

# **A CLINICAL EVALUATION OF INTERMITTENT COMPRESSION CRYOTHERAPY, MICROCURRENT STIMULATION , AND BIOFEEDBACK TRAINING IN POST-OPERATIVE TOTAL KNEE ARTHROPLASTY PATIENTS .**

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## **ABSTRACT**

**OBJECTIVE:** Determine the effectiveness of using a post - operative rehabilitation protocol that includes Intermittent Compression Cryotherapy, Microcurrent Stimulation And Biofeedback Training on Range of Motion, Pain and functional gait in Post- Operative Total Knee Arthroplasty Patients .

**DESIGN :** Our cohort of 40 TKA patients were randomly assigned to one of the following groups. Control Group: Traditional TKA protocol exercises and ice only. X Group: Traditional TKA Protocol exercises and Intermittent Compression Cryotherapy. Y Group: Traditional TKA Protocol exercises, Intermittent Compression Cryotherapy and Microcurrent Stimulation. Z Group: Traditional TKA Protocol exercises, Intermittent compression Cryotherapy , Microcurrent Stimulation and Biofeedback . All subjects were given 6 post - operative tests starting at day 6 weekly to day 37. Each subject was also given seven post- operative tests at day 90 .All tests were designed to measure one of the following :ROM ,pain , gait function ,gait distance, oral analgesic intake , and amount of assistance required to ambulate .

**SUBJECTS:** Our cohort of 40 subjects included 25 females, 15 males with an average of age of 62. The average weight was 197 lbs . All patients were non smokers. 35 subjects had hypertension with 5 having a history of NIDDM .None of the subjects had any significant joint disease or pain in the non surgical knee .All subjects were implanted with a Zimmer Prosthesis using traditional surgical methods.

**METHODS:** After each subject was treated starting at post- operative day 6 thru 37 3 times a week for 4 weeks with the specific protocol assigned to their particular group; all subjects were given a total of 13 post- operative tests designed to test the amount of assistance required to ambulate, gait safety ,gait distance, oral analgesic intake , pain and ROM .6 of the 13 tests were given weekly starting on post - operative day 6 ending on day 37 . The seven remaining tests were given on post- operative day 90. Inferential statistical analyses, Tukey's HSD (Honestly Statistically Different ) post- hoc tests ( or multiple comparison tests ) were used to determine the significant difference between the group means. Inferential Confidence intervals were also assessed comparing the Control Group to Z Group for each category tested.

**RESULTS:** The data collected and analyses revealed that Group Z required significantly less assistance to ambulate, had less pain and therefore required less oral analgesics than the other Groups in this study. The data analyses also demonstrate Group Z had significantly greater gait safety and ROM measurements than the Control Group.

**CONCLUSIONS :** A post- operative rehabilitation protocol which includes Intermittent Compression Cryotherapy , Microcurrent Stimulation , and Biofeedback Training can significantly decrease the amount of time assistance is needed to ambulate with a assistive device , pain and oral analgesic intake while also significantly increasing gait safety and R.O.M. in post- operative TKA patients .

**STATISTICAL ANALYSIS  
OF POST-OPERATIVE DATA FOR TKA PATIENTS**

Exploratory analyses were conducted to determine the clinical effectiveness of Micro-current; Intermittent Compression Cryotherapy and Biofeedback on a range of Motion; Pain and Functional Gait in Total Knee Arthroplasty (TKA) Patients. These are patients that have had surgical repair or replacement of the knee by metal or plastic parts. For the study, a sample of 40 subjects was randomly placed into 4 groups of 10: the Control Group; and Groups X, Y and Z.

The data provided by the researcher consisted of 13 tests conducted from day 6 to day 37, and day 90 post-operative. The tests are described in the following table:

Table 1  
*Post-Operative Tests conducted on TKA Patients*

| Tests Conducted:  | Post-Operative Period | Measurement         |
|---|-----------------------|---------------------|
| Knee Extension ROM  | Days 6 to 37          | Degrees             |
| % of Assistance Required to Ambulate >51ft                          | Days 6 to 37          | Percent             |
| Pain Assessment   | Days 6 to 37          | VAS                 |
| Knee Flexion ROM  | Days 6 to 37          | Degrees             |
| Average Gait Distance in 10mins                                     | Days 6 to 37          | Feet                |
| Oral Analgesic Daily Dose Needed                                    | Days 6 to 37          | mg                  |
| Average Knee Flexion ROM  | Day 90                | Degrees             |
| Dynamic Gait Index  | Day 90                | Scale: 0-24         |
| TKA Average Knee Extension ROM                                      | Day 90                | Degrees             |
| Tinetti Gait Assessment Average Scores                              | Day 90                | Scale: 0-14         |
| Oral Analgesic Daily Dose Needed (Self Administered)                | Day 90                | mg                  |
| Pain Assessment   | Day 90                | VAS                 |
| Average # days Required to Ambulate without Assistive Device >100ft | Day 90                | No. of days post-op |

