

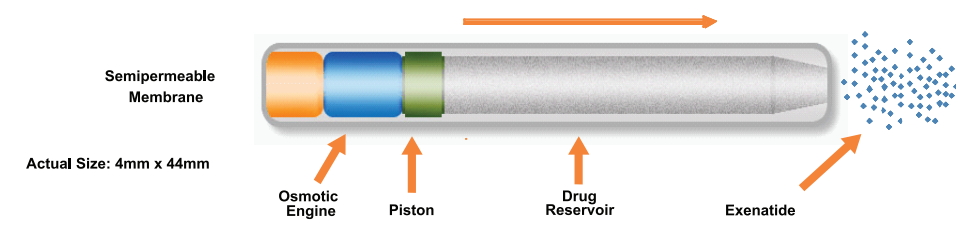
# Improved Patient Satisfaction with ITCA 650 vs. Exenatide Injections in Subjects with Metformin-Treated Type 2 Diabetes

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## Abstract

The relationship between exenatide treatment and patient satisfaction was examined in a study evaluating ITCA 650, a subcutaneous osmotic delivery system that provided for the continuous delivery of exenatide at specified doses for 3 months, and twice daily exenatide injections. **Materials and Methods:** A 24-week phase 2 study was conducted in which patients were randomized to one of two doses of ITCA 650 (20 and 40 mcg/day) or exenatide injections (5 mcg BID x 4 weeks, 10 mcg BID x 8 weeks) administered for the first 12 weeks. In the second 12 weeks, subjects receiving exenatide injections were switched to ITCA 650 (40 and 60 mcg/day) and subjects receiving ITCA 650 were randomly assigned to either continue their previous dose or the dose was escalated to 60 or 80 mcg/day. The Diabetes Medications Satisfaction Tool (DM-SAT) was administered prior to initial treatment and at week 8 and week 20 of treatment. This questionnaire consists of 16 questions and evaluates overall satisfaction as well as satisfaction grouped into four subscales: lifestyle, well-being, glucose control and convenience. **Results:** Reductions in HbA1c and weight were seen at week 12 and at week 8 the increase in overall satisfaction with treatment was greater among patients treated with either 20 or 40 mcg/d of ITCA 650 than with exenatide injections (25% and 40% vs. 15%). A similar pattern was observed for the subscale scores where increased satisfaction with either dose of ITCA 650 was greater than the change with exenatide injections. At week 20, further improvement in HbA1c and weight were seen with dose escalation and treatment satisfaction was maintained after the 2 - 3 fold dose escalation of ITCA 650. The most impressive results were observed among patients who started on exenatide injections and then switched to ITCA 650 where an average improvement of 20% in overall score was observed between week 8 (on exenatide injections for 8 weeks) and week 20 (on ITCA 650 for 8 weeks). GI side effects did not appear to impact the satisfaction score as an increase was also seen in subjects that reported nausea, similar to those that did not report nausea. **Conclusion:** This study indicates that exenatide treatment was associated with an increase in patient satisfaction; however, the improvement was substantially greater with ITCA 650 compared to twice daily injections. The ability to deliver exenatide in an injection-free manner that does not require any intervention by the patient ensures consistent compliance with prescribed treatment and results in increased satisfaction that may ultimately lead to improved persistence on long-term therapy with exenatide. Evaluation of 6- and 12-month devices will be undertaken in phase 3 studies and may further enhance patient satisfaction.

