome.	Cardiopulmonary complications: Group 1: 6, Group 2: 7; p=0.9.	Not a study outcome.	Not a study outcome.	Not a study outcome.
Gilbert (2015). - RCT - No air leak (Group 1) and	Median and 25th/75th percentiles: Group 1: Pleur-Evac = 3 (2.9, 4.9), Thopaz = 2.9 (2.2, 3.9); p=0.05.	Median and 25th/75th percentiles: Group 1: Pleur-Evac = 4 (3, 5), Thopaz	Group 1: Pleur-Evac 2/43 (5%), Thopaz 0/44 (0%); p=0.24.	Group 1: Pleur-Evac 6/43 (14%), Thopaz 3/44; p=0.31. Group 2: Pleur-Evac 8/42	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
air leak (Group 2). - Thopaz and Pleur-Evac. - Pulmonary resection.	Group 2: Pleur-Evac = 5.6 (4, 8.9), Thopaz = 4.9 (3.1, 6.4); p=0.11.	= 4 (3, 5); p=0.09. Group 2: Pleur-Evac = 6 (5, 9), Thopaz = 6 (4, 8); p=0.36.	Group 2: Pleur-Evac 3/42 (7%), Thopaz 0/43 (0%); p=0.12.	(19%), Thopaz 7/42 (17%); p=0.78.			
Lijkendijk et al. (2015). - RCT. -Thopaz, Thora-Seal (traditional). - Patients recovering from pulmonary lobectomy.	Median (IQR) hours: ITT: Optimal chest tube duration: Thopaz: 27 (18-57), Thora-Seal: 43.5 (21-66); Hazard ratio (HR) = 0.83; 95% CI: 0.55–1.25; p = 0.367 Actual chest tube duration: Thopaz: 41 (22-68), Thora-Seal: 46.5 (24-70), HR = 0.84 (95% CI: 0.55–1.26; p = 0.397)	Median (IQR), days: ITT: Thopaz: 4 (3-6), Thora-Seal: 5 (3-6), HR = 0.91 (95% CI: 0.59–1.39; p = 0.651) PP: Thopaz: 4 (3-5), Thora-Seal: 5 (3-6), HR = 0.71 (95% CI:	No drain reinsertions in either group.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
	PP: Optimal chest tube duration: Thopaz: 25 (16-56), Thora-Seal: 43.5 (21-66), HR = 0.80 (95% CI: 0.52–1.22; p = 0.297) Actual chest tube duration: Thopaz: 42 (22-68), Thora-Seal: 46.5 (24-70), HR = 0.80 (95% CI: 0.52–1.22; p = 0.301).	0.46–1.11; p = 0.137).					
Marjanski et al. (2013). - RCT. - Thopaz (Digital), conventional suction	Mean days: Digital: 4, Conventional: 4; p=0.919.	Mean days: Digital: 6, Conventional: 5.5; p=0.559.	Digital: 0%, Conventional: 3%; p=0.313.	Complication rates: Digital: 25%, Conventional: 50%; p=0.039. Of the complications cardiovascular	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
drainage using a glass bottle. - Patients recovering from pulmonary lobectomy.				and pulmonary complications were most common (Digital: 22%, Conventional: 47%; p=0.035).			
Pompili et al. (2014). - RCT. - Thopaz (Electronic), traditional 'water seal' suction drainage (Traditional). - Pulmonary lobectomy, segmentectomy and bi-lobectomy.	Mean days: Electronic: 3.6, Traditional: 4.7; p = 0.0001.	Mean days: Electronic: 4.6, Traditional: 5.6; p<0.0001).	Not a study outcome.	Not a study outcome.	Not a study outcome.	376 patients completed the satisfaction survey (Thopaz n=188; Traditional n=188). Thopaz patients reported an improved ability to arise from bed (p = 0.008) and a perceived improved system convenience for patients and personnel (p = 0.02), felt more comfortable being	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
						discharged home with the device if needed (p = 0.06). Fewer Thopaz patients (12 Thopaz vs. 25 traditional) felt that they would prefer to change the system with another one observed in another patient (p < 0.0001).	
Miller et al. (2016). - Comparative with propensity matched controls. - Thopaz (Digital), Oasis	Median days (range): Digital: 3.7 (1.9-6.1), Analogue: 5.3 (2.8-8.8); p=0.01.	Median days (range): Digital: 4.1 (2.1-6.7), Analogue: 5.6 (4-10.3); p=0.05	No drain reinsertions required in either group.	Digital: 22%, Analogue: 35%; p = 0.01. Of the complications, pulmonary complications were the most common (Digital:	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
3600 (Analogue). - VATS Pulmonary resection (85% lobectomy).				32%, Analogue, 40%; p = 0.01.			
Pompili et al. (2011). - Comparative with propensity matched controls. - Thopaz (Electronic), traditional suction drainage (Traditional). - Pulmonary lobectomy.	Mean days: Electronic: 2.5, Traditional: 4.4; p<0.0001.	Mean days: Electronic: 4.5, Traditional 6; p=0.0003.	No drain reinsertions required in either group.	No complications observed in either group.	Not a study outcome.	Not a study outcome.	Not a study outcome.
Shoji et al (2016).	Mean (range):	Not a study outcome.	Thopaz: 0, ACS: 2, p = 0.094	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
- Comparative study with propensity matched controls. -Thopaz, Analogue chest drainage system (ACS). - Patients recovering from pulmonary lobectomy. - Results from 86 propensity-matched pairs.	Thopaz: 2.7 (1-9), ACS: 3.7 (1-20); p = 0.031.						
Mier et al. (2010). - Prospective, non-randomised, comparative study.	Mean days (SD): Group A: 2.4 (±1.0), Group B: 3.3 (±1.0) Group C: 4.5 (±3.6). A vs. B, p=0.01; A vs. C, p<0.001; B vs. C, p=0.47.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
- Thopaz (Group A), DigiVent (Group B), Pleur-Evac (Group C). - Pulmonary resection							
Linder et al 2012. - Non-comparative case series. - Thopaz. - No comparator. - Pulmonary resection.	Mean (SD): 4.9 (± 2.8); p = 0.0348 across all centres. Highest mean duration (SD): 5.5 (±3.2). Lowest mean duration (SD): 3.6 (±1.9).	Mean (SD): 7.7 (±3.7); p=0.379 across all centres. Highest mean length of stay (SD): 10.8 (±3.1) Lowest mean length of stay (SD): 7.2 (±3.1).	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.
Costa Jr et al. (2016).	Mean (SD): 2.5 (±0.7).	Mean (SD): 4.9 (±2.6).	Not a study outcome.	Complications in 2/11 patients	Not a study outcome.	Not a study outcome.	Mean (SD): 270.4 (±166.7).

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
- Prospective, non-comparative. - Thopaz only. - Pulmonary resection.				(18%; atelectasis and pneumonia).			
Pneumothorax (including primary, secondary and spontaneous pneumothorax)							
Jablonski et al. (2014). - RCT. -Thopaz and Traditional chest drainage. - Spontaneous pneumothorax with persistent air leak.	Mean hours (SD): Thopaz = 47.63 (±24.85), Traditional = 84.93 (±36.58); p<0.001.	Mean days (SD): Thopaz = 5.1 (±1.09), Traditional = 7.00 (±1.96); p<0.001.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.	Not a study outcome.
Tunnicliffe and Draper (2014). - Non-comparative case series.	Median days (range): 4 (1-29).	Median days (range): 3.5 (1-92).	Not a study outcome.	Not a study outcome.	Not a study outcome.	Patient satisfaction with Thopaz was high. One patient made very positive	Not a study outcome.

Study.	Duration of chest tube placement/duration of drainage.	Length of hospital stay.	Incidence of drain re-insertion.	Rates of complications and device-related adverse events.	Staff time.	Patient satisfaction.	Fluid loss measurement (mL)
- Thopaz only. - Pneumo-thorax.						comments about Thopaz, with regards to flexibility and mobility. One patient was anxious about the device, and one asked for a change to a traditional water-sealed device.	

3.7 Description of the adverse events

Details of withdrawals have been presented in Table 3 and device-related adverse events have been presented as an outcome in Table 4.

Complications are not described in great detail in the included studies. Costa Jr et al. (2016) is the only included study which provides specific details of complications with Thopaz, and occurred in 2/11 (18%) cases in the series: one case of atelectasis and one of pneumonia.

Two of the RCTs (Miller et al. 2016 and Marjanski et al. 2013) broadly classify complications e.g. “respiratory”, or “cardiac”. Both studies present Thopaz as having significantly fewer complications than analogue systems and the majority of complications were respiratory in nature.

Gilbert et al. (2015) provide less detail again, simply giving a “complication rate” in patients with and without baseline air leak. Complication rates were not significantly different in the two randomised arms of the study.

The company attempted a search for adverse events related to Thopaz and Thopaz+ by utilising search terms, which included “MHRA” and “adverse event”, to search the same databases used for their clinical submission. The manufacturer did not appear to search the FDA MAUDE database for adverse events related to the device. However, they gave details of one adverse event reported through the MHRA. The case involved a problem with a docking station (an optional extra). No details have been given on whether a patient was affected.

The EAC identified a total of 5 MAUDE adverse event reports for Thopaz from 2012-2016 and have been presented below (Table 5):

Table 5| Summary of MAUDE adverse event relating to Thopaz.

Event date	Adverse event description	Outcome
09/02/16	Missing sealing ring lead to an air leak and the device did not alarm.	The patient suffered a tension pneumothorax and the patient's hospital stay was lengthened by 4-5 days before being discharged home with a chest tube. The manufacturer does not believe this would cause or contribute to the tension pneumothorax.
21/09/14	The canister kept disengaging from the Thopaz device whilst in use on a patient.	The patient's lung collapsed and may have been caused by the canister disengaging during use. The patient was treated with a different device.
05/03/13	The device would not charge and was being used on a patient at the time.	The pump was replaced with another Thopaz device. During this time the patient suffered a pneumothorax. When the pump was replaced the lung reinflated and the patient recovered.
21/02/13	The device stopped working properly.	The patient experienced respiratory distress. Thopaz was replaced with Pleur-Evac which resulted in a good outcome for the patient.
24/08/12	The device's air leak message alarmed and gave inaccurate readings.	The patient was unaffected and was treated with another type of chest drainage system.

3.8 Description and critique of evidence synthesis and meta-analysis

The company did not carry out evidence synthesis or meta-analysis. Instead the company presented a short narrative summary of the evidence from their three submitted studies.

In their narrative summary of the evidence, the company reach the following conclusions in relation to Thopaz+ compared to traditional chest drainage: Thopaz+ is safe and effective, reduces the length of time patients need a chest drain, reduces length of stay, improves clinician agreement on the best

time for drain removal and is popular with patients and staff due to its ease of use and the facility it gives to patients to enable them to mobilise while on chest drainage without having to disconnect any equipment.

The EAC does not believe that conclusions can be drawn on the patient's perspective from the company's submitted studies. The study by Rathinam et al. (2011) presents a small paragraph on the patient's perspective with no indication of how many patients were consulted to generate this perspective. It is also unclear how feedback was gathered from patients. Similarly, the study by Tunnicliffe and Draper (2014) contains a section on the patient's perspective generated through the administration of a questionnaire. However, there is no description of the questionnaire in the methods section and no information is provided on the number of patients who completed the questionnaire.

3.9 Ongoing studies

The company highlighted five ongoing studies, which they state should be published in the next year. They are summarised in the table below (Table 6), separated into different clinical areas:

Table 6| Company identified ongoing studies.

Clinical area	Description
Thoracic	A randomized comparison of active suction vs. passive chest tube drainage and regulated and unregulated pleural pressure after anatomic lung resection (APRU). Multicentre randomized clinical trial. Principal investigator: Dr Frank Detterbeck, Yale University, New Haven, US.
	The role of digital drainage in general thoracic surgery: a prospective Chinese multicentre database. Principal investigator: Dr Alan Sihoe; Hong Kong University, Shenzhen, China.
Pulmonology	Multicentre trial randomised ambulatory management of primary pneumothorax (RAMPP). Principal investigator: Dr Robert Hallifax; Royal Brompton Hospital, London, UK.
Cardiac	Comparison of two chest drainage systems. Single centre randomized clinical trial. Principal Investigator: Dr Arnaud Van Linden; Kerckhoff Klinik, Bad Nauheim, Denmark.
	Assessment of a new continuous chest drainage system for post-operative cardiac surgery: a prospective randomized control trial. Single centre randomized clinical trial. Principal Investigator: Dr Barozzi; Verona University hospital, Verona, Italy.

The EAC found only one of these studies in our online searching (the US-based study by Detterbeck et al), but found studies which were not included by the company (Table 7):

Table 7| Ongoing studies identified by the EAC.

ID Number	Description	Status
NCT01566032	Digital versus analogue pleural drainage following pulmonary resection. Thopaz vs. numerical air leak detector. Canada	Completed
NCT01776372	Comparison of pleural drainage systems on reducing pleural effusion formation following lung resection. Thopaz vs. Atrium Express Dry Seal Chest Drain. Canada.	Completed
ISRCTN46137912	Manual aspiration versus digital drainage system in spontaneous pneumothorax. Spain.	Completed

4 Economic evidence

4.1 Published economic evidence

Critique of the company's search strategy

The company did not carry out a literature search for economic evidence. The company carried out a literature search for clinical evidence only.

Critique of the company's study selection

The company relied on the study by Pompili et al. (2014), which was also submitted as clinical evidence, to provide data on chest tube drainage duration used in their submitted *de novo* cost model.

Included and excluded studies

The company did not carry out a literature search for economic evidence. However, the company utilised data on chest tube drainage in their model from Pompili et al. (2014), a study submitted to provide clinical evidence on patients undergoing pulmonary resection. They chose not to carry out cost modelling based on the paper submitted by Tunnicliffe and Draper (2014). In this study Thopaz was used for patients with pneumothorax.

