ABSTRACT
The results of a 10-month clinical study of a novel FDA approved biofeedback device (the Paro Robot) is presented. Staff were trained to expose patients to use of the Paro Robot using specific clinical guidelines. Variables representing positive and negative behavioral and mood observations were reported for individual patients in order to characterize pre-use, active use, and post-use observations of patients. Secondary analyses regarding medication use and staff subjective ratings of change as a result of Paro use were also reported. Significance of findings is briefly discussed.

INTRODUCTION
The Paro robot is a “mental commit robot” designed to elicit the positive biopsychosocial variables that so-called “pet therapy” is believed to elicit (Wada, Shibata, Musha, & Kimura, 2008). There is limited evidence that the Paro Robot in both group and individual settings has the effect of reducing depression (Shibata et al., 2004), increasing positive social interactions (Wada & Shibata, 2007; Kidd et al., 2006), and improving cognitive functioning in demented older adults (Wada et al., 2006). Very limited case-study evidence indicates that use of the Paro Robot reduces behavioral and psychological symptoms in dementia (Martí, Bacigalupo, Giusti, Mennecozzi, & Shibata, 2006; cited in Broekens et al., 2009). This quality improvement pilot project was conducted to evaluate the effectiveness of the Paro Robot in increasing positive outcomes and reducing negative outcomes among VA long-term care residents in a locked dementia unit.

METHOD
The Paro robot has been utilized on the unit as part of usual clinical care. This is a qualitative, clinical quality improvement project evaluating it’s impact on patient progress and provider satisfaction within a secured dementia unit. Several phases of this project were completed over a 10-month period.

A multidisciplinary staff at a Veterans Health Affairs (VHA) Community Living Center (CLC; nursing home) developed a detailed protocol for use of the Paro, and then trained nursing staff in its indicated use. Tracking sheets were developed which required unit staff to note several targeted behaviors and provider actions (i.e. decreased wandering, use / nonuse of PRN, etc). Tracking forms were entered into an SPSS data file. Negative and positive behavioral and mood observations were collapsed together to form composite variables to simplify the primary analysis. Primary analysis took the form of a comparison of mean composite variables across patients, across the three study periods (e.g., pretreatment, active treatment, and posttreatment, or Time 1, Time 2, and Time 3).

Sample Description
Sample consists of 14 residents at a secured dementia unit at the VA Palo Alto Healthcare Systems Menlo Park division (e.g., the Community Living Center). Average age of residents in the sample was 84. All residents had a diagnosis of dementia in their medical charts, are male, and are either listed as of Caucasian ethnicity or “unknown.” Five of the nine residents tracked were respite care (short stay) residents, the remainder are long term care residents.

RESULTS
A total of 47 observations were generated across a 10 month period. Each patient had an average of three recorded contacts with the Paro robot across the study period, however, contacts were very unevenly distributed across residents; the top three residents accounted for nearly 2/3 (63.6%) of observational data generated. The average duration of a patient’s use of the Paro Robot was approximately 37 minutes (st. dev. = 19).

Primary analyses (change measures) are shown in Table 1, below. Secondary analysis (e.g., use / avoidance of PRNs, staff subjective ratings of change as result of Paro use) are in Tables 2 and 3.

Table 1. Means of Composite Mood / Behavioral Variables (change measures) Across Time

<table>
<thead>
<tr>
<th>Time</th>
<th>Pos. Composite Variable</th>
<th>Neg. Composite Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1</td>
<td>0.2872</td>
<td>-0.7273</td>
</tr>
<tr>
<td>Time 2</td>
<td>-0.1206</td>
<td>0.0071</td>
</tr>
<tr>
<td>Time 3</td>
<td>0.4681</td>
<td>0.0182</td>
</tr>
</tbody>
</table>

DISCUSSION
Across 47 observations collected, data from this pilot project suggest the Paro Robot is an effective intervention for increasing positive behavioral and mood observations in VA demented nursing home residents, and decreasing negative observations of the same. Moreover, staff appeared to believe that use of the Paro avoided a measurable number of medication administrations (e.g., pain medication, anxiolytic or antipsychotic medication), and resulted in all patients using the Paro either improving or returning to baseline after it’s use (e.g., no patient seemed to do worse after using the Paro Robot). Further, more controlled research is needed to further delineate in which patients the Paro Robot is most effective and in what situations the Paro Robot can be expected to be maximally effective. Also of interest would be to investigate the overall cost-effectiveness of this intervention as compared to standard pharmacological and non-pharmacological interventions.