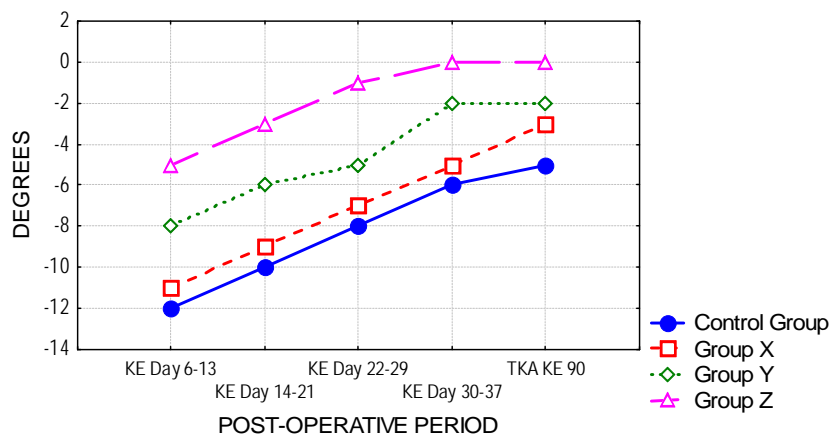
## Descriptive Statistics

The following descriptive statistics that best describe the results have been tabulated for reference of the average scores for each group with graphical representation and description of results for each test:

**Table 2**  
*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| Knee Extension ROM (Degrees) | Control Group | Group X | Group Y | Group Z |
|------------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13        | -12           | -11     | -8      | -5      |
| Week 2 – Days 14 to 21       | -10           | -9      | -6      | -3      |
| Week 3 – Days 22 to 29       | -8            | -7      | -5      | -1      |
| Week 4 – Days 30 to 37       | -6            | -5      | -2      | 0       |
| Day 90                       | -5            | -3      | -2      | 0       |

**Figure 1**  
*Post-Operative Knee Extension ROM*



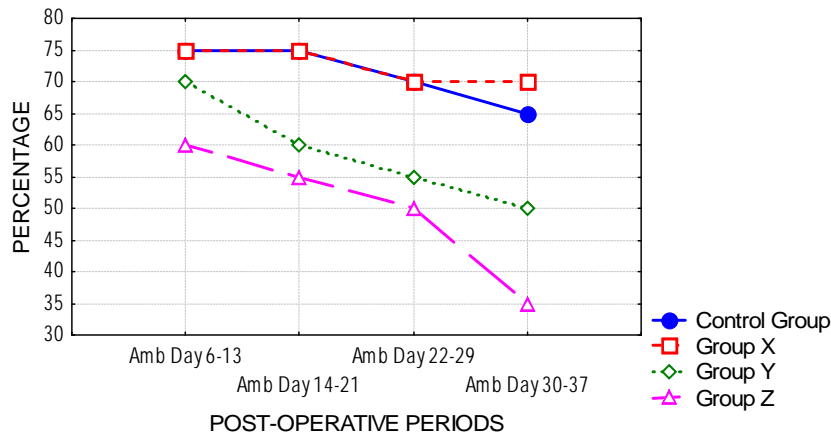
The Knee Extension ROM measures the how much the patient can extend the knee from a bent position until the leg is straight. The data show that the test results, which are averages for

each Group in the study, have progressed between 5° and 8° from -12° to 0° across the 4 Groups. Progression appears uniform for each group over the post-operative periods, however, the average measures for the Control Group and Group X show that these two groups did not achieve full extension, namely, 0°.

Table 3  
*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| % of Assistance Required to Ambulate >51ft | Control Group | Group X | Group Y | Group Z |
|--|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13                      | 75            | 75      | 70      | 60      |
| Week 2 – Days 14 to 21                     | 75            | 75      | 60      | 55      |
| Week 3 – Days 22 to 29                     | 70            | 70      | 55      | 50      |
| Week 4 – Days 30 to 37                     | 65            | 70      | 50      | 35      |

Figure 2  
*Post-Operative % of Assistance Required to Ambulate >51ft*



The data showed that the Control Group and Groups X had the same mean percentage for the first three weeks, but then the Control Group required 5% less assistance than Group X in week 4. Groups Y and Z required less assistance over the duration of the test periods with Group Z needing the least assistance in week 4.

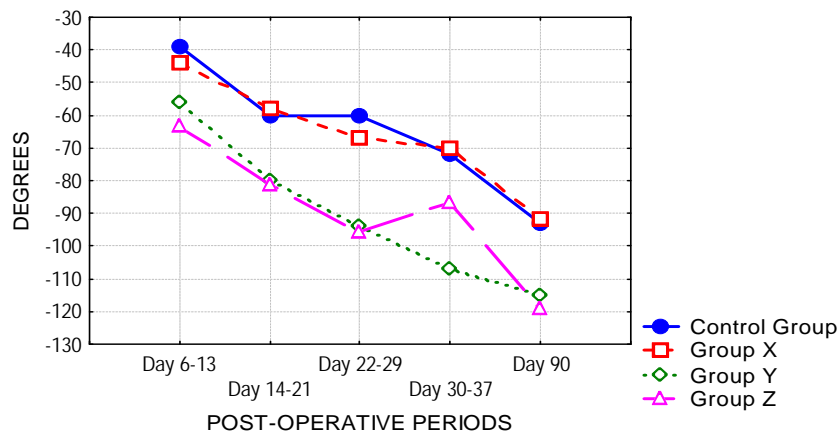
Table 4

*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| Knee Flexion ROM (Degrees) | Control Group | Group X | Group Y | Group Z |
|----------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13      | -39           | -44     | -56     | -64     |
| Week 2 – Days 14 to 21     | -60           | -58     | -80     | -82     |
| Week 3 – Days 22 to 29     | -60           | -67     | -94     | -96     |
| Week 4 – Days 30 to 37     | -72           | -70     | -107    | -87     |
| Day 90                     | -93           | -92     | -115    | -119    |

Figure 3

*Post-Operative Knee Flexion ROM*



The Knee Flexion measures the degree that the knee can bend. The data show that the test results, which are averages for each Group in the study, have progressed between 44° and 59° from -33° to -119° across the 4 Groups. Progression was not uniform for each group over the post-operative periods with week 3 showing least flexion. The data show that Group Y and Group Z achieved greater flexion than the Control Group and Group X.