The EAC believes that the company's literature search for clinical evidence did not identify all available evidence on Thopaz. With a greater body of evidence, parameters such as chest tube duration could have been altered to reflect what was observed in the literature. Similarly, the choice not to carry out economic modelling using data from patients with pneumothorax limits the applicability of the company's model.

Overview of methodologies of all included economic studies

No economic studies were identified as the company did not carry out a literature search for economic studies.

Overview and critique of the company's critical appraisal for each study

No economic studies were identified to critically appraise.

Does the company's review of economic evidence draw conclusions from the data available?

The company did not identify any economic evidence to carry out a review.

4.2 Company de novo cost analysis

Patients

The company has not explicitly stated which group of patients their economic model is based upon. However, as they used the study by Pompili et al. (2014) to provide data for model inputs the EAC assumes that the model is based on patients undergoing pulmonary resection. The patients in the study by Pompili et al. (2014) all underwent pulmonary resection (lobectomies and segmentectomies). The company did not use data on patients with pneumothorax, from the paper by Tunnicliffe and Draper (2014), in their analysis.

Technology

The economic model was based on Thopaz+, in line with the scope.

Comparator(s)

The comparator in the model was standard drainage with wall suction, in line with the scope.

Model structure

The company's model follows a simple decision tree structure with a single decision node for Thopaz+ or standard drainage with wall suction. The company did not submit a figure for the model structure, but submitted a table for the two branches (Figure 1). The company has not considered complications in their model. They have assumed that the cost of treatment with the comparator is zero, as they state that wall suction and all consumables are all readily available.

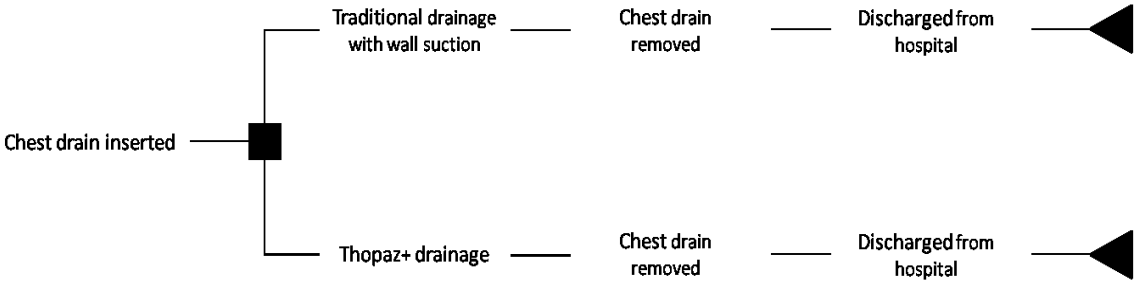

Figure 1| EAC representation of the company's submitted economic model.

Summary of the base case

Table 8| Company's base case results.

	Device	Comparator(s)	Cost saving per patient
Cost of technology per treatment/patient	£27.22	£0	-£27.22
Consumables per treatment/patient	£30.75	£0	-£30.75
Maintenance cost	£0	£0	£0
Training cost per patient	£8.10	£0	-£8.10
Total cost of device per patient	£66.07	£0	**+£66.07 (cost incurring)**
Cost of hospital stay	£1,558.20	£1,659.83	£101.63
Total cost per patient	£1,624.27	£1,659.83	**-£35.56**

Table 9| Company's submitted base-case, lowest and highest cost savings using Thopaz+.

	Base-case	Lowest estimate	Highest estimate
Range of cost-savings with device	-£35.56	+£82.26	-£149.93

Clinical parameters and variables

The company's model included data on duration of chest tube drainage and duration of hospital stay obtained from Pompili et al. (2014). This paper was submitted by the manufacturer as part of its clinical evidence submission, and has been discussed by the EAC in the clinical evidence section. The study included centres across the UK, China, Italy and USA. Data on length of stay were presented for each centre in each country. The company used the UK length of stay data from this study in its model. The data for duration of chest tube drainage was an average across all international centres. Data on duration of chest tube drainage was used by the company to calculate a per patient cost for Thopaz+, whilst data on length of stay was coupled with resource costs identified by the company. The EAC considers that Pompili et al. (2014) is a suitable study to provide clinical parameters. However, in the EAC's opinion a more robust literature search would have identified a larger number of studies with a range of chest tube duration and length of stay values to model. In terms of outcomes, the company's model focused on a reduction of post-operative stay as a driver for cost savings and was deemed appropriate by the EAC.

The company did not appear to contact Expert Advisers to inform their economic submission. In the company's model the time horizon was equal to the length of hospital stay, which was appropriate.

Resource identification, measurement and valuation

Resources identified by the company included bed costs for a range of thoracic procedures, time taken to train staff on how to use Thopaz+ and staffing costs.

A weighted average of bed costs was calculated using Healthcare Resource Groups (HRG) codes for elective and non-elective complex thoracic procedures (NHS reference costs 2015-16). The company's model also included training costs, using an estimate of the time taken for training

coupled with staffing costs (Personal Social Services Research Unit (PSSRU) unit costs of health and social care 2016).

The time taken to train staff to use Thopaz+ was an estimate by the company at 30 minutes, and clinical advice sought by the EAC indicated that this was a reasonable estimate. The company estimated that a maximum of 12 physicians/surgeons and 110 nurses/other health care staff would be trained in a unit. This cost was split over an assumed 900 uses of Thopaz+ in a year. The company was highly conservative with their estimates of staffing costs, assuming that all physicians/surgeons were at consultant level and all nurses/other health care staff were the equivalent of a Band 9. The EAC felt that assuming all nurses/other health care staff were the equivalent of a Band 9 was too conservative and increased the costs of Thopaz+. The company assumed no training was required to carry out conventional drainage. Clinical advice sought by the EAC indicated this was a reasonable assumption; medical staff usually receive training to carry out conventional drainage as medical students.

Technology and comparators' costs

Costs of the technology and comparator were presented by the company in a table. For the comparator, the company assumed there was no cost per treatment, no cost of consumables and no maintenance costs. The EAC disagrees with this approach. There are costs associated with conventional drainage including the cost of the traditional device and its associated consumables. Including these costs would increase the cost saving of Thopaz+ in the submitted model.

Costs for the treatment are based on a centre renting a Thopaz+ device and that the centre rents fewer than 25 Thopaz+ units, at a price of £115 per unit. The submitted consumable costs are based on the requirement for single tubing and using the 0.8 L canister without a solidifying agent. The company has assumed that half of patients will require two 0.8 L canisters.

The company has not explored all of the device acquisition methods available in their analysis, but this may not affect the model in a significant way. For example, high volume centres may rent more than 25 Thopaz+ units; this would reduce the monthly rental price to £105 per unit and would therefore make Thopaz+ slightly more cost saving. Other centres may purchase their devices outright, but this analysis has not been carried out by the company. The company stated that volume-dependent discounts are available when units are purchased outright. The EAC contacted the company regarding maintenance costs for purchased Thopaz+ devices and confirmed there are no routine maintenance costs. Purchased devices are covered by a warranty for the first two years then an extended warranty can be purchased at an annual cost of £165 per device for up to 3 years to give a total warranty period of 5 years. The company quoted a device lifespan of 5 years to the EAC.

Sensitivity analysis

The company did not carry out sensitivity analysis to test the structural assumptions of the model, as they state that the model was a simple decision tree. The EAC agrees this is appropriate and the model is simple. The company performed a deterministic sensitivity analysis on all variables where there was uncertainty or variability. They state that no distributions were provided in the study by Pompili et al. (2014) and therefore the duration of chest tube drainage and reduction in length of stay was varied by ±50%. The utilization rate was also varied by 50% (25%-75% utilization). The company also varied the number of canisters used, with either 1 or 2 canisters as an input. They also varied the cost of length of hospital stay between the highest and lowest unit cost identified in NHS reference costs 2015-2016. In the opinion of the EAC a more robust literature search would have provided a greater number of relevant studies to obtain data inputs for duration of chest tube drainage and reduction in length of hospital stay. However, the EAC accepts that data on length of hospital stay from the study by Pompili et al. (2014) are from a UK centre and therefore makes the model more applicable to an NHS setting, which is in line with the scope of this assessment.

The sensitivity analysis did not take into account the difference in cost of rental for Thopaz+, which is dependent on the number of units a centre rents. The sensitivity analysis also did not take into account the different canister options, in terms of canister size and whether the canister contains a solidifying agent or not. The EAC requested list prices for all consumables from the company and different canister options affect the consumable cost.

A summary of the EAC's changes to the clinical parameters in the company's model has been presented in Table 10 and a summary of additions to the model by the EAC has been presented in Table 11. In addition the EAC considered other clinical parameters whilst building its model (Table 12). These were not included in the final model due to the EAC finding no evidence to provide data for the parameters or in some instances the EAC was unable to attribute a cost to this parameter.

Table 10| EAC changes to the clinical parameters by the company in its model.

Variable	Company value	Company source and EAC comments	EAC value	EAC source and comments
Consumables (includes cost of the disposable canister).	£30.75	Company's submitted table (model). The company estimated 2 canisters would be required in 50% of patients. This gives rise to an average of 1.5 canisters used at a cost of £21.15 per patient (£14.10 per canister) and £9.60 for the disposable tubing.	£14.10 (canister) £9.70 (tubing)	The EAC kept the costs of the disposable canister and tubing separate. Single and double tubing is available. We have assumed that these are used 50/50 in patients. From the company's submitted list prices single tubing is £9.20 per piece and double tubing is £10.20 per piece.
Cost of training per patient (Thopaz+ machine).	£8.10	Company's submitted table (model). An estimate of training cost has been calculated by the company using an estimate of the time needed to carry out training, staff costs (obtained from PSSRU 2016) and an estimate of the number of patients requiring treatment with Thopaz+ as follows: • Time taken to train staff: 30 minutes	£5.29	The EAC contacted clinical experts to ask for the number of staff in their department, staff level and the number of patients treated with Thopaz+ annually. One clinical expert responded with the following information: • Time taken to train staff: 30 minutes • Number of patients treated annually with Thopaz+: 500 • 3 consultants (surgical): £137.00 per consultant per hour • 3 registrars: £59 per registrar per hour

Variable	Company value	Company source and EAC comments	EAC value	EAC source and comments
		• Number of patients requiring chest drainage following thoracic surgery: 930 • 12 physicians/surgeons at consultant level: £137 per physician/surgeon per hour. • 110 nurses at Band 9: £122 per nurse per hour.		• 6 foundation doctors (FY2): £42 per doctor per hour • 84 nurses (from band 2-7): £53 per nurse per hour (the EAC assumed all 84 nurses were at band 7 level).
Average duration of chest tube placement (Thopaz+).	3.6 days	Pompili et al. (2014).	3.5 days	The EAC calculated a weighted average using all the studies reporting mean duration of chest tube placement (8 studies).
Length of stay (Thopaz+)	4.6 days	Pompili et al. (2014). The company used results for the study's UK centre only.	5.4 days	The EAC calculated a weighted average using all the studies reporting mean length of stay for Thopaz+ (6 studies).
Length of stay (traditional)	4.9 days	Pompili et al. (2014). The study was multi-centre with results on length of stay presented for the UK centre in the	5.8 days	The EAC calculated a weighted average using all the studies reporting mean length of stay for conventional glass bottle drainage (3 studies).

Variable	Company value	Company source and EAC comments	EAC value	EAC source and comments
		study. The company used results for the UK centre only.		

Table 11| EAC additions to the company's model

Parameter	Company base-case	EAC value	Source and EAC comments
Comparator device cost per patient (Rocket drain).	Not included	£9.88	NHS supply chain. Rocket drains were identified as a comparator following advice from clinical experts.
Comparator device consumables cost per patient.	Not included	£5.81	NHS supply chain. Single and double tubing is available. We have assumed that these are used 50/50 in patients. The NHS supply chain price for single tubing is £5.69 per piece and £5.93 per piece for double tubing.
Incidence of chest drain reinsertion.	Not included	Prevalence of 0.017.	The EAC calculated a rate of chest drain reinsertion from studies presenting this outcome for Thopaz (n=5 studies) and conventional drainage (n=4 studies).
Cost of chest drain reinsertion (per patient).	Not included	£3.00 per patient	There is no NHS reference cost for chest drain reinsertion and clinical experts could not advise on an appropriate cost code. Therefore, the EAC calculated a cost per patient by multiplying the incidence of chest drain reinsertion with the cost of chest drain reinsertion. The cost for a chest drain reinsertion was estimated by the EAC following advice from clinical experts and was derived as follows:

			• Time to carry out procedure: average of 30 minutes (range: 15-45 minutes). Source: patient information sheets on chest drainage and advice from clinical experts. • Staff costs: £98 per hour (average cost based on cost per hour for a registrar and consultant). Source: PSSRU (2016). Consultant level: £137 per hour; registrar level: £59 per hour. • Rocket Seldinger chest drainage set: £60.71. Source: NHS supply chain. • New tubing cost for Rocket drain: £5.81 (assuming a 50/50 split in the need for single/double tubing). Source: NHS supply chain. • New Rocket drain: £29.64 (average of 3 required for chest drainage based on expert advice). Source: NHS supply chain. • Chest x-ray: £31.21 (average cost based on costs given in two studies): Source: Khan et al. (2008) £13.33; Beavan et al. (2010) £49.09.

