Background

The STRATFix project is an InnovateUK funded project between University College London, seven NHS Trusts and Qiagen – a leading manufacturer of molecular diagnostic reagents.

Most diagnostic pathology laboratories rely on formalin for the fixation of tissue samples sent for histopathological examination.

Whilst adequate for most existing pathological tests, formalin fixation is detrimental to DNA/RNA quality and carries with it significant health and safety considerations.

Alternatives that enable a wider and more-in-depth range of diagnostic genetic tests such as next generation sequencing are now required.

Method

- Duplicate samples of lung tumour and background lung from n=35 informed and consenting individuals with either lung adenocarcinoma or squamous cell carcinoma have been collected from patients undergoing surgery at our centre.
- Samples fixed in PAXgene tissue for 12-24 hours and placed into frozen until formalin free processing.
- Blocks were embedded in paraffin-wax and slides produced following standard laboratory practices.
- Hematoxylin and Eosin, Elastic von Gieson connective tissue stains were performed.
- Immunohistochemistry for Cytokeratin (CK) 7, CK5/6, MNF116, TTF-1, p53 and the proliferation marker Ki-67 were performed.
- Slides were blinded and examined by a pathologist with experience with the histopathology of lung cancer.

Results

<table>
<thead>
<tr>
<th></th>
<th>Adenocarcinoma</th>
<th>Squamous cell carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAXgene</td>
<td>H&amp;E, MNF116</td>
<td>H&amp;E, MNF116</td>
</tr>
<tr>
<td>Formalin</td>
<td>CK7, TTF-1, K67</td>
<td>CK5/6, p53, Ki-67</td>
</tr>
</tbody>
</table>

Conclusion

PAXgene-fixed samples are adequate for histopathological diagnosis and suitable for tests currently used in the diagnosis of lung cancer. Previous studies have indicated that PAXgene is better for DNA and RNA preservation. This should now be evaluated in a routine diagnostic setting.