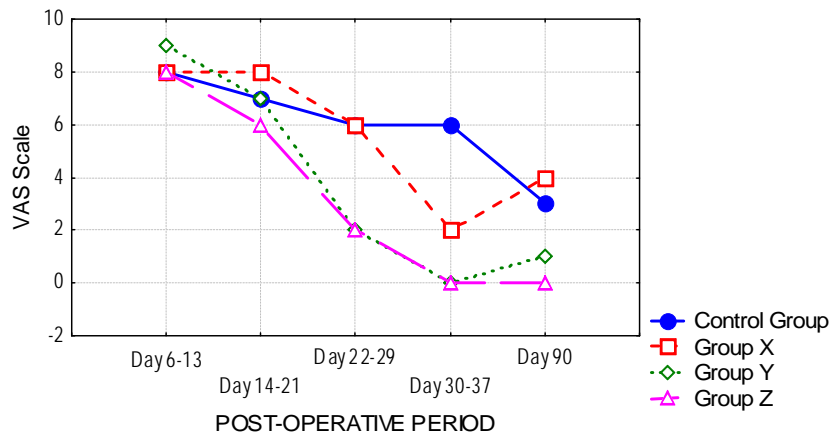
Table 5

*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| Pain Assessment (VAS Scale) | Control Group | Group X | Group Y | Group Z |
|-----------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13       | 8             | 8       | 9       | 8       |
| Week 2 – Days 14 to 21      | 7             | 8       | 7       | 6       |
| Week 3 – Days 22 to 29      | 6             | 6       | 2       | 2       |
| Week 4 – Days 30 to 37      | 6             | 2       | 0       | 0       |
| Day 90                      | 3             | 4       | 1       | 0       |

Figure 4

*Post-Operative Pain Assessment*



A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure the amount of pain that a patient feels, and ranges across a continuum from none (0) to an extreme amount of pain (10). This data shows that while the average amount of pain reported by all groups has decreased over the post-operative periods, Group X and Group Y experienced some or more pain at day 90 than after week 4. Group Z reported no pain for the last two periods, while the Control Group reported, on average, reported less pain than Group X at day 90.

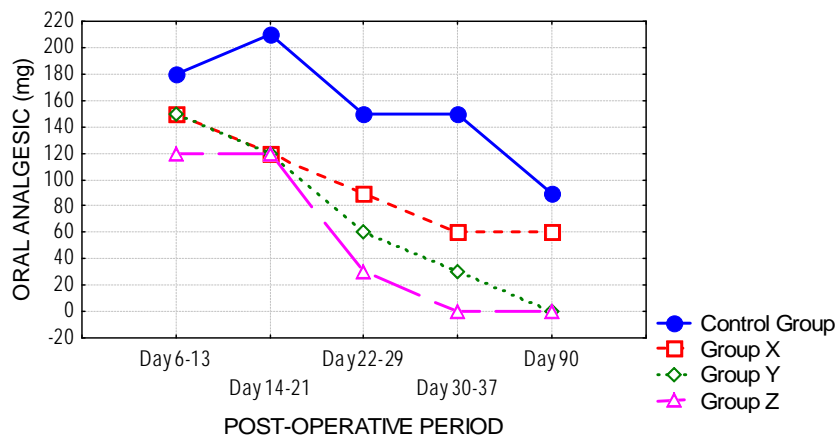
Table 6

*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| Oral Analgesic Daily Dose Required (mg) | Control Group | Group X | Group Y | Group Z |
|---|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13                   | 180           | 150     | 150     | 120     |
| Week 2 – Days 14 to 21                  | 210           | 120     | 120     | 120     |
| Week 3 – Days 22 to 29                  | 150           | 90      | 60      | 30      |
| Week 4 – Days 30 to 37                  | 150           | 60      | 30      | 0       |
| Day 90 (Self Administered)              | 90            | 60      | 0       | 0       |

Figure 5

*Post-Operative Oral Analgesic Daily Dose Required*



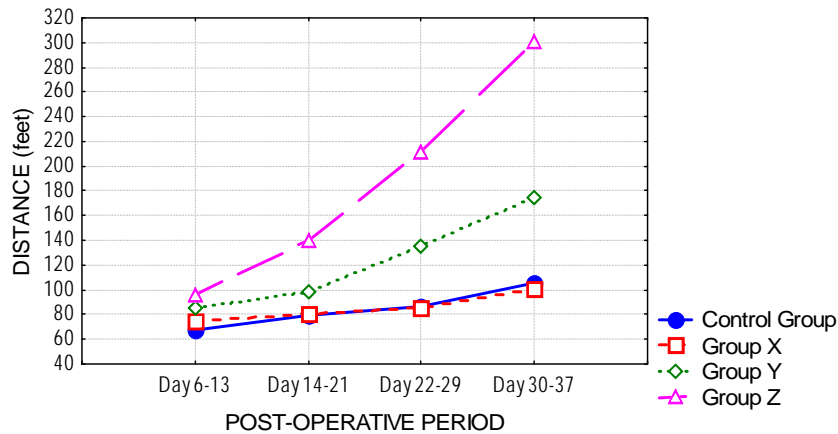
The results for oral analgesic (painkiller) dosage by each group show that the average daily dose required has decreased over the post-operative periods from a maximum of 210mg to 0mg across the groups. The data show that Group Y and Group Z were no longer self-administering oral analgesics by day 90; however, the Control Group and Group X are still self-administering an average of between 60mg and 90 mg oral analgesics daily. Interestingly, while Group Y reported on average to be feeling some pain (1 on the 0 to 10 VAS), they no longer required oral analgesics which may suggest that they were coping with the level of pain

reported.