Table 12| Additional clinical parameters considered by the EAC which were not included in its final model

Parameter	Reason for not including in final model	EAC's opinion on the effect of the parameter on the model
Additional drain management/staff time for Thopaz+.	No studies identified by the EAC included this outcome.	In the opinion of 2/3 of the clinical experts Thopaz+ drain management will save staff time through being able to take readings quicker than if conventional drainage is used. However, one of the clinical experts believes that this difference is negligible. If Thopaz+ did save staff time then this would lead to greater cost savings.
Time to set up a Thopaz+ device.	No studies identified by the EAC included this outcome.	This parameter could increase or decrease staff time dependent on whether more or less time is required to set up Thopaz+ and could impact on cost savings.
Reduction in the need for chest radiographs.	One study reported the number of postoperative chest radiographs required following chest drainage (Gilbert et al. 2015). The study reported a non-significant difference in the need for postoperative chest radiographs between Thopaz and conventional drainage. The use of Thopaz reduced the need for postoperative chest	Costs for a chest radiograph were presented in studies by Khan et al. (2008) and Beavan et al. (2010) and were £13.33 and £49.09 respectively. The EAC has not included this parameter in its model as the evidence was based on a single study where no significant reduction in the need for chest radiographs was shown.

Parameter	Reason for not including in final model	EAC's opinion on the effect of the parameter on the model
	radiographs by 2 in the air leak group and 1 in the non-air leak group.	
Rate of complications.	Complications are not described in great detail in the included studies. In most instances authors broadly classify complications. It is therefore difficult to determine whether the complications observed are as a result of the type of drainage used or whether the device used helped to avoid a particular complication. The broad classification of complications also means the EAC could not attribute a cost to these complications.	Two of the studies included in the clinical evidence section (Miller et al. 2016 and Marjanski et al. 2013) show that there were significantly fewer complications in patients treated with Thopaz than conventional drainage. Another study by Gilbert et al. (2015) showed fewer complications in patients treated with Thopaz than conventional drainage; however this was non-significant. If the decrease in complications observed could be attributed to Thopaz, and costs obtained for these complications, then this would lead to greater cost savings for Thopaz+.

4.3 Interpretation of economic evidence

The company did not identify any economic evidence so there were no studies to compare the results of their economic analysis against. The EAC identified two papers with some economic evidence. A paper by Southey et al. (2015) presented economic evidence for Thopaz when patients were discharged with their chest drains still in situ. This paper is outside of scope for this assessment and therefore cannot be included. Another paper by Pompili et al. (2011) contains some economic evidence but is limited in its detail. The authors present a saving of approximately €750 per patient receiving drainage with Thopaz (~£679.30; converted on 08/08/17) compared to conventional drainage. It is unclear whether Thopaz devices were provided for free and therefore is unclear if device cost has been considered in their calculations. However, in this paper the cost saving was driven mostly by a hospital stay reduction of 1.5 days in patients using Thopaz.

The company presented a scenario where Thopaz+ is used postoperatively in people undergoing pulmonary resection. However, they stated that the cost savings observed for thoracic surgery patients would be the same for non-thoracic surgery patients (e.g. people requiring treatment for pneumothorax) requiring chest drainage with Thopaz+. The company has not modeled this and did not identify a comparative study on non-surgical patients (e.g. people requiring treatment for pneumothorax) in their clinical submission. Therefore, the EAC does not feel there is evidence to back this statement.

The weaknesses and strengths of the economic analysis have been discussed by the company. The economic analysis was very conservative high costs assumed for Thopaz+ staff training, as staff were assumed to be consultants and band 9 nurses. Furthermore, no costs were assumed for the comparator in terms of device cost, consumables, maintenance or training. The EAC also agrees that data used in the model are from a robust study (Pompili et al. 2014). However, the company state that the study is from a UK centre, which is not strictly true. In their submission the company used data on length of stay from the UK centre results. However, the data for duration of chest tube drainage was an average across all international centres. The

company then used this in their calculation to determine the per patient cost of treatment for Thopaz+. This model focuses on patients undergoing thoracic surgery only, which is not fully in accordance with the scope of this assessment. The company's search did not identify any comparative studies for non-surgical patients. However, the EAC only identified one comparative non-surgical study using Thopaz+ in patients with pneumothorax (Jablonski et al. 2014). The company proposed that over time, clinical staff would gain confidence with Thopaz+, and this would lead to a reduction in total drainage time and the number of chest radiographs needed. Although these were not included as inputs in the model, the EAC did not identify any evidence to back these claims. In addition, it would be difficult to attribute these outcomes to an increase in clinician confidence over differences driven by the device itself. There are additional weaknesses in the manufacturer's submission that have not been addressed. For example, there are both rental and outright purchase schemes for obtaining Thopaz+, but only the rental scenario is presented by the company. The company also do not cost complication rates, although the clinical evidence indicates that this would likely favour Thopaz+ in the economic model, making it further cost saving.

The EAC agrees with the company's ideas for further analyses, which include inclusion of comparator costs, the number of chest radiographs and reduction in time drainage is required. Some of these analyses are likely to make Thopaz+ more cost saving, in particular the inclusion of comparator costs. Further analyses not identified by the company include modelling the rental/purchasing options for Thopaz+, modelling the different consumables available (there are different sized Thopaz+ canisters available with and without a solidifying agent) and the inclusion of complication rates.

4.4 Results of EAC analysis

The EAC has made changes and additions to the company's submitted model (as previously highlighted in Table 10 and Table 11). Summaries for the EAC's base-case, sensitivity and sub-group analyses follow.

Base-case analysis results

The EAC's base-case results are presented in Table 13.

Table 13| EAC's base-case

Parameter	Thopaz+	Conventional
Device cost per patient	£26.47	£0.00
Training cost	£5.29	£0.00
Consumables per patient	£30.85	£35.45
Cost of Bed Days	£1,829.20	£1,964.69
Complications (chest tube reinsertion)	£0.00	£3.00
Total	**£1,891.80**	**£2,003.14**
Incremental	**-£111.34**	**£0.00**

Sensitivity analysis results

The EAC carried out one-way sensitivity analysis after making its changes and additions to the model. The main driver for cost savings in the model is the reduced length of stay for patients receiving drainage with Thopaz+ (Figure 2). Other important factors include length of stay for conventional drainage, device utilisation and bed day cost. Values for the inputs and results of the one-way sensitivity analysis have been presented in Table 14. It is worth noting that the length of stay for Thopaz+ is the only parameter which could make the use of Thopaz+ cost incurring in this model. The high value used for length of stay was 7.7 days (Linder et al. 2012); this study was non-comparative. This is 2.6 days longer than the second longest length of stay observed in the literature (5.1 days in Brunelli et al. 2013) and is 2.3 days longer than the weighted average used in the EAC's base-case. As the sensitivity analysis was one-way only, the high value meant that patients treated with Thopaz+ effectively had a longer length of stay than those treated conventionally. This was observed in only one of the comparative studies included in the clinical evidence section (Marjanski et al. 2013) and was non-significant. Therefore it is not considered realistic by the EAC.

The EAC investigated the impact of length of stay in a threshold diagram (Figure 2), showing the change in cost saving in relation to the change in

length of stay for Thopaz+ compared to conventional treatment. Only a very short reduction in length of stay is required for Thopaz+ to become cost saving.

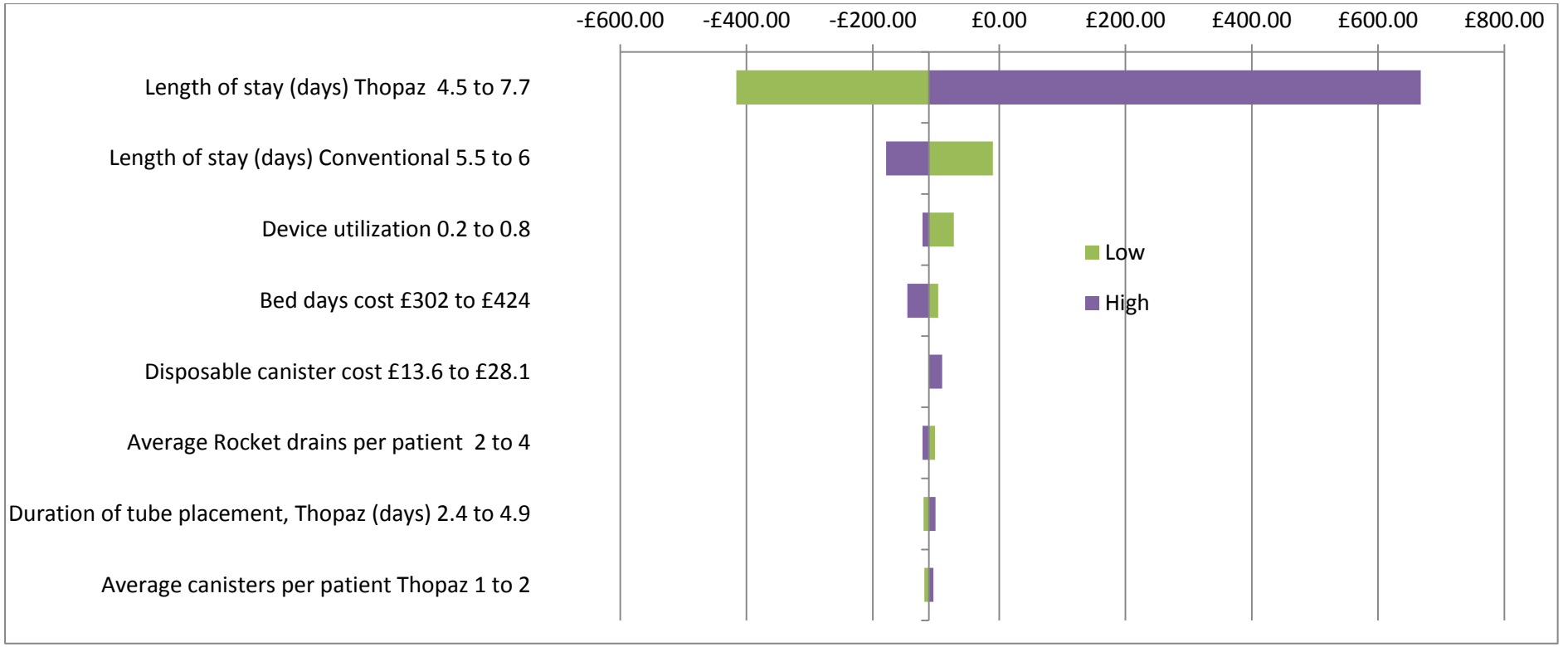

Figure 2| Tornado diagram of Thopaz+ incremental cost using the EAC's base-case, showing 8 parameters with highest impact.

Table 14| Impact of parameters in one-way sensitivity analysis of EAC's base-case

Parameter	Inputs		Results		Source of inputs
	Low	High	Low	High	
Length of stay (days): Thopaz	4.5	7.7	-£416.20	£667.77	Low and high length of stay from lowest and highest mean length of stay from studies reporting this outcome.
Length of stay (days): Conventional	5.5	6	-£9.71	-£179.08	Low and high length of stay from lowest and highest mean length of stay from studies reporting this outcome.
Device utilization	0.2	0.8	-£71.64	-£121.26	Company estimate was varied by ±30%.
Bed days cost	302	423.7	-£96.52	-£145.32	Low and high costs based on NHS reference costs for thoracic procedures.
Cost of disposable canister: Thopaz	13.6	28.09	-£112.09	-£90.35	Low cost based on list price; high cost based on NHS supply chain cost.
Average Rocket drains per patient	2	4	-£101.46	-£121.22	Low and high inputs derived from advice from a clinical expert.
Duration of tube placement (days): Thopaz	2.4	4.9	-£119.65	-£100.75	Low and high duration from lowest and highest across studies reporting mean duration of chest tube drainage.
Average canisters per patient: Thopaz	1	2	-£118.39	-£104.29	Low and high inputs derived from advice from clinical experts and from manufacturer's submission.
Rocket drain	7.9	11.86	-£105.40	-£117.28	Base cost was varied by ±20%.
Disposable tubing: Thopaz	9.2	19.66	-£111.84	-£101.38	Low cost based on single tubing list price and high cost based on double tubing NHS supply chain cost.
Daily cost: Thopaz	3.45	4.53	-£113.65	-£106.09	Low cost based on £105 rental and high cost based on base cost +20%.
Training cost: Thopaz	4.02	8.1	-£112.61	-£108.53	Low cost based on EAC calculation and high cost based on company submission.
Reinsertion rate of chest drains Conventional	0	0.007	-£108.34	-£109.57	High cost based on base rate +20%

Chest drain re-insertion cost	114	258	-£110.28	-£112.72	Low cost estimate based on a registrar taking 15 minutes to carry out the procedure using a Rocket Seldinger chest drainage set, new tubing (single), 2 Rocket drains (lowest estimate of Rocket drains required by a clinical expert) and the lowest cost for a chest X-ray. High cost estimate based on a consultant (surgical) taking 45 minutes to carry out the procedure using a Rocket Seldinger chest drainage set, new tubing (double), 4 Rocket drains (highest estimate of Rocket drains required by a clinical expert) and the highest cost for a chest X-ray.
Disposable tubing (Rocket)	5.69	5.93	-£111.22	-£111.46	Low cost based on single tubing NHS supply chain cost; high cost based on double tubing NHS supply chain cost.