## ITCA 650 Cross-Section



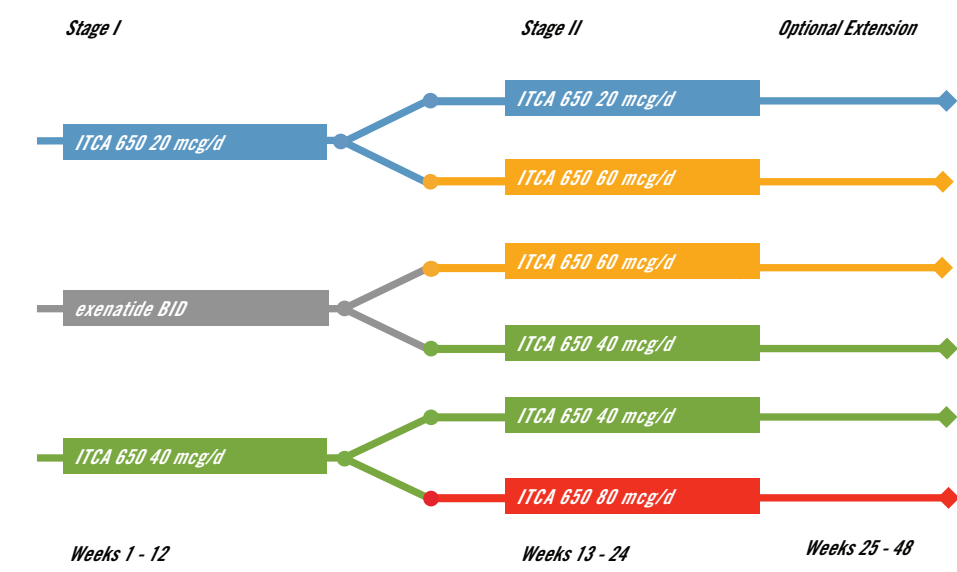
## Phase 2 Study Design

- Randomized, open-label study
- Stage I (Weeks 1-12)
  - ITCA 650 – 20 mcg/d (n=51)
  - ITCA 650 – 40 mcg/d (n=51)
  - Exenatide injections – 5 mcg BID x 4 weeks, 10 mcg BID x 8 weeks (n=53)
- Stage II (Weeks 13-24)
  - Groups randomized 1:1 as indicated in Study Design diagram
- Optional Extension Period
  - subjects offered the option to continue treatment at same dose to 48 weeks
- DM-SAT Quality of Life (QOL) survey conducted at baseline, weeks 8 and 20 of treatment (Anderson, RT, Girman, CJ, et al, Diabetes Care 32:51, 2009)