Table 7  
*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

| Average Gait Distance in 10 minutes | Control Group | Group X | Group Y | Group Z |
|-------------------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13               | 67            | 74      | 85      | 96      |
| Week 2 – Days 14 to 21              | 79            | 80      | 98      | 140     |
| Week 3 – Days 22 to 29              | 86            | 85      | 135     | 212     |
| Week 4 – Days 30 to 37              | 106           | 101     | 175     | 301     |

Figure 6  
*Post-Operative Average Gait Distance in 10 mins*



The results show that the average gait distance in 10 minutes for the Control Group and Group X has only improved by 39ft and 27ft respectively from day 6 to day 37, while Group Z showed the greatest improvement of 205ft for the post-operative period of day 6 to day 37.

Table 8  
*Descriptive Statistics of Post-Operative Tests conducted on TKA Patients (Measurements are the Averages per Group)*

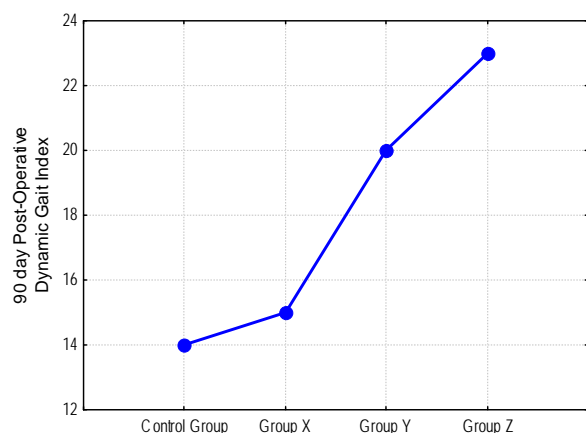
| Tests: | Control | Group X | Group Y | Group Z |
|--------|---------|---------|---------|---------|
|--------|---------|---------|---------|---------|



|                         | Group |    |    |    |
|-------------------------|-------|----|----|----|
| Dynamic Gait Index      | 14    | 15 | 20 | 23 |
| Tinetti Gait Assessment | 8     | 9  | 11 | 13 |

The Dynamic Gait Index (DGI) is a measure of likelihood of falling. The DGI measures gait on level surface; change in gait speed; gait with horizontal head turns; gait with vertical head turns; gait and pivot turn; step over and around obstacles; up and down stairs. The combined maximum score for these tests is 24. The results show that the average measures for the Control Group and Group X (14/24 and 15/24 respectively) is predictive of falls, the average measure of 20/24 indicates some risk of falling for Group Y while for Group Z, 23/24 implies they are safe ambulators.

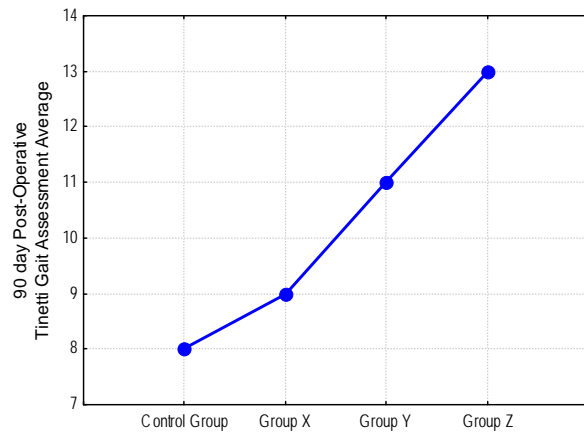
Figure 7  
90 Day Post-Operative Dynamic Gait Index



The Tinetti Gait Assessment provides a measure which is a combination of balance and gait scores. The gait measures the step length, height, continuity and symmetry, trunk sway and walk stance (heels apart or not), while the balance measures sitting balance and standing balance with eyes open or not. Measures that are less than 10/14 show the patient is at risk of falling and

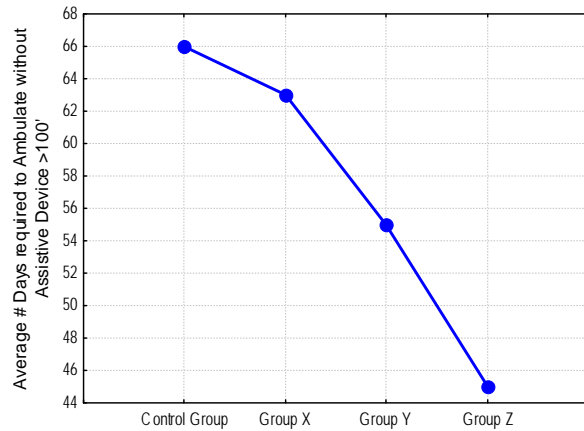
measures that are more than 12/14 indicate the patient is a safe ambulator. Similar to the results for the Dynamic Gait Index, the Control Group (8/14) and Group X (9/14) are at risk of falling, Group Y (11/14) shows some risk of falling while Group Z (13/14) can be regarded as safe ambulators.

Figure 8  
*90 Day Post-Operative Tinetti Gait Assessment*



The final test looked at the number of days required to ambulate more than 100ft without an assistive device. The data showed that it took the Control Group on average 66 days; Group X took 63 days; Group Y took 55 days and Group Z took 45 days.