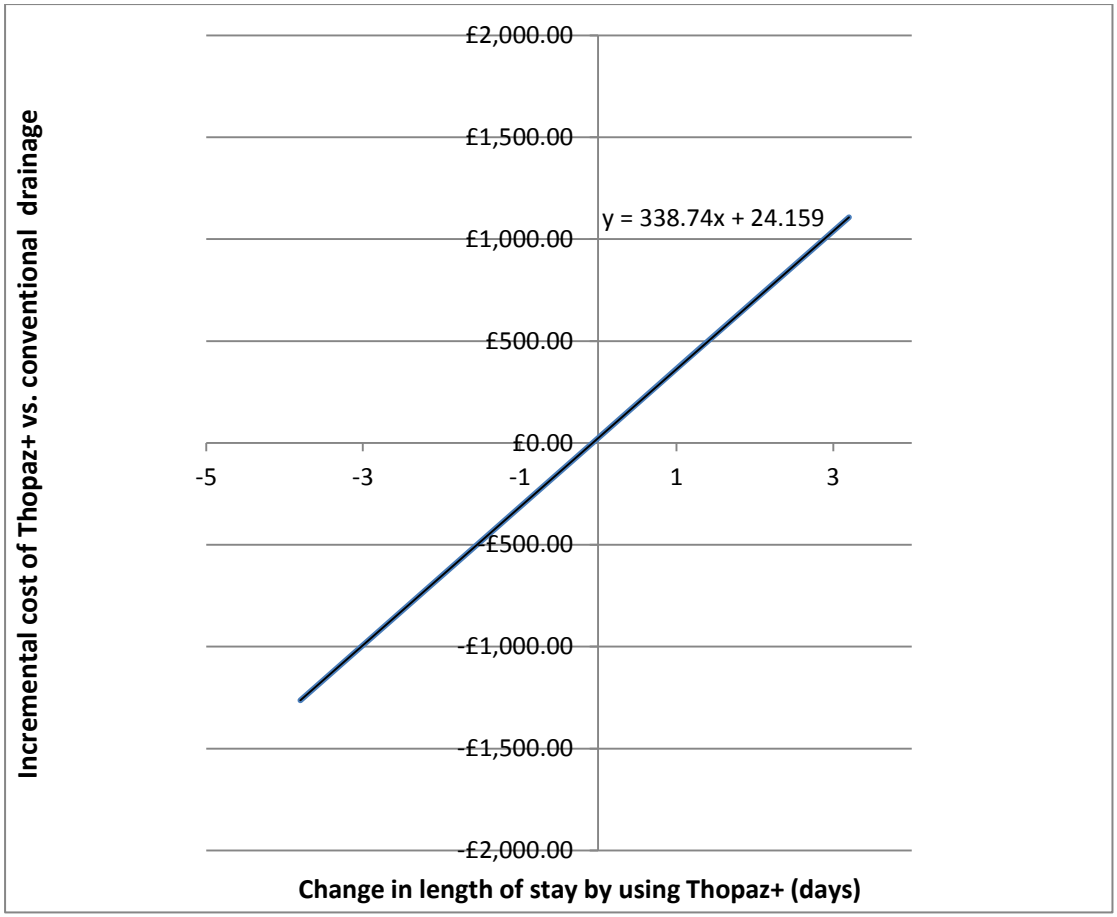

Figure 3| Threshold diagram of the incremental cost of Thopaz+ vs. conventional drainage as length of stay by using Thopaz+ changes

Subgroup and scenario analyses

The EAC carried out sub-group and scenario analyses on its base case to determine the effect on the model of purchasing a Thopaz+ device and to consider potential cost-savings if Thopaz+ is used in people with pneumothorax. Changes to the model and its effect have been presented in Table 15. Briefly, buying a Thopaz+ device leads to greater cost savings than the EAC's base-case where a Thopaz+ device is rented. This is due to a lower daily cost of the device, over a 5 year period. If users experienced higher purchase costs for consumables or increased maintenance costs the full cost savings may not be realised.

The use of Thopaz+ in patients with pneumothorax also leads to greater cost savings than the EAC's base-case, where rented Thopaz+ machines were used postoperatively for people undergoing pulmonary resection. The increased cost saving is mainly due to the greater reduction in length of stay found in this group of patients.

In addition, the EAC combined the effect of buying a Thopaz+ machine when used in patients with pneumothorax; this lead to greater cost savings than the base-case. The EAC would like to note that modelling for pneumothorax is based on length of stay data from a single study (Jablonski et al. 2014). This was the only comparative study identified by the EAC during its search for clinical evidence which assessed the use of Thopaz+ in the treatment of pneumothorax.

Table 15| Subgroup and scenario analyses carried out by the EAC

Scenario	Cost savings	Changes to the model in this scenario
Base-case (Thopaz+ machine rented and used postoperatively in people undergoing pulmonary resection).	-£111.34	Not applicable.
Buying a Thopaz+ device (Thopaz+ machine is used postoperatively in people undergoing pulmonary resection).	-£124.76	The daily device cost calculation was altered to utilise the list price and lifespan for a Thopaz+ device. No other parameters were changed. A 2 year warranty is included; consumables are priced at the same level as base case. The EAC considered the effect of purchasing an extended warranty for 3 years as part of its one-way sensitivity analysis.
Use of Thopaz+ for pneumothorax treatment (Thopaz+ machine is rented).	-£550.90	Duration of chest tube placement and length of stay for both Thopaz and conventional devices were updated with figures from Jablonski et al. (2014). The incidence of chest drain reinsertion was changed to 0 for conventional drainage as this was not an outcome in the study by Jablonski et al. (2014). No other parameters were changed.

Use of a purchased Thopaz+ machine for pneumothorax treatment	-£558.57	The daily device cost calculation was altered to utilise the list price and lifespan for a Thopaz+ device. Duration of chest tube placement and length of stay for both Thopaz and conventional devices were updated with figures from Jablonski et al. (2014). The incidence of chest drain reinsertion was changed to 0 for conventional drainage as this was not an outcome in the study by Jablonski et al. (2014).

One-way sensitivity analysis has been used to investigate the response of the model to uncertainty in parameter values where appropriate. The EAC used figures obtained from the clinical submission/clinical part of this assessment for model inputs and consulted clinical experts if required information was unavailable.

4.5 EAC Interpretation of economic evidence

Due to the simplicity of the submitted model, and the lack of comparator information, the EAC created an additional model, based on the structure of the company's submitted model. Changes made by the EAC to the clinical paramaters used by the company and additional clinical parameters have previously been presented (Table 10 and Table 11). A full list of the parameters used by the EAC in its economic model has been presented in Appendix B. Results of the EAC's new model including the base-case, sensitivity analysis results, sub-group and scenario analysis results have previously been presented (see Results of EAC analysis). The impact of the EAC's changes and additions are summarised in the "Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the External Assessment Centre" section.

The company's submission contained many assumptions. Therefore, the EAC endeavoured to use figures from the identified clinical evidence wherever possible. However, advice from clinical experts was required and sought where appropriate. The EAC has indicated the source of its parameters in Appendix C.

The EAC would like to highlight that the company's economic submission showed the use of Thopaz+ to be cost saving in the base-case. The EAC aimed to use better sources of evidence in its model to ensure that the presented cost savings were based on meaningful clinical data. In addition, the EAC considered comparator costs whilst the company did not. Incidence and cost of chest tube drainage was not considered by the company but was considered by the EAC. The changes and additions the EAC carried out in its model have lead to greater cost-savings for Thopaz+.

Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the External Assessment Centre

The EAC's base-case analysis shows that the use of Thopaz+ would save £111.34 per patient compared to the use of conventional drainage. The company's base-case showed a saving £35.55 per patient. The effect of changes to clinical and cost parameters by the EAC, which have driven the difference in cost savings between the EAC's model and the company's model, have been presented in Table 16.

Table 16| Changes and additions by the EAC to the company's base-case and its effect on cost savings.

	Company submission **Cost per patient**	**EAC model** **Cost per patient**
Changes made affecting costs of Thopaz+ • Duration of chest tube placement data (used to calculate cost per patient of device) • Thopaz+ consumable costs • Training costs for Thopaz+ • Costs for reinsertion	£66.07	£62.61
Changes made affecting costs of conventional drainage: • Consumable costs • Costs for reinsertion	£0.00	£38.45
Length of stay for Thopaz+	£1558.20	£1829.20
Length of stay for conventional drainage	£1659.83	£1964.69

5 Conclusions

5.1 Conclusions on the clinical evidence

A total of 13 studies were included by the EAC and this included 2 studies submitted by the company (Pompili et al. 2014; Tunnicliffe and Draper 2014). In the majority of the included comparative studies of Thopaz and conventional/analogue drainage, patients who underwent pulmonary resection who were treated postoperatively with Thopaz had a shorter duration of chest tube drainage (7/8 studies reporting this outcome) and a shorter length of stay (4/6 studies reporting this outcome). Only one study reported a non-significant longer length of stay for Thopaz (Marjanksi et al. 2013). No studies reported a longer duration of chest tube drainage with Thopaz. Two of the identified studies presented results for Thopaz used in patients with pneumothorax, one of which was comparative (Jablonski et al. 2013). The results of this paper show that both the duration of drainage and length of hospital stay are significantly shorter when using Thopaz. A single included study compared patient satisfaction between Thopaz and traditional drainage in patients undergoing pulmonary resection (Pompili et al. 2014). This study showed that patients treated with Thopaz had an improved ability to arise from bed, improved perceived system convenience, felt more comfortable being discharged home with the device if needed and fewer felt they would want to change the system compared with those treated with a traditional drainage device. The incidence of drain re-insertion was reported in 4 comparative papers where the incidence was non-significantly lower for Thopaz in 3 of these studies (Gilbert et al. 2015; Marjanski et al. 2013; Shoji et al. 2016) than traditional drainage. No drain re-insertions were required for patients treated with Thopaz or traditional drainage in one paper (Lijkendijk et al. 2015). The EAC found no quantitative, comparative evidence for staff time when using Thopaz.

The evidence identified by the EAC presents an unbiased estimate of the technology's treatment effect and is relevant as the population, intervention, comparators and outcomes match the scope. However, the evidence identified is mainly in patients treated with Thopaz postoperatively following

pulmonary resection. The EAC identified two studies where Thopaz was used for treatment of pneumothorax and only one was a comparative study. It would therefore be difficult to draw conclusions the effectiveness of Thopaz in this patient group. Additionally, the population identified in the scope was broad and the EAC found no evidence for the use of Thopaz outside of postoperative use in patients undergoing pulmonary resection or for the treatment of pneumothorax. The EAC did not find comparative evidence on the use of Thopaz for fluid loss measurement, an outcome in the scope. Furthermore, the EAC found no quantitative evidence for staff time using Thopaz. One identified paper looked at the use of Thopaz in a paediatric cohort (Costa Jr et al. 2016). Although non-comparative, this study was included to provide evidence for use in children in line with the "sub-groups to be considered" column of the scope. Further evidence is required to draw any conclusions on the effectiveness of Thopaz+ other than in patients undergoing pulmonary resection. It is also worth noting that centres included in each study followed different procedures for chest drain management. These are likely to affect the duration of chest tube drainage and in turn length of hospital stay.

5.2 Conclusions on the economic evidence

The company's economic submission was very simple and as such the EAC developed a model based on the company submission with its own changes and additions to clinical parameters. All changes and additions made by the EAC further increased the cost savings for Thopaz+ presented by the company in their base-case. The EAC added costs to the comparator arm of the model, which were assumed to be zero by the company. In addition, Thopaz+ remained cost saving throughout all realistic one way sensitivity analyses.

The EAC considered the effect of buying a Thopaz+ machine, which further increased cost savings, as this costs less than renting the device on a per-day/per year basis. In addition, the EAC considered the effect of using Thopaz+ in the treatment of pneumothorax and showed further cost savings, which were driven by a reduced length of stay when using Thopaz+. However,

as the EAC has previously highlighted the main driver for cost savings is the length of stay for Thopaz+ (Figure 2). Model inputs on length of stay for the EAC's pneumothorax scenario came from a single paper (Jablonski et al. 2014) and so should be treated with caution. This was the only comparative paper identified by the EAC on the use of Thopaz+ for the treatment of pneumothorax.

In conclusion, the EAC's model shows that the use of Thopaz+ leads to cost savings when used postoperatively in patients undergoing pulmonary resection. Cost savings are driven by a reduced length of stay for patients receiving chest drainage using Thopaz+.

6 Summary of the combined clinical and economic sections

The EAC identified a total of 13 studies following its own literature searching. The clinical evidence showed that postoperative use of Thopaz in patients who underwent pulmonary resection: gave rise to a shorter duration of chest tube drainage, a shorter length of stay, an improved ability to arise from bed, patients feeling more comfortable being discharged home with the device if necessary and fewer patients felt they would want to change the system compared to those treated with conventional chest drainage. Furthermore, the literature showed that no chest drain reinsertions were required when treated with Thopaz but were required infrequently when conventional drainage was used. The EAC found no quantitative evidence on the effect of Thopaz on staff time. The EAC developed its own economic model based on the company's economic submission which showed that the postoperative use of Thopaz+ in patients who underwent pulmonary resection was cost saving. In the model the main driver of cost savings was a reduction in the length of stay by using Thopaz+.

7 Implications for research

The EAC has identified a lack of evidence for the use of Thopaz+ in the treatment of pneumothorax. Further research would add to the work by Jablonski et al. (2014), where length of stay was shorter for patients treated with Thopaz than conventional drainage. Further data on length of stay would

strengthen the model inputs used by the EAC in its scenario analysis of the use of Thopaz+ to treat patients with pneumothorax. The clinical evidence included by the EAC is for Thopaz only. The company and clinical experts advised that there are no significant upgrades in Thopaz+ and therefore the clinical evidence is applicable to Thopaz+. However, the use of Thopaz+ in future studies would be welcomed in order to provide direct evidence of its effectiveness.

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Rathinam, S., Bradley, A., Cantlin, T. & Rajesh, P. (2011) Thopaz Portable Suction Systems in Thoracic Surgery: an end user assessment and feedback in a tertiary unit. Journal Of Cardiothoracic Surgery, 6, 59.

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Appendices

Appendix A – Company and EAC literature search strategies and PRISMA diagrams.

Appendix B – Costs and resources used in EAC's economic model, their sources and explanation of calculations.

Appendix C – EAC critical appraisal of included studies.

Appendix A - Company and EAC literature search strategies and PRISMA diagrams

Company search strategy:

Using OVID, searches were undertaken of Medline, Medline(R) In-process and EMBASE using the search terms (“Thopaz” OR “Thopaz+” OR “digital drainage device”) in Title OR Abstract OR Text. A search was also made of the Cochrane database, using the same search terms. Papers were included if they were written in English and published between 2008 (when Thopaz was first licensed for use in the UK) and 2017.

