A novel device for the treatment of accessible tumours - Papillon+™ x-ray brachytherapy system

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Clinical Aim

Intraoperative radiotherapy (IORT) using a miniature x-ray source has been shown to impart the same clinical benefit as external beam radiotherapy (EBRT), in a single fraction\(^1,2\).

Benefit

The patient benefits are significant, since IORT replaces several weeks of fractionated EBRT.


Clinical Rationale

- Over 90% of local recurrences after breast conservative therapy occur near the original tumour, even when radiotherapy is not given. Therefore, the remote occult cancer foci may be clinically irrelevant and radiotherapy to the index quadrant alone might be sufficient [6].

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients</th>
<th>Proportion of recurrences in the index quadrant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clark RM, 1982</td>
<td>680</td>
<td>96%</td>
</tr>
<tr>
<td>Schmidt SJ, 1984</td>
<td>231</td>
<td>83%</td>
</tr>
<tr>
<td>Boyages J, 1990</td>
<td>783</td>
<td>81%</td>
</tr>
<tr>
<td>Kurtz, JM, 1990</td>
<td>1593</td>
<td>86%</td>
</tr>
<tr>
<td>Fisher B, 1992 (RT)</td>
<td>488</td>
<td>100%</td>
</tr>
<tr>
<td>Veronesi U, 1993</td>
<td>570</td>
<td>90%</td>
</tr>
<tr>
<td>Clark 1992 (RT arm)</td>
<td>416</td>
<td>(19/23) 83%</td>
</tr>
<tr>
<td>Clark 1992 (no RT arm)</td>
<td>421</td>
<td>(103/108) 86%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>5182</strong></td>
<td><strong>91%</strong></td>
</tr>
</tbody>
</table>
IntraOperative RadioTherapy (IORT) is defined as the delivery of a single, large radiation dose to the bed of a resected tumour at the time of surgical intervention.

In early stage breast cancer, IORT avoids unnecessary irradiation of the whole breast and reduces cardiac dose.
Papillon+ X-Ray Brachytherapy System
Papillon+ X-Ray Brachytherapy System

1. Breast
2. Rectal
3. Skin

and more to come ..
The anode is made of tungsten (Z = 74). This tungsten anode is very thin (6 μm) and works as a transmission anode.

The tube is cooled using an oil circuit, which allows the machine to dissipate heat and reach a high dose rate.

A temperature sensor prevents overheating of the tube by controlling the cooling time. With this controlled Duty Cycle, the stability in the dose rate is achieved.
Electrons are electrostatically focussed, accelerated and travel along a cylindrical tube onto a tungsten target producing a near-spherical distribution of x-rays.

The tube is sealed with a beryllium window producing inherent filtration of 0.2 mm Al which increases beam penetration through removal of low energy x-rays.

When it is not used, the tube is stored in a shielded tube. This parking tube can also be used to test the x-ray emission.
Papillon+ Console I
Papillon+ Console II
Papillon+ Console III

QA Test History

QA Test Parameters
Delivery Time: 60
Tube KV: 50
Tube mA: 2.7

Information

Please put the Nitro in the Parking Tube

Test Status

Electrometer

Papillon
Running KV: 0.00
Running mA: 0.00
Acc. MUs: 0
Acc. Time: 0

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## Papillon+ Product Specifications

### Product Specification

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy (kVp)</td>
<td>30 or 50</td>
</tr>
<tr>
<td>HVL (mm Al.)</td>
<td>0.25 - 0.8</td>
</tr>
<tr>
<td>Focal spot diameter</td>
<td>4 mm</td>
</tr>
</tbody>
</table>
| Dose rate at 20 mm FSD | >8 Gy/min, 30 kVp  
>20 Gy/min, 50 kVp |
| Beam angle, maximum    | 310 degrees                                  |
| Applications           | Breast, Rectal, skin, Vaginal, General IORT (all require appropriate accessory package) |

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Comparison of Normalised Dose Depth Curves

- 30kV No Filter
- 50kV No Filter
- 50kV 0.3mm Filter
- 50kV 0.5mm Filter
- 50kV 0.7mm Filter

Dose Percentage

Distance (mm)
1. Why is HDR X-Br effective?
2. Is HDR X-Br clinically equivalent to EBRT?
3. How do you compare the two modalities?