Figure 9  
*Number of days required to ambulate more than 100ft without assistive device*



### Summary of Descriptive Statistics Results

The findings of the descriptive statistics across the 13 tests show that the Control Group and Group X have on average: less knee extension and flexion than the other groups; they have higher measures for pain and hence continued dosage of oral analgesics; are at a high risk of falling (according to the gait measures) and took the longest to ambulate without an assistive device.

However, Group Z showed on average: complete knee extension and the highest degree of flexion; they reported that they no longer felt pain and therefore no longer required oral analgesics; the gait tests indicated that they were safe ambulators and they took the least number of days to ambulate without an assistive device.

Group Y, on the other hand showed similar results for Group Z, but are still at some risk of falling which is probably why they took 10 days longer to ambulate without an assistive device than Group Z.

### Inferential Statistics

In an effort to determine whether there were any significant differences between the

groups, firstly, Tukey’s HSD (Honestly Statistically Different) post-hoc tests (or multiple comparison tests) were conducted to determine the significant differences between group means in an analysis of variance setting, in particular for the project tests that were conducted over the 5 time periods (week1; week2; week 3; week 4 and 90 days) including Pain Assessment; Knee Flexion and Extension ROM, % Assistance required; Average Gait Distance and Oral Analgesic Daily Dose Required.

These tests are based on the studentized range statistic and are best suited to samples of the same size (here N=10). For each pair of means, we assess the probability under the null hypothesis (no differences between means) of obtaining differences between means of this (or greater) magnitude, given the respective number of groups. Thus, it actually tests the significance of ranges, given the respective number of groups. The values in the tables represent these probabilities which are significant if <0.05. The following Tables show the results for these tests.

Table 9  
*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Pain Assessment        | Control Group | Group X | Group Y | Group Z |
|------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13  | Control Group | -       | -       | -       |
|                        | Group X       | 0.99    | -       | -       |
|                        | Group Y       | 0.46    | 0.30    | -       |
|                        | Group Z       | 1.00    | 0.99    | 0.46    |
| Week 2 – Days 14 to 21 | Control Group | -       | -       | -       |
|                        | Group X       | 0.93    | -       | -       |
|                        | Group Y       | 0.14    | 0.39    | -       |
|                        | Group Z       | 0.76    | 0.98    | 0.61    |
| Week 3 – Days 22 to 29 | Control Group | -       | -       | -       |
|                        | Group X       | 0.85    | -       | -       |
|                        | Group Y       | 0.07    | 0.01*   | -       |
|                        | Group Z       | 0.01*   | 0.00*   | 0.89    |
| Week 4 – Days 30 to 37 | Control Group | -       | -       | -       |
|                        | Group X       | 0.00*   | -       | -       |

|        |               |       |       |      |   |
|--------|---------------|-------|-------|------|---|
|        | Group Y       | 0.00* | 0.00* | -    | - |
|        | Group Z       | 0.00* | 0.00* | 0.97 | - |
| Day 90 | Control Group | -     | -     | -    | - |
|        | Group X       | 0.15  | -     | -    | - |
|        | Group Y       | 0.00* | 0.00* | -    | - |
|        | Group Z       | 0.00* | 0.00* | 1.00 | - |

For the Pain Assessment (Refer Table 9), there were no significant differences between the Groups after the first two weeks; however, after the third week Group Z scores for pain were significantly less than the Control Group and Group X. Also, Group Y showed significantly less pain than group X but the difference was not significant with Group Z. After the fourth week all Group scores were significantly different from each other except for between Groups Y and Z. On day 90, however, while pain for both Groups Y and Z were significantly less than the Control Group and Group X, there was no significant difference between Groups Y and Z; and the Control Group and Group X.

Table 10  
*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Oral Analgesic Daily Dose Required | Control Group | Group X | Group Y | Group Z |
|------------------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13              | Control Group | -       | -       | -       |
|                                    | Group X       | 0.26    | -       | -       |
|                                    | Group Y       | 0.34    | 0.99    | -       |
|                                    | Group Z       | 0.01*   | 0.40    | 0.31    |
| Week 2 – Days 14 to 21             | Control Group | -       | -       | -       |
|                                    | Group X       | 0.00*   | -       | -       |
|                                    | Group Y       | 0.00*   | 0.99    | -       |
|                                    | Group Z       | 0.00*   | 0.99    | 0.99    |
| Week 3 – Days 22 to 29             | Control Group | -       | -       | -       |
|                                    | Group X       | 0.00*   | -       | -       |
|                                    | Group Y       | 0.00*   | 0.00*   | -       |
|                                    | Group Z       | 0.00*   | 0.16    | 0.21    |
| Week 4 – Days 30 to 37             | Control Group | -       | -       | -       |
|                                    | Group X       | 0.00*   | -       | -       |

|        |               |       |       |      |   |
|--------|---------------|-------|-------|------|---|
|        | Group Y       | 0.00* | 0.10  | -    | - |
|        | Group Z       | 0.00* | 0.00* | 0.33 | - |
| Day 90 | Control Group | -     | -     | -    | - |
|        | Group X       | 0.00* | -     | -    | - |
|        | Group Y       | 0.00* | 0.00* | -    | - |
|        | Group Z       | 0.00* | 0.00* | 1.00 | - |

Results from Table 10 show that the Control Groups' daily dose of oral analgesic needed is significantly greater than the other groups from week 2 up to day 90, while the need is not significantly different between Groups Y and Z for all periods.