EAC search strategy:

Ovid MEDLINE(R)

1 ((Digital or electronic or portable) adj3 chest drain).tw. (3)

2 (((Digital or electronic or portable) adj5 (air leak or suction)) and (lung* or pleural or thora*)).tw. (25)

3 Drainage/is [Instrumentation] (4205)

4 exp Thorax/ (34199)

5 3 and 4 (76)

6 thopaz.tw. (5)

7 Drainage/is and ((chest or thoracic) and (portable or digital or electronic)).tw. (38)

8 1 or 2 or 5 or 6 or 7 (129)

9 exp animals/ not humans.sh. (4394780)

10 8 not 9 (125)

11 limit 10 to yr="2010 -Current" (62)

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations

1 ((Digital or electronic or portable) adj3 chest drain).tw. (1)

2 (((Digital or electronic or portable) adj5 (air leak or suction)) and (lung* or pleural or thora*)).tw. (3)

3 thopaz.tw. (2)

4 1 or 2 or 3 (6)

Embase

1 ((Digital or electronic or portable) adj3 chest drain).tw. (10)

2 (((Digital or electronic or portable) adj5 (air leak or suction)) and (lung* or pleural or thora*)).tw. (79)

3 thorax drainage/ (7452)

4 devices/ (74851)

5 3 and 4 (53)

6 thopaz.tw. (27)

7 1 or 2 or 5 or 6 (144)

8 limit 7 to (human and yr="2010 -Current") (134)

Scopus

(TITLE-ABS-KEY ("chest drain" AND (electronic OR digital OR portable)) OR TITLE-ABS-KEY ((digital OR electronic OR portable) AND (air

AND leak OR suction) AND (lung* OR pleural OR thora*)) OR TITLE-ABS-KEY (thopaz)) AND PUBYEAR > 2009

Cochrane Library (all relevant components)

#1 (Digital or electronic or portable) near/3 (chest drain):ti,ab,kw (Word variations have been searched)

#2 (Digital or electronic or portable) and (air leak or suction) and (lung* or pleural or thora*):ti,ab,kw (Word variations have been searched)

#3 MeSH descriptor: [Drainage] this term only and with qualifier(s): [Instrumentation - IS]

#4 MeSH descriptor: [Thorax] explode all trees

#5 #3 and #4

#6 thopaz:ti,ab,kw (Word variations have been searched)

#7 (chest or thoracic) and (portable or digital or electronic):ti,ab,kw (Word variations have been searched)

#8 #3 and #7

#9 #1 or #2 or #5 or #6 or #8

Web of Science

(TITLE-ABS-KEY ("chest drain" AND (electronic OR digital OR portable)) OR TITLE-ABS-KEY ((digital OR electronic OR portable) AND (air AND leak OR suction) AND (lung* OR pleural OR thora*)) OR TITLE-ABS-KEY (thopaz)) AND PUBYEAR > 2009

ECONLit

TX thopaz OR TX chest drain* OR TX (air leak or suction) and (lung* or pleural or thora*)

Pubmed (‘epub ahead of press’ search for ‘pubstatusaheadofprint AND key subject term’)

(((pubstatusaheadofprint AND digital chest drain*) OR (thopaz) OR (pubstatusaheadofprint AND digital leak lung)) OR (pubstatusaheadofprint

AND digital suction lung) OR (pubstatusaheadofprint AND digital thorac* drain*)))

ICTRP

Searched for Thopaz.

Clinicaltrials.gov

Searched for Thopaz.

MAUDE FDA

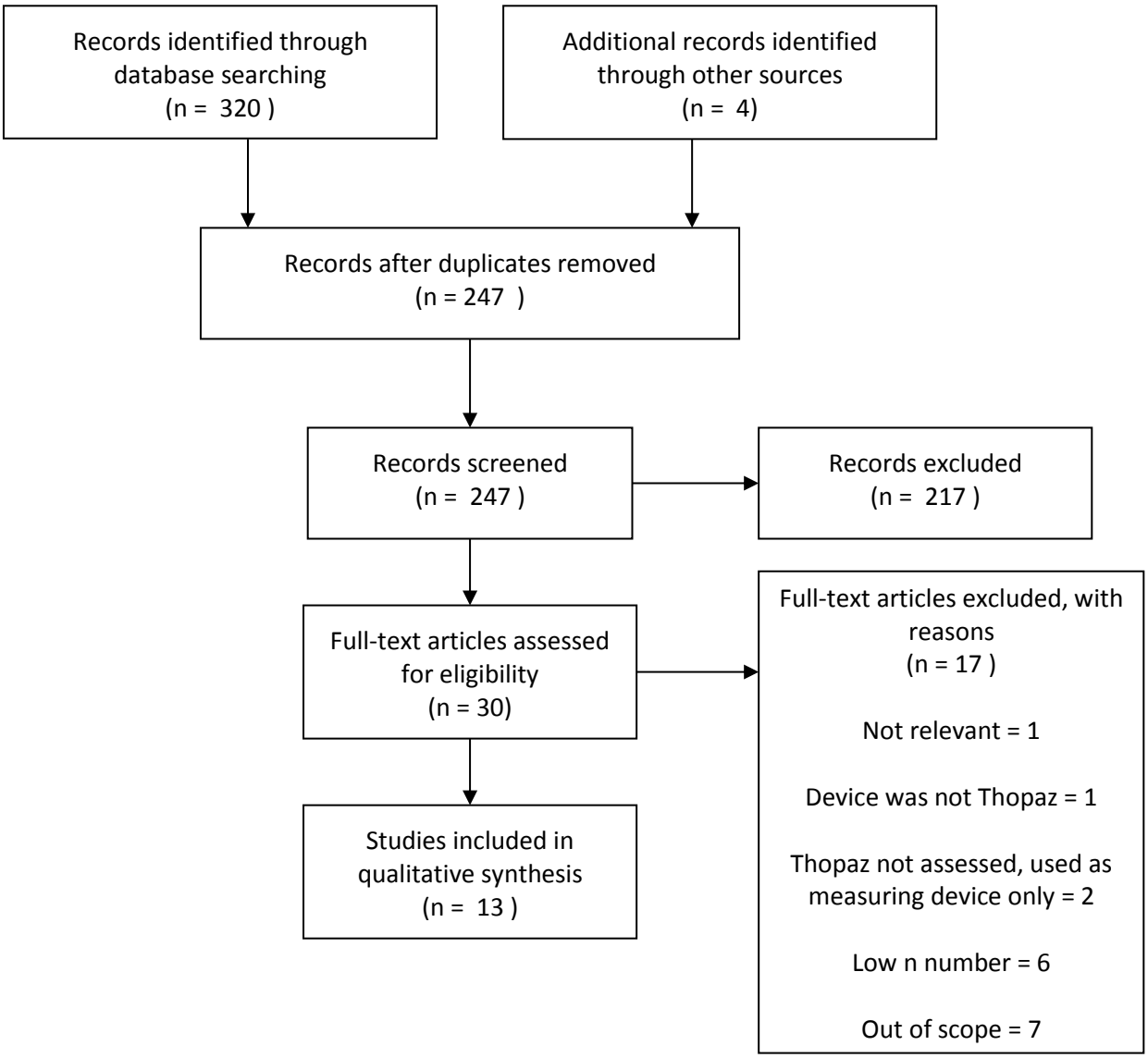
Searched for Thopaz.

MHRA

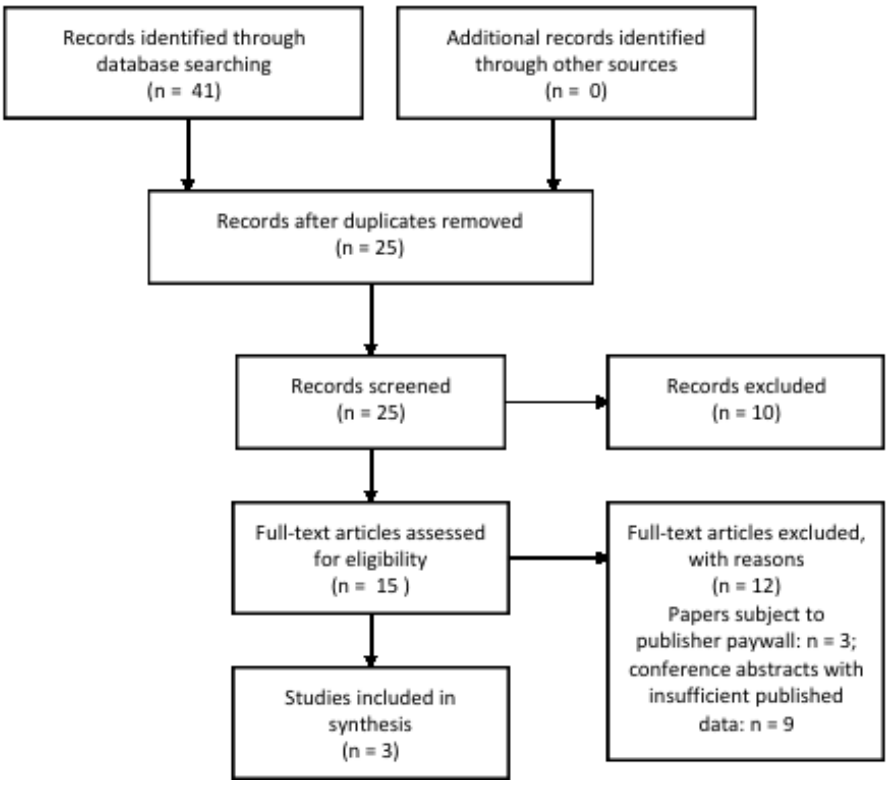
Searched for Thopaz or Medela.

National Technical Reports Library

Searched for Thopaz.



Appendix Figure 1| PRISMA diagram of clinical studies included by EAC.



Appendix Figure 2**|** PRISMA diagram of clinical studies included by the manufacturer.

Appendix B – Costs and resources used in EAC's economic model, their sources and explanation of calculations.

Parameter	Cost/number	Source
Thopaz+ Equipment costs		
Device capital cost	£3,400.00	Company statement and company submitted list prices.
Lifespan (years)	5	From company.
Calculated daily cost for purchase	£1.86	EAC calculation based on the cost of the device spread over 5 years. Maintenance costs included in price. Warranty for 2 years and then an extended warranty can be purchased.
Monthly rental	£115.00	Company statement, Price for <25 units, includes any repairs.
Daily cost for rental	£3.78	Calculated from the monthly rental cost.
Thopaz+ Consumable items		
Disposable canister	£14.10	From company's economic submission. Different sizes and types are available.
Disposable tubing	£9.70	From company's submitted list prices. Different sizes and types are available.
Conventional equipment costs		
Rocket drain	£9.88	2/3 clinical experts advised that Rocket drains are used by their trust. NHS Supply chain - no tubing.
Wall suction unit	£0.00	EAC. This is already in place for other procedures.
Sterilisation cost for bottles	£0.00	EAC considered this early on but it is not applicable to Rocket drains.
Disposable tubing	£5.81	NHS Supply chain.

Staff costs		
Consultant (surgical)	£137.00	PSSRU 2016.
Registrar	£59.00	PSSRU 2016.
FY2	£42.00	PSSRU 2016.
Nurse, band 9	£122.00	PSSRU 2016.
Nurse, band 8a	£62.00	PSSRU 2016.
Nurse, band 7	£53.00	PSSRU 2016.
Nurse, band 6	£44.00	PSSRU 2016.
Bed days cost		
Bed day cost	£338.74	Company weighted mean calculation based on NHS reference costs.
Cost of complications		
Chest drain re-insertion	£176.37	EAC estimate based on information from a clinical expert.

Resources	**Number**	**Source**
Consultants on unit	3	Advice from a clinical expert.
Registrars on unit	3	Advice from a clinical expert.
FY2	6	Advice from a clinical expert.
Band 9 nurses on unit	0	Advice from a clinical expert.
Band 8a nurses on unit	0	
Band 7 nurses on unit	84	
Band 6 nurses on unit	0	
Total hourly staff cost for unit	5292	Calculated by multiplying the number of staff with their associated costs.

Number of patients annually on unit	500	Estimate by clinical expert.

Resources	Thopaz+	Source	Conventional	Source
Training time (hours)	0.5	Company estimate and corroborated by clinical advice.	0	A clinical expert advised that medical staff are usually trained conventional drainage as medical students.
Device utilization	0.5	Company estimate and corroborated by clinical advice.	N/A	
Average canisters used per patient	1.5	Company estimate and corroborated by clinical advice.	3	Advice from clinical expert.
Additional set up for Thopaz (hours)	0		0	
Additional drain management/staff time for Thopaz (hours)	0		0	
Duration of tube placement (days)	3.5	Weighted average. EAC calculation from the literature.	4.3	Weighted average. EAC calculation from the literature
Length of stay (days)	5.4	Weighted average. EAC calculation from the literature.	5.8	Weighted average. EAC calculation from the literature

Postoperative chest radiographs	N/A		N/A	
Reinsertion of chest drains	0	From all clinical studies	0.017	Prevalence ratio. EAC calculation from the literature.
Complication rate	N/A		N/A	

Calculations	**Thopaz**		**Conventional**	
Device cost per patient	£26.47	Calculated by dividing the daily cost of Thopaz by the device utilisation and multiplying by the duration of chest tube drainage.	£0.00	N/A
Training cost	£5.29	Calculated by multiplying the total hourly staff cost per unit by training time and dividing by the number of patients annually on the unit.	£0.00	N/A
Additional time using device	£0.00	N/A	£0.00	N/A
Consumables per patient	£30.85	Calculated by multiplying the cost of a Thopaz+ canister with the average number of canisters used per patient then adding the cost of tubing for Thopaz+.	£35.45	Calculated by multiplying the cost of a Rocket drain by the number of canisters (Rocket drains) used per patient then adding the cost of tubing for a Rocket drain.
Cost of Bed Days	£1,829.20	Calculated by multiplying the bed day cost by the length of stay for Thopaz+.	£1,964.69	Calculated by multiplying the bed day cost by the length of stay for conventional drainage.

