THE EFFICACY AND SAFETY OF PNEUMATIC TRABECULOPLASTY: RESULTS OF A 6-MONTH, MULTICENTER STUDY
Fogagnolo P (1), Rossetti L (2), Marraffa M (3), Rolando M (4), Ciancaglini M (5), Marchini G (3), Calabria G (4), Mastropasqua L (5), Orzalesi N (2)

(1) G.B. Bietti Foundation for the Study and Research in Ophthalmology, IRCCS, Rome, Italy
(2) Eye Clinic, San Paolo Hospital, University of Milan, Italy
(3) Eye Clinic, Department of Neurological and Vision Science, University of Verona, Italy
(4) Department of Ophthalmology, University of Genoa, Italy
(5) Ophthalmic Clinic, University of Chieti, Italy
Pneumatic trabeculoplasty (PNT) is a novel device for the treatment of OHN and POAG. Few clinical data are up-to-now available.
PURPOSE

To evaluate the efficacy and safety of PNT in patients with OHT and POAG
METHODS

- 4 Italian academic sites
- 63 patients
- Worse eye = PNT
- Fellow eyes = CONTROLS

INCLUSION CRITERIA
- diagnosis of OHT or POAG
- IOP = 20 – 25 mmHg
  (treated & untreated – washout not required)

EXCLUSION CRITERIA
- mean defect < -12 dB
- past intraocular surgery or inflammation
- significant eye diseases
- myopia > 6 D
SCHEDULED VISITS

BASELINE (day -1)

PNT TREATMENT (day 0, day 7)

SAFETY VISIT (day 1, day 8)

FOLLOW-UP VISITS (month 1, 2, 3, 4, 5, 6)

daytime IOP curve (8, 10 am, 2, 4 pm)
THE PROCEDURE

Tetracaine 0.5%
The lids are gently spread by the physician using his fingers
A sterile PNT ring is centered on the cornea
Moderate downward pressure to facilitate the initial attachment of the ring
Vacuum of 20 inches Hg is applied to the ring and to the eyes
60 seconds; rest of 5 minutes; 60 seconds
Topical antibiotic + non steroid anti-inflammatory eyedrops (QID, 1/52)
### PATIENTS’ CHARACTERISTICS

<table>
<thead>
<tr>
<th></th>
<th>mean ± SD (range)</th>
<th>66 ± 10 years (42-87)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age at inclusion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race, n</strong></td>
<td>Caucasian / Black</td>
<td>98% / 2%</td>
</tr>
<tr>
<td><strong>Male / Female, %</strong></td>
<td></td>
<td>57% / 43%</td>
</tr>
<tr>
<td><strong>Iris, %</strong></td>
<td>Pigmented / Not pigmented</td>
<td>74% / 26%</td>
</tr>
<tr>
<td><strong>Study discontinuations, n (%)</strong></td>
<td></td>
<td>8 (13%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>PNT eye</strong></th>
<th><strong>Not-PNT eye</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OD / OS</strong></td>
<td>60% / 40%</td>
<td>40% / 60%</td>
</tr>
<tr>
<td><strong>POAG / OHT</strong></td>
<td>40% / 60%</td>
<td>56% / 44%</td>
</tr>
<tr>
<td><strong>Treatment, n</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>21%</td>
<td>17%</td>
</tr>
<tr>
<td>Prostaglandin analogues</td>
<td>49%</td>
<td>25%</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>35%</td>
<td>29%</td>
</tr>
<tr>
<td>Others</td>
<td>3%</td>
<td>5%</td>
</tr>
</tbody>
</table>
**RESULTS**

![Graph showing IOP (mmHg) over time.](image)

- **IOP (mmHg)**

- **Time (minutes):** baseline, 30, 60, 90, 120, 150, 180

- **Graph Key:**
  - Red: NON-PNT
  - Purple: PNT (responder)
  - Blue: PNT (all patients)

- **Statistical Significance:**
  - * = P < 0.00001
Mean IOP decrease from baseline: 17.9% ± 19.1%

Rate of non-responders (≤ 5%): 23% – 32%

Mean IOP decrease in responders: 23.0% ± 18.2%

Significant decrease also in untreated eyes (except at day 180)

Trend for better responses in PNT group using prostaglandin analogues compared to beta-blockers (22.8% ± 16.0% vs 11.0% ± 14.9%, P = 0.17)
% IOP reduction compared to baseline

![Graph showing IOP reduction](image-url)
<table>
<thead>
<tr>
<th>SIDE EFFECTS</th>
<th>N (%)</th>
<th>DURATION, mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunctival hyperaemia</td>
<td>31 (49%)</td>
<td>12 ± 20 days (1; 90)</td>
</tr>
<tr>
<td>Foreign body sensation</td>
<td>11 (17%)</td>
<td>10 ± 13 days (1; 45)</td>
</tr>
<tr>
<td>Punctuate keratitis</td>
<td>8 (13%)</td>
<td>7 ± 0 days</td>
</tr>
<tr>
<td>Blurred vision</td>
<td>7 (11%)</td>
<td>1 ± 2 hours (15 mins – 5 hours)</td>
</tr>
<tr>
<td>Subconjunctival haemorrhage</td>
<td>5 (8%)</td>
<td>5 ± 6 days (1; 14)</td>
</tr>
<tr>
<td>Burning</td>
<td>4 (6%)</td>
<td>6 ± 6 days (1; 14)</td>
</tr>
<tr>
<td>Dry eye sensation</td>
<td>3 (5%)</td>
<td>10 ± 6 days (1; 14)</td>
</tr>
<tr>
<td>Corneal abrasion</td>
<td>1 (2%)</td>
<td>7 days</td>
</tr>
<tr>
<td>Corneal oedema</td>
<td>1 (2%)</td>
<td>7 days</td>
</tr>
<tr>
<td>IOP increase to 40 mmHg</td>
<td>1 (2%)</td>
<td>1 day</td>
</tr>
<tr>
<td>Photophobia</td>
<td>1 (2%)</td>
<td>1 day</td>
</tr>
</tbody>
</table>
**CONCLUSIONS**

- **SAFE** (up to 6 months)
- **EFFECTIVE**
- **UNEXPLAINED DECREASE IN FELLOW EYES**
- **HIGH RATE OF NON-RESPONDERS**

*Many unresolved questions:*

... mechanism of action? synergic to PG?

... repetitions: how often? are they effective?

... decrease in fellow eye?
“Oculus” by Andrea Mantegna (1431 – 1506)
La Camera degli Sposi, 
Palazzo Ducale, 
Mantova – Italy

contact: fogagnolopaolo@googlemail.com