Table 11

*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Knee Extension ROM     | Control Group | Group X | Group Y | Group Z |
|------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13  | Control Group | -       | -       | -       |
|                        | Group X       | 0.41    | -       | -       |
|                        | Group Y       | 0.06    | 0.70    | -       |
|                        | Group Z       | 0.00*   | 0.03*   | 0.23    |
| Week 2 – Days 14 to 21 | Control Group | -       | -       | -       |
|                        | Group X       | 0.92    | -       | -       |
|                        | Group Y       | 0.01*   | 0.04*   | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.12    |
| Week 3 – Days 22 to 29 | Control Group | -       | -       | -       |
|                        | Group X       | 0.89    | -       | -       |
|                        | Group Y       | 0.10    | 0.33    | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.01*   |
| Week 4 – Days 30 to 37 | Control Group | -       | -       | -       |
|                        | Group X       | 0.50    | -       | -       |
|                        | Group Y       | 0.00*   | 0.04*   | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.26    |
| Day 90                 | Control Group | -       | -       | -       |
|                        | Group X       | 0.00*   | -       | -       |
|                        | Group Y       | 0.00*   | 0.39    | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.06    |

In all five time periods (Refer Table 11), Group Z scores for Knee Extension ROM were

significantly greater than the Control Group and Group X and only significantly greater to Group Y after week 3. Group Y had significantly greater extension than the Control Group and Group X for the periods: week 2 and day 90. On day 90, the Control Group was significantly less than all the other groups.

The results show that Groups Y and Z had significantly greater knee flexion than the Control Group and Group X at all post-operative test periods, except at the end of week 4 where all 4 groups showed no significant difference (Refer Table 12). Also, the Control Group was not significantly different to Group X at all post-operative test periods, and similarly with Groups Y and Z.

Table 12  
*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Knee Flexion ROM       | Control Group | Group X | Group Y | Group Z |
|------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13  | Control Group | -       | -       | -       |
|                        | Group X       | 0.71    | -       | -       |
|                        | Group Y       | 0.00*   | 0.05*   | -       |
|                        | Group Z       | 0.00*   | 0.03*   | 0.35    |
| Week 2 – Days 14 to 21 | Control Group | -       | -       | -       |
|                        | Group X       | 0.98    | -       | -       |
|                        | Group Y       | 0.03*   | 0.01*   | -       |
|                        | Group Z       | 0.02*   | 0.01*   | 0.99    |
| Week 3 – Days 22 to 29 | Control Group | -       | -       | -       |
|                        | Group X       | 0.58    | -       | -       |
|                        | Group Y       | 0.00*   | 0.00*   | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.99    |
| Week 4 – Days 30 to 37 | Control Group | -       | -       | -       |
|                        | Group X       | 1.00    | -       | -       |
|                        | Group Y       | 0.21    | 0.15    | -       |
|                        | Group Z       | 0.84    | 0.77    | 0.66    |
| Day 90                 | Control Group | -       | -       | -       |
|                        | Group X       | 0.89    | -       | -       |
|                        | Group Y       | 0.00*   | 0.00*   | -       |
|                        | Group Z       | 0.00*   | 0.00*   | 0.36    |

From Table 13 below, we see that the percentage of assistance required to ambulate more than 51ft for Groups Y and Z was significantly less than for the Control Group and Group X at all post-operative test periods, except at the end of the first week where all 4 groups showed no significant difference apart from Group Z being significantly less than Group X. Also, Group Z showed significantly less need for assistance than Group Y in week 4.

Table 13

*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| % of Assistance Required to Ambulate >51ft | Control Group | Group X | Group Y | Group Z |
|--|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13                      | Control Group | -       | -       | -       |
|  | Group X       | 0.99    | -       | -       |
|  | Group Y       | 0.84    | 0.79    | -       |
|  | Group Z       | 0.05    | 0.04*   | 0.27    |
| Week 2 – Days 14 to 21                     | Control Group | -       | -       | -       |
|  | Group X       | 1.00    | -       | -       |
|  | Group Y       | 0.01*   | 0.01*   | -       |
|  | Group Z       | 0.00*   | 0.00*   | 0.65    |
| Week 3 – Days 22 to 29                     | Control Group | -       | -       | -       |
|  | Group X       | 1.00    | -       | -       |
|  | Group Y       | 0.01*   | 0.01*   | -       |
|  | Group Z       | 0.00*   | 0.00*   | 0.15    |
| Week 4 – Days 30 to 37                     | Control Group | -       | -       | -       |
|  | Group X       | 0.76    | -       | -       |
|  | Group Y       | 0.02*   | 0.00*   | -       |
|  | Group Z       | 0.00*   | 0.00*   | 0.00*   |

As the results show in Table 14, the average gait distance in 10 minutes is significantly greater for Group Z than for all the other Groups over the post operative periods, except in week 1 when the difference was not significant from Group Y. Group Y showed significantly greater gait distance than the Control Group in the first three weeks, and was significantly greater than



Groups X in weeks 2 and 3. Group X, though, did not show any significant difference in average gait distance from the Control Group.