Complications	£0.00	Calculated by multiplying the EAC's estimated cost of reinsertion by the EAC's calculated reinsertion rate for Thopaz+.	£3.00	Calculated by multiplying the EAC's estimated cost of reinsertion by the EAC's calculated reinsertion rate for conventional drainage.

Appendix C – EAC critical appraisal of included studies.

The critical appraisal checklists used below are produced by the Specialist Unit for Review Evidence (SURE). The following checklists were used:

- Specialist Unit for Review Evidence (SURE) 2016. Questions to assist with the critical appraisal of randomised controlled trials and other experimental studies available at: http://www.cardiff.ac.uk/insrv/libraries/sure/checklists.html
- Specialist Unit for Review Evidence (SURE) 2016. Questions to assist with the critical appraisal of a case series Available at: http://www.cardiff.ac.uk/insrv/libraries/sure/checklists.html
- Specialist Unit for Review Evidence (SURE) 2016. Questions to assist with the critical appraisal of cohort studies. Available at: http://www.cardiff.ac.uk/insrv/libraries/sure/checklists.html

Citation: Brunelli et al. (2013)	
Study Design: Single centre RCT with blinded air leak assessment.	
1. Does the study address a clearly focused question/hypothesis	Yes To compare the effect of two controlled chest tube modes on the duration of air leak following pulmonary lobectomy by using an electronic regulated suction system.
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Pulmonary lobectomy for lung cancer. Intervention: Thopaz in regulated individualised suction mode. Comparator: Thopaz in regulated seal mode. Outcomes: Average air leak duration, incidence of air leak lasting longer than 7 days and complications. Primary outcome: Average air leak duration.
2. Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	Yes. Simple unrestricted randomisation was performed following the Consolidated Standards of Reporting Trials (CONSORT) criteria and guidelines.

		The exact method used for randomisation was not stated.
3.	Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	Uncertain. There is no mention of concealment in the paper.
4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	Investigator was blinded. The duration of air leak was assessed from the data downloaded from the device and analysed by an investigator blinded to the patients' group assignments.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. Well described. Aside from the intervention the groups were treated equally.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. The study was approved by the local Institutional Review Board, and all patients gave their consent to participate in the trial.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	No trial protocol was published.
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	No. Authors present baseline characteristics of the two groups. There was a significant difference between the groups in terms of gender and FEV1/FVC ratio.
9.	Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Yes. Sample size was calculated to detect a difference of 1 day in air leak duration based on historical internal data and to reach a statistical power of 80% ($\alpha = 0.05$).
10.	Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised?	Yes. All patients allocated received the intervention, none discontinued and none were lost to follow up.

Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	ITT analysis was not required. Follow-up was not required.
11. Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. A statistical method and variables section adequately describes the methods used. There were no missing data. Steps were taken to minimise the effect of age, sex and height on certain variables. There was no loss to follow-up.
12. Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	Outcome measures were objective and based on quantitative data. All outcome measures were complete and all outcomes that were relevant to this study were assessed. Yes, the conclusions are supported by the results.
13. Is any sponsorship/conflict of interest reported?	A. Brunelli has a consultancy agreement with Medela.
14. Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	The authors identified several limitations: Results may not be generalisable to patients receiving other types of resections. The authors also commented on the appropriateness of the level of suction in the regulated suction group. The authors were not able to analyse the effect of regulated suction on patients with prolonged air leak as patients were not discharged with Thopaz because of “regulatory reasons”.

Citation: Costa Jr et al. (2016) *Are there other companion papers from the same study?*	
	Not that I can find. There may be future papers as the authors state this paper is part of a project called “Dreno Digital”.
1. Is the study design clearly stated? Consider if retrospective or prospective	Yes. Prospective non-comparative observational study involving consecutive patients.
2. Does the study address a clearly focused question? Consider: population and outcomes (are these appropriate?)	Yes. Population: Paediatric patients undergoing pulmonary resection. Exposure: Thopaz (parameters used have been described).

	Comparator: No comparator. Outcomes: air leak, biosafety, duration of drainage, length of hospital stay and complications.
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; follow-up & data collection.	Not in full. The setting has been described (paediatric thoracic surgery outpatient clinic). Recruitment period, follow-up and data collection dates have not been stated.
4. Are there explicit inclusion/exclusion criteria?	Yes. Inclusion criteria were stated and were as follows: being treated at a paediatric thoracic surgery outpatient clinic; being ≤ 14 years of age; and having an indication for pulmonary resection (lobectomy or segmentectomy via muscle-sparing thoracotomy). Exclusion criteria were stated and were as follows: renal or hepatic failure; neurological dysfunction; reoperation; emergency operation; preoperative chemotherapy or radiotherapy; and chest wall resection.
5. Were patients enrolled consecutively?	Yes.
6. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Some participant characteristics have been supplied. These include age, gender procedure carried out and clinical condition. A baseline table has not been included. These characteristics have been described in the body of the paper.
7. Are outcome measures appropriate? Consider if: the methods of assessment are valid & reliable.	Yes. The measures of exposures appear reliable. Thopaz was used in assess when a chest tube could be removed.
8. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) considered/controlled for.	Not required. No statistical analysis has been carried out as this was a non-comparative study and so there were no statistical methods to describe. There does not appear to have been missing data.

	There was no mention of confounding factors and no statistical analysis was carried out.
9. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	Not much. The number of patients that have been enrolled has been presented and that is all. There is no flow diagram. Missing participant data and information on follow-up has not been presented. It appears that the outcome results have been generated from all study participants. It is not clear if all participants at enrolled at the start of the study completed it.
10. Are the results well described? Consider if: effect sizes, confidence intervals/standard deviations provided; the results support the conclusions and are they the same in the abstract and the full text.	Yes. The main study outcomes have been presented in a table with means, standard deviations and range. The results support the conclusions and are the same in the abstract and full text.
11. Is any sponsorship/conflict of interest reported?	No information on conflict of interest has been included in the study.
12. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes, the authors identified the following limitations: the study contained a limited number of patients. This has been captured above.

Citation: Gilbert et al. (2015)	
Study Design: Single centre, un-blinded RCT.	
1. Does the study address a clearly focused question/hypothesis	Yes The hypothesis was that clinical outcomes associated with the use of digital drainage devices would improve, irrespective of air leak status after lung resection.
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: patients undergoing pulmonary resection (lobectomy and segmentectomy). Intervention: Thopaz Comparator: Pleur-Evac (analogue water sealed device). Outcomes: duration of drainage, length of hospital stay, number of chest tube

		reinsertions, complications, number of chest tube clamping trials and the number of postoperative chest radiographs. Primary outcome was length of hospitalization (as defined by the interval between the end of surgery and the time of discharge from inpatient thoracic surgical care).
2.	Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	Yes Patients were stratified to presence or absence of air leak and then randomised. Patients were randomised using variable-size randomisation blocks (1:1) ratio generated using atmospheric noise entropy.
3.	Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	Unsure A computer programmer within the research team created an encrypted randomisation database. But it is not clear if allocation was concealed.
4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	No. Participants and investigators were not blinded due to difficulties concealing differences in size and function between the two devices. However, the operating surgeon was blinded to the air leak group assignment, as a means to reduce potential bias in postoperative bedside assessment and clinical management.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes Both the intervention and the control groups for the air leak and no air leak stratified patients have been described well. Intervention and comparator groups were treated equally.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. The authors report approval was obtained from the institutional research ethics board.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical	No.

	trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	Yes. Baseline characteristics have been provided for each stratified group and within each group for the two device arms. Statistical analysis of baseline characteristics has been carried out for the device arms within each stratified group but not between stratified groups. For the no air leak group FEV1% was significantly different between analogue and Thopaz groups. There were no statistically significant baseline characteristics in the air leak group.
9.	Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Yes. To determine if the use of digital devices could significantly shorten hospitalization, by 1 full day, the required sample size was 40 patients in each of the 4 randomization arms (n = 160; α-error = 5%; β-error = 20%). Each group had >40 participants.
10.	Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Yes. No patients were lost to follow-up. Patients were analysed in the groups they were randomised and allocated to. ITT was not carried out. Follow-up period was not stated.
11.	Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. A statistical analysis section describes the statistical analyses carried out. There does not appear to be missing data. No patients were lost to follow-up.
12.	Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	The outcomes were objective measures with statistical analysis carried out, 25th and 75th percentiles have been presented where appropriate. All the outcome measures outlined by the authors have been addressed and all important outcomes were assessed. The conclusions are backed by the results.
13.	Is any sponsorship/conflict of interest reported?	Disposable items for Thopaz were purchased from Medela at a discounted price. The authors state Medela was not involved with any part of the study.
14.	Finally…consider: Did the authors identify any limitations?	The authors identified some limitations: Results of a single centre study may not be generalisable to other centres.

Are the conclusions the same in the abstract and the full text?	Misclassification of air leak status may have occurred due to the low accuracy of analogue devices used. The lack of blinding may have affected the results but it is a common problem with previous digital drainage trials. Length of stay can be influenced by other factors. The study was not powered to detect significant differences in length of stay when <1 day. The 24 hours delay in randomisation is a study artefact and would not happen in a real-world setting. Yes.

Citation: Jablonski et al. (2014)	
Study Design: Single centre, RCT (unsure if blinded).	
1. Does the study address a clearly focused question/hypothesis	Yes The efficacy of the treatment of air leak in patients with spontaneous pneumothorax was assessed with the use of two types of drainage.
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Patients with symptomatic spontaneous pneumothorax, in whom air leak was observed during treatment with the use of chest suction drainage. Intervention: Thopaz Comparator: Traditional analogue system connected to wall suction. Outcomes: size of air leak, duration of chest tube drainage, delay in surgery, overall length of hospital stay and hospitalisation costs.
2. Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	Yes. Authors do not state how patients were randomised.
3. Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	Unsure. Details on the randomisation process have not been presented in the paper.

4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	Unsure. Details on the randomisation process have not been presented in the paper.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. Both the intervention and comparator have been well described. The intervention and comparator groups were not treated equally. Both groups received the same value of negative pressure. However, the criteria for chest tube removal were different and were tailored to the device used.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. A local research ethics committee approved the study protocol.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	No.
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	Yes. A limited number of patient characteristics including age and gender have been presented by the authors. However, no statistical analysis of these characteristics has been presented.
9.	Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Unsure. No sample size calculation has been provided.
10.	Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Yes. All patients randomised were analysed and it appears none were lost to follow-up. No ITT was carried out as no patients were lost. Follow-up period was not stated.
11.	Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. Statistical analyses carried out are described in a dedicated section with a description of how the analyses were carried out. There does not appear to have been any missing data. No patients were lost to follow-up.
12.	Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed?	All outcome measures were objective and complete. Important outcome measures were assessed. The conclusions are supported by the results.

	Are the authors' conclusions adequately supported by the results?	
13.	Is any sponsorship/conflict of interest reported?	No conflicts of interest were declared.
14.	Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	No. However, there are a few limitations that include the lack of information on the randomisation procedures and lack of sample size calculation. The study does not describe baseline characteristics in detail and does not contain statistical analysis of demographic variables. In addition, this is a single centre study and so may affect the generalisability of the results to other centres. The conclusions in the abstract match the full text and are supported by the results.

Citation: Lijkendijk et al. (2015)		
Study Design: Single centre, un-blinded RCT		
1.	Does the study address a clearly focused question/hypothesis	No The RCT was conducted as an evaluation before adopting electronic drainage systems as a routine following thoracic surgery.
	Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Patients undergoing pulmonary lobectomy. Intervention: Thopaz. Comparator: Thora-Seal (analogue system) Outcomes: Chest drain duration, length of hospital stay and number of chest tube replacements. The primary outcome was
2.	Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	Yes. Randomization was done by use of sequentially numbered, opaque, sealed envelopes managed by the research unit of the department.
3.	Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to?	Yes. The sealed envelope was opened by the research unit, and read to the surgeon at the end of surgery.

	As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	
4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	No. Neither participants nor the investigators were blinded due to visible differences between the two drainage systems used in the study. Assessment of outcomes was not blinded.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. The intervention and comparator was well described. The two groups were not treated equally. Both groups received the same routine postoperative observation regimen, pain management and were mobilised on the same day of surgery. However, suction was applied to in the Thopaz group whilst gravity (with no suction) was used for the traditional drainage group. Air leak assessment was different in each group due to the devices used.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. The study was approved by the Regional Ethics Committee and the Danish Data Protection Agency.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	No.
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	Yes. A comprehensive table of baseline characteristics was presented by the authors and included age, gender, FEV1% etc. No significant differences in the baseline characteristics between the two groups were observed.
9.	Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Unsure. The study was powered to detect a difference in length of hospitalization of a least 1 day because a shorter hospital stay would reduce costs. However, the number of patients needed to recruit into the study to satisfy the power calculation has not been presented.
10.	Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which	Yes. No patients were lost to follow-up. It is unclear what the duration of follow-up was.

	they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Five patients were excluded from per-protocol analysis (study protocol violation n=4; outlier n=1). ITT was carried out and included the 5 excluded patients. In addition a per-protocol analysis was also carried out. The duration of follow-up was not noted.
11.	Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. The methods used by the authors have been presented. There was no missing data, but the 5 excluded patients were included in an ITT analysis. A per-protocol analysis was also carried out without the 5 excluded patients. Patients were randomised in order to reduce potential sources of bias. Statistical analysis of baseline characteristics shows that these patients were similar in terms of baseline characteristics. Cox proportional hazard regression analysis was carried out by the authors and was adjusted for FEV_1, gender, age, BMI, surgical approach, pleural adhesions and/or incomplete inter-lobar fissures to control for confounding factors. There was no loss to follow up. However, the 5 excluded participants were included in an ITT analysis.
12.	Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	The outcomes were objective. All outcome measures were complete. All important outcomes were assessed in an ITT and per-protocol analysis. The results support the conclusions.
13.	Is any sponsorship/conflict of interest reported?	The authors declared no conflict of interest.
14.	Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	Yes. The authors identified the following limitations: the intervention was not blinded to the patients and staff in the ward, the electronic drainage system group did in fact consist of two simultaneous interventions compared with the control group (it was electronic and at the same time applied suction) our routine is to facilitate early mobilization in all patients, and this would not have been possible if we applied external suction to our traditional drainage system, the limited sample size, we may have overlooked a difference between the two drainage systems (which was less than 1 day), but the study was powered to detect a

	difference in length of hospitalization of a least 1 day because this was considered to be a clinically relevant difference for the patient as a shorter hospital stay would reduce costs. The conclusions in the abstract match those in the text and are backed by the results.