### Inclusion/Exclusion Criteria

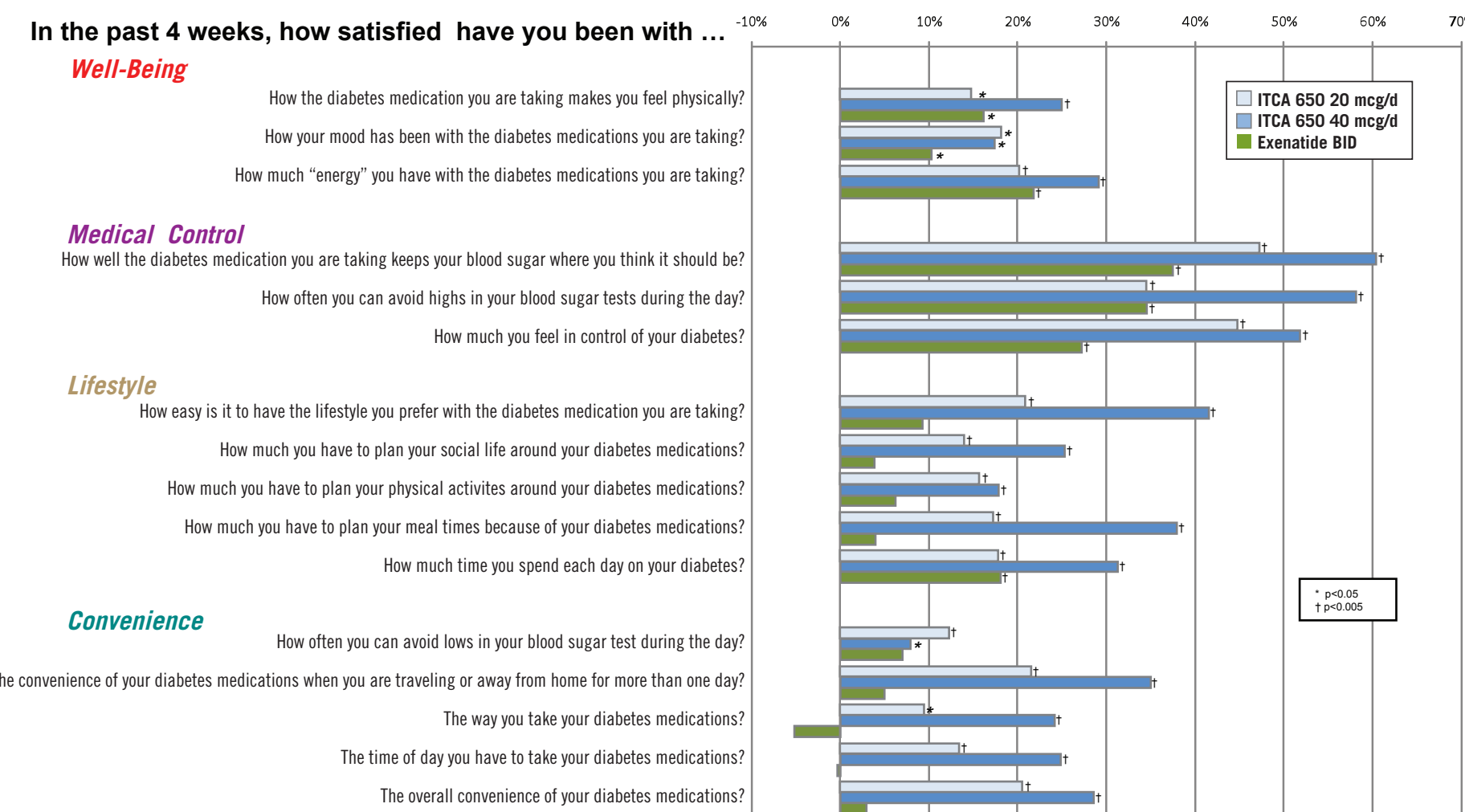
- 18 - 70 years of age
- Diagnosis of type 2 diabetes mellitus >6 months prior to screening
- Stable treatment with regimen of diet and exercise in combination with metformin monotherapy
- Hemoglobin A1c (HbA1c) ≥7.0% and ≤10%
- BMI ≤40kg/m<sup>2</sup>

## Study Design



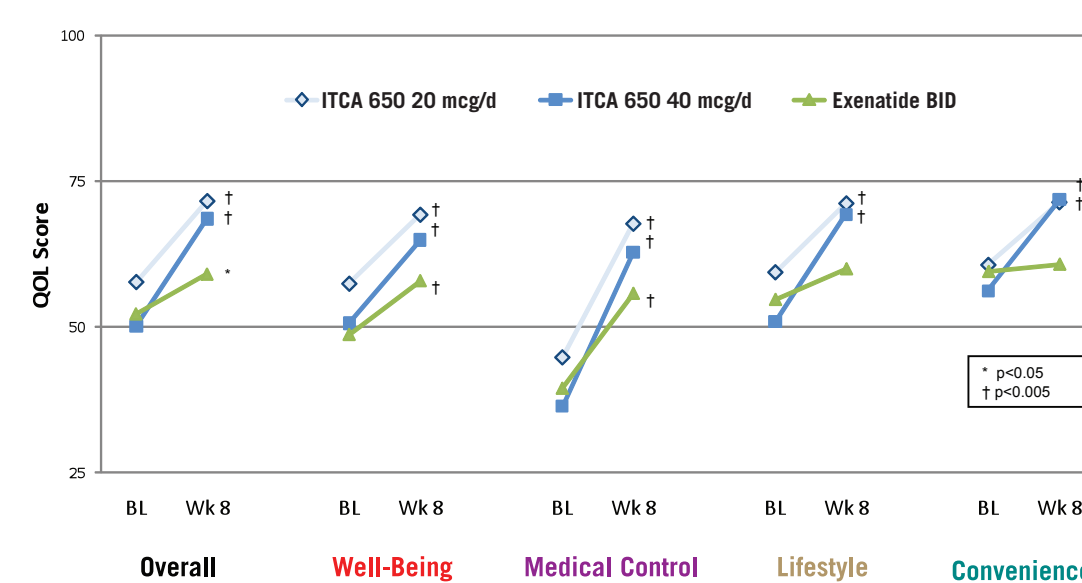
## Stage I - Responses to Individual Questions

### % Change at Week 8 vs. Baseline



Each of the 16 questions in the DM-SAT is listed as well as the subscale groupings. Improvement observed at week 8 vs. baseline for each treatment group is shown in the bar graph. ITCA 650 treatment (at either 20 or 40 mcg/day) received the highest score for every question in the DM-SAT whereas exenatide BID was consistently the lowest scoring treatment option.