Table 14

*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Average Gait Distance in 10mins | Control Group | Group X | Group Y | Group Z |
|---------------------------------|---------------|---------|---------|---------|
| Week 1 – Days 6 to 13           | Control Group | -       | -       | -       |
|                                 | Group X       | 0.24    | -       | -       |
|                                 | Group Y       | 0.00*   | 0.17    | -       |
|                                 | Group Z       | 0.00*   | 0.00*   | 0.07    |
| Week 2 – Days 14 to 21          | Control Group | -       | -       | -       |
|                                 | Group X       | 0.99    | -       | -       |
|                                 | Group Y       | 0.00*   | 0.00*   | -       |
|                                 | Group Z       | 0.00*   | 0.00*   | 0.00*   |
| Week 3 – Days 22 to 29          | Control Group | -       | -       | -       |
|                                 | Group X       | 0.99    | -       | -       |
|                                 | Group Y       | 0.01*   | 0.00*   | -       |
|                                 | Group Z       | 0.00*   | 0.00*   | 0.00*   |
| Week 4 – Days 30 to 37          | Control Group | -       | -       | -       |
|                                 | Group X       | 0.99    | -       | -       |
|                                 | Group Y       | 0.52    | 0.38    | -       |
|                                 | Group Z       | 0.00*   | 0.00*   | 0.00*   |

Table 15

*Tukey HSD tests Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Tests:                  | Control Group | Group X | Group Y | Group Z |
|-------------------------|---------------|---------|---------|---------|
| Dynamic Gait Index      | Control Group | -       | -       | -       |
|                         | Group X       | 0.97    | -       | -       |
|                         | Group Y       | 0.01*   | 0.03*   | -       |
|                         | Group Z       | 0.04*   | 0.10    | 0.95    |
| Tinetti Gait Assessment | Control Group | -       | -       | -       |
|                         | Group X       | 0.07    | -       | -       |

|                                   |               |       |       |      |   |
|-----------------------------------|---------------|-------|-------|------|---|
|                                   | Group Y       | 0.00* | 0.83  | -    | - |
|                                   | Group Z       | 0.00* | 0.03* | 0.17 | - |
| Number of days walking without AD |               |       |       |      |   |
|                                   | Control Group | -     | -     | -    | - |
|                                   | Group X       | 0.84  | -     | -    | - |
|                                   | Group Y       | 0.55  | 0.96  | -    | - |
|                                   | Group Z       | 0.01* | 0.04* | 0.14 | - |

The results for the Dynamic Gait Index and Tinetti Gait Assessment show that those participants in the study in Groups Y and Z are significantly less likely to fall than those in the Control Group and Group X, with no significant difference for average scores between Groups Y and Z (Refer Table 15). However, the average Dynamic Gait Index between Groups Z and X is not significantly different, while the Tinetti Gait Assessment shows the difference is significant between these groups. Conversely, the average Dynamic Gait Index between Groups Y and X is significantly different, while the Tinetti Gait Assessment shows the difference is not significant between these groups. For the average number of days required to ambulate without and assistive device more than 100ft, the results show that means scores for Group Z only are significantly less than the Control Group and Group X. Further analyses were conducted to assess the correlational relationships; and predictive potential between the variables using general linear regression tests, at day 90. Figure 10 below shows the significant negative correlation ( $r = -0.6863$ ,  $p = 0.000002$ ) between knee extension and flexion ROM measures across the whole sample. This implies that the likelihood of full knee extension is significantly related to the likelihood of greater knee flexion, which is to be expected. Within the Groups, the correlational relationships were not significant (Refer Table 16).

Table 16  
*Pearson's Correlations (r) for 90-day Post-Operative Tests conducted on TKA Patients*

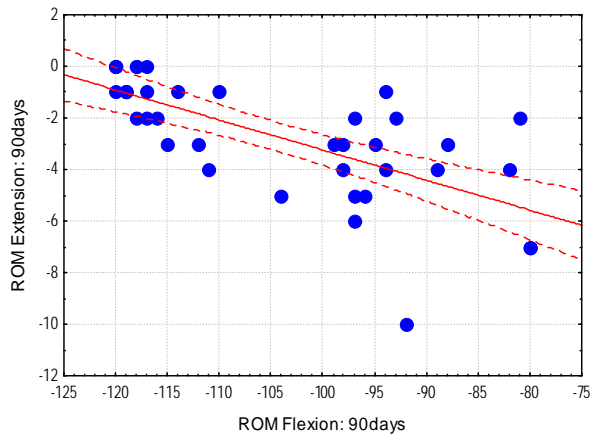
|                  |              |
|------------------|--------------|
| Group Variables: | Knee Flexion |
|------------------|--------------|

|                               |       |
|-------------------------------|-------|
| Control Group: Knee Extension | -0.53 |
| Group X: Knee Extension       | 0.04  |
| Group Y: Knee Extension       | -0.38 |
| Group Z: Knee Extension       | 0.22  |

\*Significance at  $p < 0.05$

Figure 10

Scatterplot of measures for Knee Extension and Flexion ROM at day 90 post-operative



Further results showed that, across the sample, significant relationships between knee extension and flexion, gait measures and the number of day to ambulate without an assistive device. The data show that the greater the knee extension and flexion, the more likely the patient will be a safe ambulator, and therefore the more likely the patient will be able to ambulate more than 100ft without an assistive device (Refer Table 17).

Table 17

Pearson's Correlations ( $r$ ) for 90-day Post-Operative Tests conducted on TKA Patients

| Group Variables: | DGI    | Tinnetti | Ambulate >100ft |
|------------------|--------|----------|-----------------|
| Knee Extension   | 0.29   | 0.58*    | -0.41*          |
| Knee Flexion     | -0.46* | -0.45*   | 0.39*           |

\*Significance at  $p < 0.05$

The Group data revealed the following results (Refer Table 18). Group Z data showed a significant negative correlation between knee extension and Tinnetti's gait assessment; and the

Control Group showed a significant negative correlation between knee flexion and the Dynamic gait index measures.