HDR X-Br 20Gy/1#
vs.
EBRT 50Gy/25#
1. Why is HDR X-Br effective?

**Graphs and Equations:**

- **Text:** The range of dose rates over which repair, reassortment, and repopulation modify radiosensitivity depends upon the speed of these processes.

- **Equation:**
  \[ G = \left[ \frac{2}{(\lambda T)^2} \right] (\theta - 1 + \lambda T) \]

  where \( \theta = \exp(-\lambda T) \) and \( \lambda = \ln(2)/T_{1/2} \), and \( T_{1/2} \) is the half-time for sublethal damage repair.
Clinical RBE of HDR X-Br

From Brenner et al.,

$$RBE(D_H) = \frac{Y_L}{2GD_H} \cdot \left[ 1 + \frac{4G}{Y_L} \left( \frac{\alpha_H \cdot D_H + G \cdot D_H^2}{\alpha_L - Y_L} \right) \right]$$

Where $Y_L = \frac{\alpha}{\beta}$ ratio for tumour relapse in the breast.

Use $\frac{\alpha}{\beta} = 3.5\,\text{Gy}$ from START data published in SABCS Dec. 2012

As previously stated, since $T < T_{1/2}$, $G \to 1$

Also $D_H = 20\,\text{Gy}$ (to surface of 40mm diameter)

$$RBE(D_H) = \frac{3.5}{40} \left[ 1 + \frac{4}{3.5} \left( \frac{\alpha_H \cdot 20 + 400}{\alpha_L - 3.5} \right) \right]$$

As $G \to 1$ RBE $\uparrow$

2. Is IORT clinically equivalent to EBRT?

“Clinical trials have demonstrated the safety and efficacy of some forms of partial breast irradiation in selected patients.”

13th St Gallen International Breast Cancer Conference (March 2013)
3. How do you compare the two modalities?

Not easy to make a direct comparison. Need a common metric to compare the two.
What are the targets?

Firstly, if we consider only clonogens as targets, their distribution is very uncertain, but might well be described by an inverse square function. This in turn might depend significantly on biological features such as molecular phenotype.

Secondly, there are a number of reasons for thinking that the true biological target might include some components of the tumour microenvironment, which might well be concentrated near the excision margins rather than at depth.
Common metric – ‘Point of Isoeffect’
Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) showed a reduction in 10-yr incidence of local recurrences to 10%.
Radiation Protection I

1. With the applicator in the patient and with no additional shielding, the dose rate at 3m was 1390 uSvh-1 (Calculated using ISL).

2. With the applicator in the patient and with additional shielding (0.35 mm Pb), the dose rate at 5m was 7.2 uSvh-1.

NB: It is desirable to keep the dose rate below 7.5 uSvh-1 (ALARA)
Radiation Protection II

1. Recommended to use mobile Pb-glass screens (0.35 mm Pb) in Theatre.

2. Typical ‘beam on’ time will be 2 minutes (0.24 µSvh⁻¹)

3. Treating 3 patients per session 0.72 µSvh⁻¹

4. Would have to treat 1250 patients to exceed 300 µSv in a year

5. Remote monitoring system so no one needs to remain in Theatre
Acceptance

- There will be initial scepticism to IORT.
- IORT increases anaesthetic time (elderly, infirm patients).
- Theatres need to be efficient.
- IORT Nurse Coordinator important.
- Acceptance increases with time.
- Practice becomes routine.
Conclusion

The Papillon+ offers a clinical alternative to mastectomy for older breast cancer patients.

Beam characteristics enable delivery of treatments similar to those reported in literature.

A major advantage is the high (> 12 Gy/min) dose rate facilitating delivery of 20 Gy to the breast tumour bed in < 2 minutes – a major advantage from a clinical perspective.
References


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