Citation: Linder et al. (2012). Are there other companion papers from the same study?	
	Can't tell – there is another study looking at a standardised chest tube protocol in a specified subgroup of patients. However, this study appears to have been terminated.
1. Is the study design clearly stated? Consider if retrospective or prospective	Yes. Prospective multicentre case series.
2. Does the study address a clearly focused question? Consider: population and outcomes (are these appropriate?)	Yes. Population: Patients undergoing pulmonary resection (wedge resection, anatomic segmentectomy or lobectomy) treated with Thopaz. Outcomes: Duration of chest tube therapy, post-operative hospital stay, air leak duration, lag of chest tube therapy and lag of discharge.
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; follow-up & data collection.	Yes. This was a multi-centre study across 4 German thoracic surgery specialist units (Klinikum Bremen Ost (KBO), Bremen; Klinik Schillerhoehe (KSH), Gerlingen; Katholisches Klinikum (KKK), Koblenz; Evangelische Lungenklinik Berlin (ELK), Berlin). The recruitment (and data collection) period was between April-August 2009. Follow-up time was not noted.
4. Are there explicit inclusion/exclusion criteria?	Yes. Inclusion criteria were as follows: age 18–85, pulmonary wedge resection, anatomic segmentectomy or lobectomy with informed consent.

	Exclusion criteria: spontaneous pneumothorax (primary and secondary), pleural empyema, medication with corticoids, immunosuppressive drugs or platelet aggregation inhibitors other than Aspirin, previous chemotherapy, previous radiotherapy of the chest and previous ipsilateral thoracic surgery.
5. Were patients enrolled consecutively?	Unclear. This has not been mentioned in the paper.
6. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Yes. A table has been included and contains a summary of patient demographics across the 4 centres in the study. The table includes: age, gender, BMI, indication for surgery and type of surgery. There was no significant difference across the centres for these variables.
7. Are outcome measures appropriate? Consider if: the methods of assessment are valid & reliable.	Yes. The methods of assessment appear valid and reliable.
8. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) considered/controlled for.	Yes. The authors have included a section to describe the statistical methods followed. There does not appear to be any missing data. Confounding factors were controlled for through randomisation. None of the statistical methods used controlled for baseline characteristics.
9. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	Yes. There is no flow diagram of patient flow. One patient was excluded die to damage of their Thopaz log file. There were no other drop outs. There does not appear to be any missing data. Follow-up time has not been noted.
10. Are the results well described?	Yes. The main study outcomes have been

Consider if: effect sizes, confidence intervals/standard deviations provided; the results support the conclusions and are they the same in the abstract and the full text.	presented in a table, with baseline patient characteristics, for each centre and then overall. Means have been presented with standard deviation. The results match the conclusions and are the same in the abstract and full text. The full text however pays particular attention to the difference in chest tube protocols that are followed in different centres.
11. Is any sponsorship/conflict of interest reported?	The study was funded by Medela.
12. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes. The authors note the following limitation: varying postoperative ChT management protocols on one hand limits the significance of our findings, and on the other hand provides useful comparative-effectiveness evidence and therefore is specific to the German health care situation, but may be applicable to other European settings that unequivocally differ from the health care system of the USA, where most of the published evidence and recommendations on ChT therapy and fast-track approaches have been made. The limitation is not captured above.

Citation: Marjanski et al. (2013)	
Study Design: Single centre, un-blinded RCT	
1. Does the study address a clearly focused question/hypothesis	Yes To evaluate the influence of digital drainage on complication rates, drainage duration, and hospitalization time after lobectomy.
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Patients undergoing pulmonary lobectomy. Intervention: Thopaz Comparator: Traditional suction drainage using Sherwood glass bottles with suction provided via a central wall suction system. Outcomes: Complication rates, number of chest tube replacements, drainage duration,

		hospitalisation time after lobectomy, histology of resections and stages of resected non-small cell carcinomas. Unsure there appear to be a few primary outcomes including: the effect of digital drainage on hospital duration and postoperative complications.
2.	Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	Yes. Unsure, the method of randomisation has not been noted by the authors.
3.	Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	Unsure. Randomisation methods have not been presented by the authors.
4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	No. Neither the participants nor investigators were blinded. Assessment of outcomes did not appear to be blinded.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. The intervention and comparators were described adequately. The two groups were treated differently as air leak assessment differs in the two groups.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. Ethical approval was granted by the University Ethics Committee of the Medical University of Gdańsk.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	No.
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	Yes. Comprehensive baseline characteristics were presented by the authors. All baseline characteristics were similar in the two groups. The only significant difference was in the number of right lower lobectomies carried

	out with a higher number in the control group.
9. Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Unsure. There was no sample size calculation.
10. Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Yes. Follow-up period is unclear. However, all patients who entered the study were analysed. Patients were analysed in the groups they were allocated. No ITT was carried out as no patients withdrew from the study Unsure, the duration of follow-up has not been stated.
11. Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. The methods followed have been described in a paragraph. There were no missing data. Potential confounding factors have been accounted for through randomisation and the two groups appear similar. There was no loss to follow-up. All patients entered on the study were analysed.
12. Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	Results were objective and quantifiable. It would have been helpful to state the drainage duration and length of hospital stay in the results section of the paper. These have been mentioned in the abstract but in the body of the paper are presented as graphs with no figures. All outcome measurements appear complete. All outcome measures identified by the authors have been analysed. The authors' conclusions are supported by the results.
13. Is any sponsorship/conflict of interest reported?	There is no section declaring conflicts of interest in the paper.
14. Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	Yes, the authors identified the following limitations: The study was not blinded, and in this case this could cause some bias, low patient numbers gives rise to a chance that the results are incidental. The study was single centre and so may affect the generalisability of the results. Conclusions in the text match the abstract

	and are supported by the results.

Citation: Mier et al. (2010)	
Study Design: Prospective, comparative, non-randomised trial.	
1. Does the study address a clearly focused question/hypothesis	No. The aim of the study was to report the authors' experience by comparing the performance of two digital devices and, in turn that of the one normally used.
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Patients undergoing pulmonary resection. Intervention: Thopaz Comparators: DigiVent (digital device) and Pleur-Evac (analogue system). Outcomes: Duration of chest tube therapy, air leak at insertion and at drain removal and a survey for nursing staff. Cannot identify the primary outcome.
2. Was the population randomised? If YES, were appropriate methods used? Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	No.
3. Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	No. Patients were not randomised to each device.
4. Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	No. Patients were not randomised to each device.
5. Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. The intervention and comparators were described well. There were differences in the way the patients in each group were treated. The same surgical technique was used for all patients. Drains were removed based on different thresholds dependent on whether the patient received digital or analogue

	drainage.
6. Was ethical approval sought and received? Do the authors report this?	Yes. Ethical approval was granted by the Sagrat Cor University Hospital Ethics Committee.
7. Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	No.
8. Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)? Are any differences >10%?	Yes. A table of baseline characteristics has been presented by the authors. There were no significant differences between the group for any of the variables listed in the table; these included: age, sex, procedure and FEV1.
9. Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Unsure. There was no sample size calculation.
10. Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Unsure if there was a follow-up. Two patients from each group were excluded from the study as they were discharged home with a Heimlich valve. The patients were analysed in the groups which they were randomised to. ITT was not carried out. It is unclear if there was a follow-up.
11. Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. The authors have included a section detailing the methods used for statistical analysis. There does not appear to be missing data. Potential sources of bias have not been controlled for through statistical analysis and patients were not randomised. However, patients appeared to be similar in terms of baseline characteristics.
12. Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	The majority of the results were objective. However, the study included a questionnaire made up of 5 questions with a 3 point Likert-like scale and was therefore slightly subjective. All important outcomes were assessed. The results do not adequately support all of the authors' conclusions. The authors conclusions state that "patients were subjectively more comfortable with digital devices" but patients did not receive a questionnaire

13. Is any sponsorship/conflict of interest reported?	The authors declare no conflicts of interest.
14. Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	Yes. The authors identified the following limitations: the sample size was reduced due to the lack of digital devices, patients were not randomised groups, as we did not have all types of drainage from the very beginning. The conclusions in the abstract match the full text.

Citation: Miller et al. (2016) Are there other companion papers from the same study?	
	Can't tell. The paper says that there are 40 units involved with a multi-centre randomised prospective study and so there may be future companion papers.
1. Is the study design clearly stated?	Retrospective, comparative, non-randomised, un-blinded pilot study.
2. Does the study address a clearly focused question? Consider: Population; Exposure (defined and accurately measured?); Comparator/Control; Outcomes.	Yes. Population: People undergoing VATS lung resections. Exposure: Thopaz Comparator: Express Mini 500 (traditional analogues system). Outcomes: Duration of chest tube, length of hospital stay, number of chest tube replacement procedures, complications, air leak duration and the number of patients sent home with chest tube. The primary outcome is length of hospital stay.
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; exposure; follow-up & data collection.	Yes, in part. The study is single centre. Dates for recruitment were from July 2014 until the end of January 2015. Data collection has been outlined but the follow-up period, if there was one, has not been stated.
4. Were participants fairly selected? Consider: eligibility criteria; sources & selection of participants; method of follow-up; for matched studies	Yes. Patients were eligible if they underwent VATS anatomic lung resection from July 1, 2014, through January 31, 2015, for

– details of matching criteria and number of exposed or unexposed.	lung cancer. Patients were excluded if they were younger than 18 years or older than 80 years, had previous thoracic surgery, were oxygen dependent, or had undergone neoadjuvant (chemotherapy or radiation) treatment. Patients who had associated risk factors that are known to increase postoperative air leaks were not included. Patients who received traditional chest drainage were matched with patients who received chest drainage with Thopaz in a 2:1 ratio (traditional to Thopaz) using propensity score matching.
5. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Yes. Baseline patient demographics have been presented in a table. There were no significant differences between groups for the variables presented; these included: age, gender, FEV1% predicted, type of resection, etc.
6. Are the measures of exposures & outcomes appropriate? Consider if the methods of assessment are valid & reliable.	Yes. The methods of assessment appear reliable.
7. Was bias considered? e.g. recall or selection bias	Bias was considered and so the authors used propensity score matching to pair patients in the two groups.
8. Is there a description of how the study size was arrived at?	Yes. During the 7 month period, 75 patients were treated using the traditional system and 33 patients were treated with Thopaz. These patients were then matched using propensity score to give 40 patients treated with the traditional system and 20 patients treated with Thopaz.
9. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	No. The authors have stated that propensity score matching was used, but do not state what variables were used for matching. The authors state that an α level of 0.05 was used for significance testing. However, the authors do not state which statistical analyses were

	used.
10. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	No. The authors explain how the study size was arrived at but there is no flow diagram. There do not appear to be any drop outs.
11. Are the results well described? Consider if: effect sizes, confidence intervals/standard deviations provided; the conclusions are the same in the abstract and the full text.	Yes. Results have been presented in tables with primary and secondary outcomes presented as median with ranges. P values for significance have been given. However, as stated earlier, it is unclear what statistical tests were used. The conclusions in the abstract match those in the full text. The conclusions in the full text do not mention the decreased complications observed with Thopaz but the conclusions in the abstract do. This conclusion is backed by the results.
12. Is any sponsorship/conflict of interest reported?	Two of the authors have disclosed a financial relationship with Medela.
13. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes. The authors note the following limitations: the sample size is small, it is a single-centre study and the digital system was new to our health care system, so we decided to use it in all lung procedures, open and VATS approach, to become more comfortable with the device and to work out the utilization and education issues in the operating room and most importantly on the floors and in the intensive care units. Most of the limitations identified by the authors have been captured above. However, the authors do not comment on the lack of statistical analysis details.

Citation: Pompili et al. (2011).	
Are there other companion papers from the same study?	
	No

1. Is the study design clearly stated?	Observational case-matched study.
2. Does the study address a clearly focused question? Consider: Population; Exposure (defined and accurately measured?); Comparator/Control; Outcomes.	Yes. Population: Patients undergoing pulmonary lobectomy. Exposure: Thopaz. Comparator: Traditional suction drainage. Outcomes: Duration of chest tube drainage, length of hospital stay, complications and chest tube replacements.
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; exposure; follow-up & data collection.	Yes. The study took place at a single centre. Patients treated with Thopaz were operated on in 2010 and then propensity score matched to a pool of 235 patients who underwent lobectomy from 2008-2010. Follow-up period has not been stated.
4. Were participants fairly selected? Consider: eligibility criteria; sources & selection of participants; method of follow-up; for matched studies – details of matching criteria and number of exposed or unexposed.	Yes. The authors did not provide inclusion criteria. Exclusion criteria included: air leak longer than seven days (after which all patients are connected to a portable chest drainage device and possibly sent home); admission to the intensive care unit and the use of assisted mechanical ventilation; chest wall/diaphragm resection; reoperation for any cause; and postoperative death.
5. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Yes. The authors have included a table with baseline characteristics of the two matched groups. There was no significant difference between the two groups in the characteristics presented; these included: age, FEV1%, BMI, site of surgery, but did not include gender.
6. Are the measures of exposures & outcomes appropriate? Consider if the methods of assessment are valid & reliable.	The measures of exposure and outcomes appear appropriate.

