The Oswestry Disability Index (ODI) is a patient-completed questionnaire that gives a subjective assessment of pain. The patient marks the line at a point that indicates their current level of pain compared to the worst imaginable pain. The patient chooses a value that best describes their average pain in the previous week.

The numeric rating scale (NRS) is an 11-point scale (0-10), with 0 meaning no pain and 10 meaning worst possible pain. The NRS is used in three different assessments:

- **Pain History**: Used to identify the patient's pain history and current pain level.
- **Programmed Drug Volume Ratio**: Used to calculate the programmed morphine dose.
- **Delivered-to-Programmed Drug Volume Ratio**: Used to determine the accuracy of drug delivery.

### Results

#### Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender - %</td>
<td>Male</td>
</tr>
<tr>
<td>55 (54%)</td>
<td>47 (46%)</td>
</tr>
</tbody>
</table>

#### Pain History

<table>
<thead>
<tr>
<th>Category</th>
<th>Total (N=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of Pain (Mean ± SD)</td>
<td>12.3 ± 9.8 years</td>
</tr>
<tr>
<td>Pain Category - %</td>
<td>Neuropathic</td>
</tr>
<tr>
<td>59 (58%)</td>
<td>41 (40%)</td>
</tr>
</tbody>
</table>

#### Morphin Dosage

Daily programmed morphine dosage is presented in Figure 1. The increases in median daily dose range from the time of implant to consistent with previous studies.

#### Efficacy

Clinically significant improvements from baseline in average pain and disability were observed. Decreases from baseline in ODI, VAS, and NRS scores were reported at each visit during the first 6 months and at 12 months. Improvements from baseline were reported by at least 61% of subjects completing the 12 months of follow-up questionnaires, and at least 66% of subjects completing 12 months of follow-up questionnaires. A negative change from baseline indicates an improvement (decrease) in pain or disability due to pain.

#### Accuracy

Accuracy data were collected from 107 patients. Three patients required explants prior to the Month 1 visit due to infections. Based on 957 refill procedures completed in 107 patients, the average accuracy of drug delivery was 97.3% ± 0.4%. Accuracy results remain consistent when viewed over the range of flow rates programmed during the study.

#### DISCUSSION

Morphine delivered intrathecally via the Prometra Pump provided substantial pain relief and decreased disability scores for 12 months post-implantation. Pain relief was evident by the first post-operative month. Only 3% of patients reported lack of pain relief that was significant enough to cause them to terminate the study, while 66% of patients reported sustained pain relief at 12 months post-implantation.

#### CONCLUSION

This study shows that the new Prometra Pump System can provide effective intrathecal therapy with improved accuracy, and therefore offers the potential for improved patient outcomes through the reduced risk of under- and over-dosing. The unique pump design also offers:

- Improved sensitivity to environmental temperature and pressure
- Sustained accuracy at low pump volumes (i.e., throughout the entire refill interval)
- Ability to program zero flows, enabling bolus delivery as an alternate therapeutic approach

### References