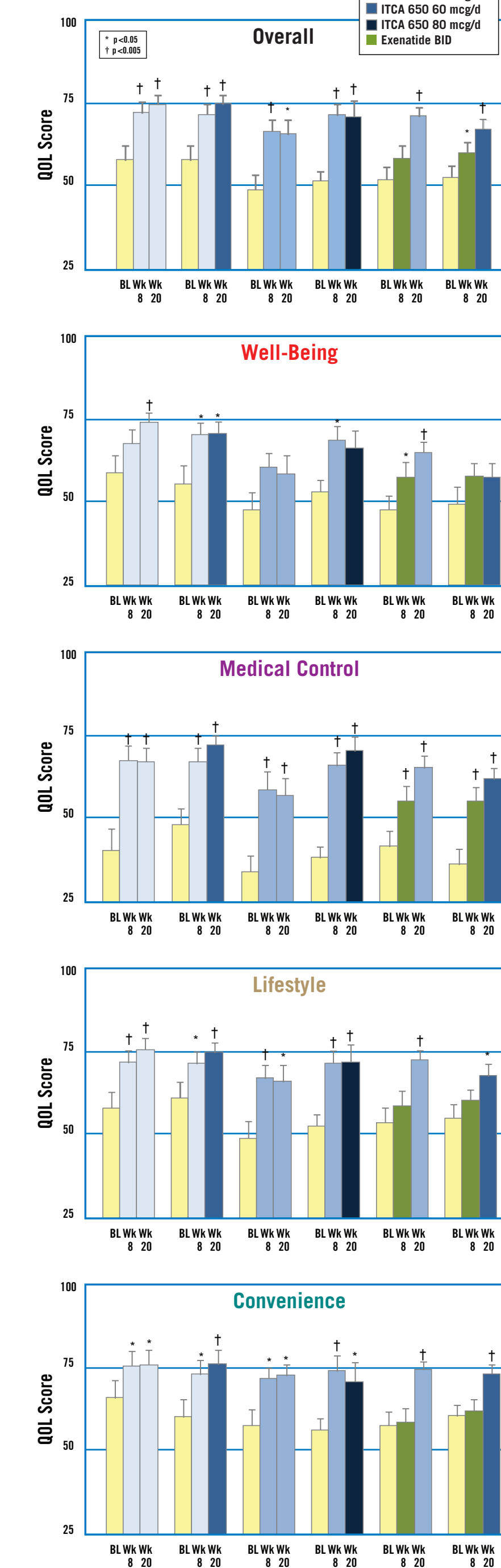
## Stage I - Overall and Subscale Scores



