Prevention of Air Leaks in Cardiothoracic Surgery; Business Case

Post-operative air leaks have long been seen as an occupational hazard for surgeons operating in the thoracic cavity. Abolhoda et al stated "Prolonged Air Leak is an alarmingly common postoperative complication and is the most frequent cause of an extended length of hospital stay in patients undergoing radical upper lobectomy"[1]. Yet until recently it was somewhat brushed under the carpet because air leak monitoring was relatively unsophisticated and prevention measures were largely unsuccessful. As progress has been made in monitoring the course and consequences of air leaks, so the focus has returned to their prevention.

Air leaks in lung surgery are a daily concern for the Thoracic Surgeon, and can also be encountered by the Cardiothoracic Surgeon. Prolonged air leaks are increasingly recognised as a serious post-operative complication, with the potential to impact upon patient recovery and hospital stay. Minimising the incidence of post-operative air leak is the most likely influencing factor in minimising hospital stay for this group of patients, with obvious benefits for patient and reduced cost for the healthcare provider. Furthermore, a high incidence of air leaks may even prevent certain procedures such as lung volume reduction surgery from being performed, meaning that with the appropriate surgical solution patients for whom treatments may have been not available may be rendered operable.

A cost-effective, convenient and successful treatment option for the surgeon is the final piece of the jigsaw. Presented here is the case for TissuePatchThoracic, a self-adhesive, synthetic absorbable membrane for use by surgeons.

The Economic consequences of prolonged Air Leaks

Healthcare providers are faced with economic pressures and an enduring desire to improve surgical outcomes for patients. Extended inpatient stay and additional treatments for prolonged air leaks can have a significant implication for the budget and outcome statistics for the thoracic services provided by the hospital, as follows:

Increase in post-operative morbidities associated with post-operative air leak

- Nosocomial pneumonia
- Pleural Empyema
- Surgical Emphysema
- Lobar Collapse

Consequential treatments associated with these complications

- Longer in-patient stay
- Prolonged requirement for Chest drainage
- Antibiotic therapy
- Possible return to theatre
- Social and Psychological effect for the patient with a longer hospital stay

Published reports[2] give a mean daily hospital stay cost for lobectomy as €632.49 (£531.50), patients with prolonged air leak (over 5 days) incurring this extra cost on a daily basis.

If air leakage can be prevented intra-operatively with a small cost calculated into the operating budget for products that are reliable and economically viable (< £300), this is significantly less than the estimated cost for just 1 day additional to the average stay (5 days).

Table showing the extra daily costs associated with prolonged Air Leak[2]

(over 5 day stay)	*Day 6*	*Day 7*	*Day 8*	*Day 9*	*Day 10*
Average extra cost	***£531***	***£1,062***	***£1,694***	***£2,124***	***£2,655***

References:

1. Abolhoda A, Liu D, Brooks A and Burt M. Prolonged Air Leak following Radical Upper Lobectomy: An analysis of incidence and possible risk factors. Chest 1998; 13; 1507-1510
2.Varela G, Jimenez MF, Novoa N, Aranda JL. Estimating hospital costs attributable to prolonged air leak in pulmonary lobectomy. EJ of Cardio-thoracic Surgery 2005;27:329-333
3.Lackey A, Mitchell J D. The cost of Air Leak: Physicians' and Patients' Perspective. Thoracic Surg Clin 2010;20: 407-411

The Surgical Quest to prevent Air Leaks

It's unsurprising that Thoracic and Cardiothoracic surgeons want to evaluate products that will reduce the risk of air leaks and their negative consequences for their patients. Over the years several product types have been and continue to be used in this quest; spray glues (synthetic and animal / human derived); staple buttress materials and even products designed to be haemostats rather than sealants have been used to limited effect.

Tissuemed presents a different technological solution in TissuePatchThoracic™, a self-adhesive film that covalently bonds to the lung tissue surface and seals against leaks with advantages over liquid glues and sealants.

Tissuemed® Ltd. Company Background

Founded in Leeds in 1985 Tissuemed has a reputation for technical innovation dating back over twenty years. The company has its origins in the development of tissue-based therapeutic devices including developing the first tissue heart valve to gain regulatory approval in Europe, subsequently developing "living" vascular grafts and collagen patches. The company developed light-activated surgical adhesives for which it was the Gold Winner of the Medical Design Excellence Award in 2001. Tissuemed's expertise now lies in developing synthetic, absorbable surgical sealant films using its proprietary advanced adhesive polymers.

TissuePatchThoracic™

Derived from TissuePatch3, which has been in clinical use since 2007, TissuePatchThoracic is dedicated to the task of addressing air leaks encountered during lung surgery. The product works on the principle that the surgeon and theatre staff want an immediately available product that is easy to apply and effective.

Clinical Support

In a two-centre, independently monitored post-marketing study TissuePatch3;

- eliminated air leaks at chest closure
- reduced the time to the last recorded air leak when compared to control patients (statistically significant for patients treated at the Norfolk and Norwich centre).
- resulted in 12 out of the 15 subjects (80%) being air leak free at the end of the surgical procedure.
- provided a high degree of surgeon satisfaction
- was associated with no device related adverse events

Product Features

- TissuePatchThoracic is synthetic, eliminating the risk of reaction to human or bovine/equine derived products
- 40micron thickness, represents a tiny volume of foreign material compared with other products
- Being a fine film it conforms to complex tissue surfaces, giving the advantage of uniform coverage as it covalently bonds to the underlying tissue
- TissuePatchThoracic has increased strength and resilience to offer further confidence and is now suited to loading and dispensing through a dedicated VATS applicator system
- "Open and Apply", the product requires no preparation, takes only 60 seconds from surgeon request to being functionally effective on the tissue, so can reduce theatre time
- Transparency allows visualisation of underlying tissues
- Economically packaged in different sizes and costed appropriately per size so you only pay for what you need to use. Boxed as single items
- Realistically and competitively priced please see enclosed quotation

Reduced operating time, coupled with the potential to reduce hospital stay forms a compelling argument that taking proactive measures to seal tissues against air leaks is an economically viable proposition.

For further clinical documentation and feedback refer to website

www.tissuepatchthoracic.com

The Thoracic Surgeon's Choice