7. Was bias considered? e.g. recall or selection bias	Yes. The groups have been propensity score matched in an effort to reduce bias and there is no significant difference in the patient characteristics presented. Although gender was not presented in the table of characteristics the authors state that age was used, in addition to other variables, for the propensity score matching.
8. Is there a description of how the study size was arrived at?	Yes. All 51 patients managed with the new electronic system were operated on in 2010 and were matched using a propensity score with a sample of patients drawn from a pool of 235 individuals undergoing lobectomy from 2008 through 2010.
9. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. The authors have described the statistical methods they followed in a statistical analysis section. The statistical methods used do not control for confounders. However, the two groups have been matched using propensity scores. There does not appear to be any loss to follow-up.
10. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	Yes, in part. There is no flow diagram. But how the two groups were generated has been well described. There does not appear to be any missing participant data. No follow-up time has been presented.
11. Are the results well described? Consider if: effect sizes, confidence intervals/standard deviations provided; the conclusions are the same in the abstract and the full text.	No. Results have been described in a narrative manner. Whilst p-values have been presented for the outcomes, it is unclear if the outcomes presented are means (it is likely but has not been explicitly described as such). No indication of variation (e.g. standard deviation, range, IQR) has been presented.

	The conclusions in the full text match those in the abstract.
12. Is any sponsorship/conflict of interest reported?	One of the authors has a consultancy agreement with Medela.
13. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes. The authors identified the following limitations: the results from this analysis were generated in a unit already experienced with digital chest drainage devices, this may have influenced the results; the analysis was limited to pulmonary lobectomies therefore the generalisability of the present results to minor resections therefore needs specific investigation; the learning curve period presented in this investigation refers to a general thoracic surgery division with a surgical volume of approximately 100 pulmonary lobectomies per year. The reproducibility of this curve to other settings with larger or smaller volumes needs to be verified. The limitations have not been captured above.

Citation: Pompili et al. (2014)	
Study Design: Multi-centre, un-blinded RCT	
1. Does the study address a clearly focused question/hypothesis	Yes. to compare objective (duration of chest tube placement) and subjective (patient satisfaction) outcomes with a novel portable electronic chest drainage system compared with a traditional one
Population/Problem? Intervention? Comparator/control? Outcomes? Can you identify the primary outcome?	Population: Patients undergoing lobectomy or segmentectomy. Intervention: Thopaz. Comparator: Traditional device with wall suction. Outcomes: The primary outcome was duration of chest tube placement.
2. Was the population randomised? If YES, were appropriate methods used?	Yes. Simple unrestricted randomization was

	Eg: random number tables, opaque envelopes Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week	performed in each centre according to a computer-generated randomization list concealed in sequentially numbered sealed envelopes.
3.	Was allocation to intervention or comparator groups concealed? Is it possible for those allocating to know which group they are allocating people to? As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.	Yes. The sealed envelopes were opened by a nurse at the end of each operation to allocate the participants to the traditional or digital arm of the study.
4.	Were participants/investigators blinded to group allocation? If NO, was assessment of outcomes blinded?	No. The study was un-blinded for both patients and investigators.
5.	Were interventions (and comparisons) well described and appropriate? Aside from the intervention, were the groups treated equally? Was exposure to intervention and comparison adequate? Was contamination acceptably low?	Yes. The intervention and comparator was described well. The intervention and comparator groups were treated differently due to differences in the way that the two devices manage chest drainage.
6.	Was ethical approval sought and received? Do the authors report this?	Yes. The protocol was approved by the respective institutional review board in each hospital.
7.	Was a trial protocol published? Was a protocol published in a journal or clinical trial registry before participants were recruited? If a protocol is available, are the outcomes reported in the paper listed in the protocol?	Yes. A protocol was published on clinicaltrials.gov before participant recruitment. The protocol can be found here https://clinicaltrials.gov/ct2/show/NCT01747889?term=pompili&rank=1 The protocol includes some of the outcomes presented in the paper. The protocol lists “total distance of ambulation in the first 48 postoperative hours” as an outcome; this was not included in the paper. The paper also includes postoperative length of stay and air leak cessation to tube removal outcomes; these were not listed in the protocol published on clinicaltrials.gov.
8.	Were the groups similar at the start of the trial? Are baseline characteristics provided and discussed (e.g. age, sex, social class, life style etc.)?	Yes. A comprehensive table of baseline characteristics has been included and

	Are any differences >10%?	includes: age, sex, BMI, type of surgery, FEV1%, etc. There were no significant differences in the variables presented
9.	Was the sample size sufficient? Were there enough participants? Was there a power calculation? If YES, for which outcome? Were there sufficient participants?	Yes. The study was powered based on its primary end point: the duration of chest tube placement. Sample size was calculated to detect a difference in duration of chest tube placement after segmentectomy or lobectomy of at least 1 day and based on previously published data (standard deviation = 3). A sample size of 380 patients (190 patients per group) was determined based on a 90% statistical power, with a significance level of 0.05, and allowing for dropouts. The number of patients in each arm matched the power calculation.
10.	Were participants properly accounted for? Was follow-up ≥ 80%? Were patients analysed in the groups to which they were randomised? Was an Intention to Treat analysis conducted? Was the follow-up period long enough?	Yes. It is unclear how long the follow-up period was but no participants were lost to follow-up. 3 patients (Thopaz arm n=1; Traditional arm n=2) discontinued the intervention due to death. Patients were analysed in the groups which they were randomised to. ITT analysis was not conducted as no patients were lost to follow-up. It is unclear how long the follow-up period was.
11.	Data analysis Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes. The authors have presented the methods they followed in a statistical analysis section. There did not appear to be any missing data. Confounding factors were controlled for through randomisation. Statistical analysis of both groups showed that they were similar in terms of baseline characteristics. No patients were lost to follow up.
12.	Results Were outcome measures reliable (e.g. objective or subjective measures)? Were all outcome measurements complete? Were all important outcomes assessed? Are the authors' conclusions adequately supported by the results?	The majority of the study outcomes were objective. Patient satisfaction was measured through the distribution of a questionnaire containing 8 questions with a 5-point Likert-type scale and is therefore slightly subjective. The authors assessed all important outcomes but did not assess total distance of ambulation in the first 48 postoperative hours (an outcome listed in the published protocol).
13.	Is any sponsorship/conflict of interest reported?	Four of the authors have disclosed a financial relationship with Medela. However, they state that Medela had no role in designing,

	conducting, data acquisition, analysis or writing of the results.
14. Finally…consider: Did the authors identify any limitations? Are the conclusions the same in the abstract and the full text?	Yes. The authors identified the following limitations: results should be interpreted by taking into consideration that different thresholds may lead to different results, The four centres did not contribute evenly to recruitment, the study was un-blinded for both patients and investigators so the possibility of a systematic bias in the postoperative management of patients across treatment and control groups cannot be ruled out entirely, an ad hoc instrument was created to measure patient satisfaction. This metric lacks reference values for the general population, which makes it impossible to make comparisons and estimate the magnitude of differences. The conclusions in the text match the abstract and are backed by the results.

Citation: Shoji et al. (2016) Are there other companion papers from the same study?	
	No
1. Is the study design clearly stated?	No. The description of the study design is confusing. It appears that patients treated with Thopaz were prospectively and consecutively recruited and the compared retrospectively to patients who were treated postoperatively with an analogue system.
2. Does the study address a clearly focused question? Consider: Population; Exposure (defined and accurately measured?); Comparator/Control; Outcomes.	To an extent. Population: patients undergoing and who underwent pulmonary resection (including lobectomy, segmentectomy and wedge resection. Exposure: Thopaz Comparator: Analogue chest drainage system. Outcomes: Chest drain duration, complications and air leak incidence.

3. Are the setting, locations and relevant dates provided? Consider: recruitment period; exposure; follow-up & data collection.	Yes. The setting was a single department of surgery in Japan. Recruitment period for the prospective patients treated with Thopaz was between August 2015 and March 2016. Patients considered in the retrospective cohort were received chest drainage using an analogue chest drainage system between January 2015 and July 2015. Follow-up period was not stated.
4. Were participants fairly selected? Consider: eligibility criteria; sources & selection of participants; method of follow-up; for matched studies – details of matching criteria and number of exposed or unexposed.	Yes. Eligibility criteria for the Thopaz group included: patients who underwent pulmonary resection, including lobectomy, segmentectomy, and wedge resection. Patients who underwent pneumonectomy were excluded. Eligibility criteria for the analogue group included: patients who had undergone lobectomy, segmentectomy, or wedge resection. Patients who underwent pneumonectomy were excluded. Patients from both groups were matched using propensity scoring. This gave a total of 86 matched patients in each group.
5. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Yes. A patient characteristic table was included by the authors for patients in both groups before and after matching. The table includes age, gender, type of surgery etc.
6. Are the measures of exposures & outcomes appropriate? Consider if the methods of assessment are valid & reliable.	Yes. The measures of the outcomes appear appropriate and reliable.
7. Was bias considered? e.g. recall or selection bias	Bias was considered and the authors aimed to control for this through propensity score matching.
8. Is there a description of how the study size was arrived at?	Yes. The authors have described how the final study numbers were reached. However, the description was a little confusing.

9. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.	Yes, in part. The statistical methods used have been described in a section by the authors. The authors have described how the propensity scoring was carried out to match the patients. However, the authors do not state which tests were used in their analyses and instead have only presented an alpha level.
10. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	Yes, in part. A description of how the final numbers in each group was reached has been included. There is no flow diagram. There do not appear to be any drop-outs or missing data. Follow-up time has not been presented.
11. Are the results well described? Consider if: effect sizes, confidence intervals/standard deviations provided; the conclusions are the same in the abstract and the full text.	Yes. The authors have summarised the results in a table. Where appropriate means have been presented with ranges. Conclusions in the full text match those in the abstract.
12. Is any sponsorship/conflict of interest reported?	The authors do not have any conflicts of interest to declare.
13. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes. The authors highlight that the comparison in this study was retrospective and was undertaken in a single-centre. They suggest that a multicenter prospective study should be conducted. This has been captured above.

Citation: Tunnicliffe and Draper (2014) Are there other companion papers from the same study?	
	No
1. Is the study design clearly stated? Consider if retrospective or prospective	Yes. Prospective, non-comparative pilot study.

2. Does the study address a clearly focused question? Consider: population and outcomes (are these appropriate?)	Yes. Population: patients with pneumothorax. Exposure: Thopaz Outcomes: Length of hospital stay, length of time device was in situ, complications, patient satisfaction of the device, nurse and clinician experience of using the device and data gathered from the device.
3. Are the setting, locations and relevant dates provided? Consider: recruitment period; follow-up & data collection.	Yes. The setting was a single centre (UK) study. Dates have been provided for the recruitment period, which was from September 2012-April 2013; data were collected during this period. Follow-up was 120 days following discharge.
4. Are there explicit inclusion/exclusion criteria?	Patients between the ages of 18 and 80 with a chest drain in situ for the purpose of treating pneumothorax and who were able to consent were eligible for the study. There were no explicit exclusion criteria.
5. Were patients enrolled consecutively?	Yes.
6. Are participant characteristics provided? Consider if: sufficient details; a baseline table is included.	Yes. A table has been included and has includes baseline characteristics for each of the study's participants. The table includes age, gender, whether they have a primary or secondary pneumothorax and whether they have had a pneumothorax previously.
7. Are outcome measures appropriate? Consider if: the methods of assessment are valid & reliable.	Yes. The outcome measures are appropriate and the method of assessment appears valid and reliable.
8. Are the statistical methods well described? Consider: How missing data was handled; were potential sources of bias (confounding factors) considered/controlled for.	No. The authors have included a section on data analysis. However, as this was a non-comparative study no statistical analysis was carried out. There does not appear to be any missing data. There does not appear to have been any controlling for potential bias, apart from

	enrolling patients consecutively.
9. Is information provided on participant flow? Consider if following provided: flow diagram; numbers of participants at each stage; details of drop-outs; details of missing participant data; follow-up time summarised; numbers of outcome events.	Yes, in part. Details on the numbers of participants in the study gave been provided. No flow diagram has been provided. There does not appear to be missing participant data. The follow-up time has been summarised in the methods section and the outcomes at follow-up have been presented in a table.
10. Are the results well described? Consider if: effect sizes, confidence intervals/standard deviations provided; the results support the conclusions and are they the same in the abstract and the full text.	Yes, in part. The main clinical outcomes have been presented in a table with the patient characteristics. Results on patient satisfaction have been described in a narrative manner. There is no indication of how many patients answered the questionnaire or even how the questionnaire was structured.
11. Is any sponsorship/conflict of interest reported?	One of the authors received payment for presenting data at a Medela company training day.
12. Finally…Did the authors identify any limitations and, if so, are they captured above?	Yes. The authors identified the following limitations: the study had a heterogeneous group of patients. It is unclear as to which patients may benefit from the use of digital air leak monitoring over the conventional system in the management of their pneumothorax; this study of only 13 patients is not powered to draw robust conclusions about the benefit of digital devices or to clearly state when suction should be applied or indeed the exact timing of chest drain removal; the study was performed at a centre, which had thoracic surgery on site, and that this may influence the referral practice for surgical intervention. The authors didn't identify the poor way of presenting patient satisfaction. It is unclear how many of the patients completed the questionnaire. The authors didn't even present the questionnaire's structure and have only stated that a

	questionnaire was given to patients.