## HbA1c and Weight Summary

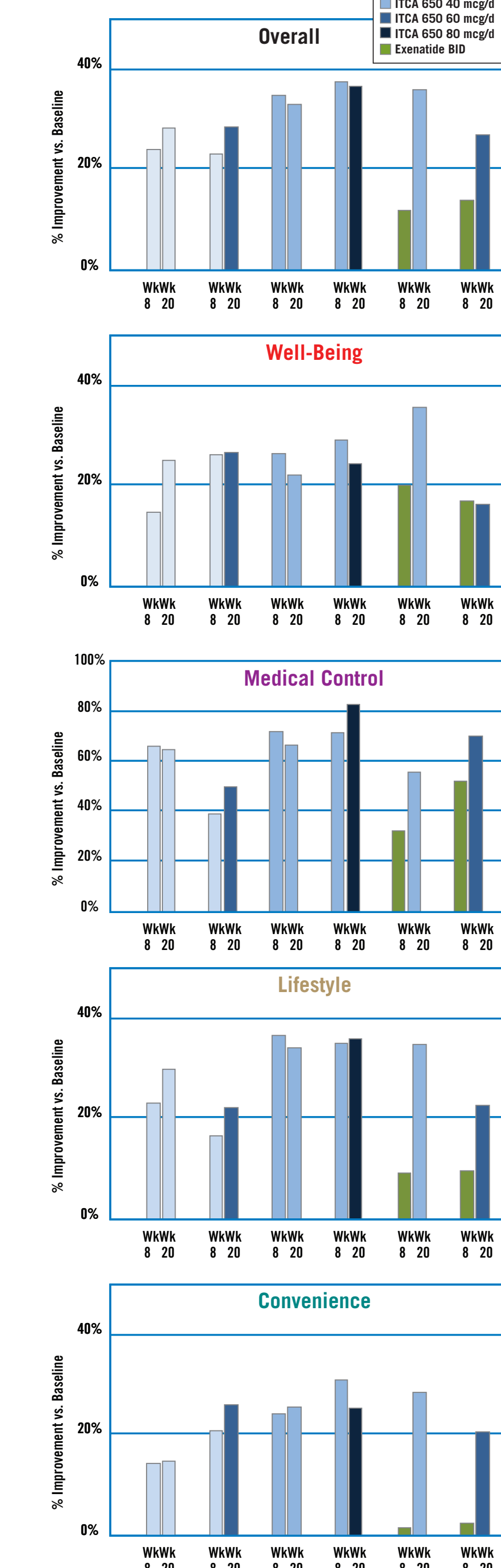
	N	Change in HbA1c (%)	Change in Weight (kg)
<b>Stage I (week 1-12)</b>			
ITCA 650 20 mcg/day	41	-1.0 ± 1.1	-0.6 ± 2.5
ITCA 650 40 mcg/day	42	-1.2 ± 1.2	-2.0 ± 3.1
Exenatide BID	43	-0.8 ± 1.1	-1.5 ± 2.4
<b>Stage II (weeks 13-24)</b>			
ITCA 650 20 mcg/day	20	-0.9 ± 0.7	-0.9 ± 4.3
ITCA 650 40 mcg/day	44	-0.9 ± 0.9	-3.5 ± 3.2
ITCA 650 60 mcg/day	41	-1.4 ± 1.1	-3.4 ± 3.9
ITCA 650 80 mcg/day	21	-1.4 ± 0.7	-2.8 ± 4.7

## Stage II - Scores



ITCA 650 treatment consistently resulted in significant increases in the overall and subscale scores relative to their baseline evaluations on metformin monotherapy. Changes with exenatide BID injections were lower and in the case of their lifestyle and convenience subscales did not reach statistical significance.

## Stage II - Improvement



## Optional Extension Period

After 24 weeks, 36 sites elected to continue participation in the study. Subjects were offered the option to continue treatment with ITCA 650 for an additional 24 weeks at their current dose. 86 out of 101 subjects (85%) elected to continue treatment. This high continuation rate is another indication of the degree of patient satisfaction with ITCA 650.

## Conclusions

- Treatment with ITCA 650 at all doses studied resulted in significant improvements in QOL overall and subscale scores relative to previous treatment with metformin monotherapy
- Treatment with ITCA 650 resulted in substantially greater improvements in QOL scores compared to exenatide BID, especially with respect to lifestyle and convenience subscales
- Subjects initially treated with exenatide BID who were switched to ITCA 650 had substantial improvements in their overall and subscale treatment satisfaction after receiving ITCA 650 therapy
- Subjects initially treated with ITCA 650 sustained their improved QOL when treated with higher doses of ITCA 650
- A high percentage of subjects (85%) elected to continue treatment with ITCA 650 beyond 24 weeks when offered this option
- Phase 3 studies are planned to start in the near future
- Assessment of devices that deliver 6 months of treatment from a single device in phase 3 will offer the opportunity to further improve patient satisfaction with ITCA 650 treatment

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 This poster will be made available online after the EASD meeting at <http://www.intarcia.com/media>