Confidence is having strong randomised clinical trial data in vertebral augmentation².

Cortoss has been clinically proven to meet the safety and effectiveness of Polymethylmethacrylate (PMMA) for vertebral augmentation²:

- **Flow and Fill:** Properties improve short-term pain and long-term function²
- **Safety:** Low incidence of adjacent fractures⁵; minimal exotherm⁶ and monomer release⁷
- **Control:** Procedural flexibility with mix-on-demand and start/stop delivery¹
- **Data:** Robust compilation of clinical data²

CT images of Cortoss in a vertebral compression fracture⁸.
The new alternative with a great history

International Multi-Centre Clinical Trials: Clinical testing provides the proof.

The safety and efficacy of Cortoss has been demonstrated in three U.S. clinical investigations and multiple European studies. In total, 47 spine specialists treated 527 patients at over 30 centres in the United States, Sweden, the United Kingdom, and Italy. This robust compilation of studies in vertebral augmentation clearly demonstrates clinical benefit.

Cortoss Pivotal IDE Study

Study Design
The Cortoss pivotal study was a multi-centre, prospective, randomised, controlled non-inferiority clinical trial with a 2:1 randomisation ratio of Cortoss to PMMA patients.

Study Objective
The objective was to evaluate the safety and effectiveness of Cortoss compared to PMMA for vertebral augmentation using the vertebroplasty technique.

Methods
Twenty-one sites enrolled 256 patients (162 Cortoss, 94 PMMA) with painful osteoporotic vertebral compression fractures. Patient outcomes were assessed by the Visual analogue Pain Score (VAS), Oswestry Disability Index (ODI), and Short Form 12 (SF-12). A primary composite endpoint was used to assess clinical outcomes. The primary measures and their definitions of success were as follows:

- Improvement of at least 20 points on VAS and an overall VAS score of less than 50 on a 100 point scale
- Maintenance or improvement in ODI
- Maintenance of vertebral height and alignment
- No device-related subsequent surgical interventions at the study treated level

Results
The mean values characterising the study are provided in the following table. Individual endpoints were also evaluated and there was no statistically significant difference between the test and control, except as noted below for the individual assessments at the 3 and 24 month time points. In total 84% of Cortoss and 81% of PMMA patients completed their 24-month visit.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Cortoss (n=162)</th>
<th>PMMA (n=94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection Volume</td>
<td>2.3 cc</td>
<td>3.5 cc</td>
</tr>
<tr>
<td>Combined Treatment Success (3 months)</td>
<td>82.8%</td>
<td>73.7%</td>
</tr>
<tr>
<td>VAS Improvement (3 months)</td>
<td>86.6%</td>
<td>75.0%</td>
</tr>
<tr>
<td>ODI Maintenance†</td>
<td>96.7%</td>
<td>88.4%</td>
</tr>
<tr>
<td>Vertebral Body Height Maintenance and Alignment</td>
<td>98.3%</td>
<td>100%</td>
</tr>
<tr>
<td>SF-12 Physical Component Improvement†</td>
<td>11.1</td>
<td>8.9</td>
</tr>
<tr>
<td>SF-12 Mental Component Improvement†</td>
<td>9.4</td>
<td>8.4</td>
</tr>
<tr>
<td>Subsequent Adjacent Fractures**</td>
<td>10.3%</td>
<td>18.2%</td>
</tr>
<tr>
<td>Symptomatic Leaks</td>
<td>0.9%</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

† Improvement from baseline
** In patients with one level treated and no previous fracture

Conclusions
The results of this rigorous long-term study confirm those presented in the literature: vertebroplasty is effective in the treatment of pain caused by osteoporotic vertebral compression fractures. While both PMMA and Cortoss are safe and efficacious materials, the data demonstrated a statistically significant difference in early pain improvement and long-term functional outcome.