Table 18  
*Pearson's Correlations (r) for 90-day Tests conducted on TKA*

| Group Variables: |                | DGI    | Tinnetti | Ambulate >100ft |
|------------------|----------------|--------|----------|-----------------|
| Control Group    | Knee Extension | -0.38  | -0.13    | -0.12           |
|                  | Knee Flexion   | -0.78* | 0.49     | -0.09           |
| Group X          | Knee Extension | -0.02  | 0.42     | 0.22            |
|                  | Knee Flexion   | 0.21   | -0.30    | 0.05            |
| Group Y          | Knee Extension | -0.26  | 0.31     | -0.42           |
|                  | Knee Flexion   | -0.16  | 0.23     | 0.37            |
| Group Z          | Knee Extension | 0.34   | -0.71*   | 0.21            |
|                  | Knee Flexion   | -0.34  | -0.16    | 0.27            |

\*Significance at  $p < 0.05$

A general regression analysis, using analysis of covariance, showed there was a significant regression ( $F = 2.65$ ;  $p = 0.029^*$ ) on the number of days required to ambulate without and assistive device more than 100ft as a function of the dependent variables, knee extension and flexion and gait measures, for the different groups. This test result implies that the amount of variance in the 'number of days required to ambulate without and assistive device more than 100ft' is explained by the variance in the measures for the independent variables used in this regression. .

#### Summary of Inferential Statistical Results

Pain levels reported were significantly less for Groups Y and Z than for the Control Group and Group X from the end of the third week up to day 90, but the difference was not

significant between Group Y and Group Z. Accordingly, the Control Groups' daily dose of oral analgesic needed is significantly greater than the other groups.

Knee Extension ROM was greater for Group Z than all the other groups since the beginning of the post-operative tests. By day 90, the Control Group showed significantly less knee extension than Groups X, Y and Z. Most post-operative periods the results showed that Groups Y and Z had significantly greater knee flexion than the Control Group and Group X. Also, the Control Group was not significantly different to Group X at all post-operative test periods, and similarly with Groups Y and Z.

The percentage of assistance required to ambulate more than 51ft for Groups Y and Z was significantly less than for the Control Group and Group X at most post-operative test periods. The average gait distance in 10 minutes is significantly greater for Group Z than for all the other Groups in weeks 2 to 4 and Group Y showed significantly greater gait distance than the Control Group in the first three weeks, and was significantly greater than Groups X in weeks 2 and 3. Group X, though, did not show any significant difference in average gait distance from the Control Group.

The results show that those participants in the study in Groups Y and Z are significantly less likely to fall than those in the Control Group and Group X. . For the average number of days required to ambulate without and assistive device more than 100ft, the results show that means scores for Group Z are significantly less than the Control Group and Group X.

Results showed that the likelihood of full knee extension is significantly related to the likelihood of greater knee flexion . The data also showed that the greater the knee extension and flexion, the more likely the patient will be a safe ambulator, and therefore the more likely the patient will be able to ambulate more than 100ft without an assistive device. Regression results

showed that the amount of variance in the ‘number of days required to ambulate without and assistive device more than 100ft’ is explained by the variance in the measures for the independent variables used in this regression.

## STATISTICAL ANALYSIS OF POST-OPERATIVE DATA FOR TKA PATIENTS

### Inferential Statistical Analysis Control Group vs. Group Z

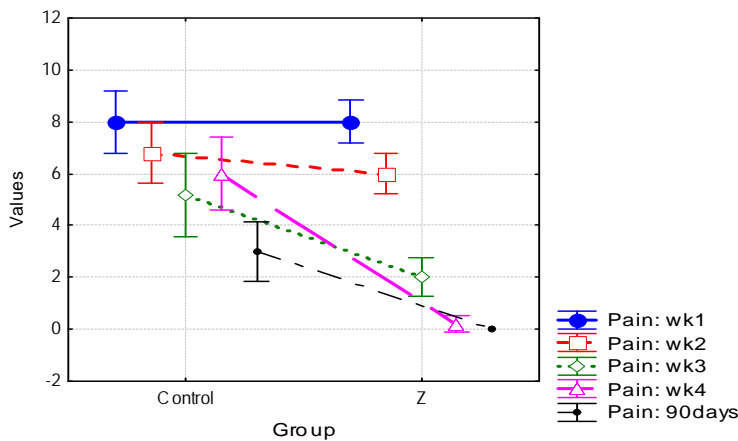
In addition to the previous analysis, this document will provide results for analyses conducted on only two of the groups in the study, namely, the Control Group and Group Z. To determine whether there were any significant differences between the groups, Tukey's HSD (Honest Statistical Different) post-hoc tests (or multiple comparison tests) were conducted to determine the significant differences between the Control Group and Group Z means in an analysis of variance setting, in particular for the project tests that were conducted over the 5 time periods (week1; week2; week 3; week 4 and 90 days) including Pain Assessment; Oral Analgesic Daily Dose Required Knee Flexion and Extension ROM, % Assistance required and Average Gait Distance.

These tests are based on the studentized range statistic and are best suited to samples of the same size (here  $N=10$ ). For each pair of means, we assess the probability under the null hypothesis (no differences between means) of obtaining differences between means of this (or greater) magnitude, given the respective number of groups. Thus, it actually tests the significance of ranges, given the respective number of groups. The values in the tables represent these probabilities which are significant if  $<0.05$ . The following Tables show the results for these tests.

Table 1  
*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients*  
 (\*=Significant Difference)

| Pain Assessment        | Control Group |
|------------------------|---------------|
| Week 1 – Days 6 to 13  | 1.000000      |
| Week 2 – Days 14 to 21 | 0.207029      |
| Week 3 – Days 22 to 29 | 0.000858*     |
| Week 4 – Days 30 to 37 | 0.000161*     |
| Day 90                 | 0.000174*     |

Figure 1  
*Interactive plot of means for Pain (vertical lines: 95% confidence intervals)*



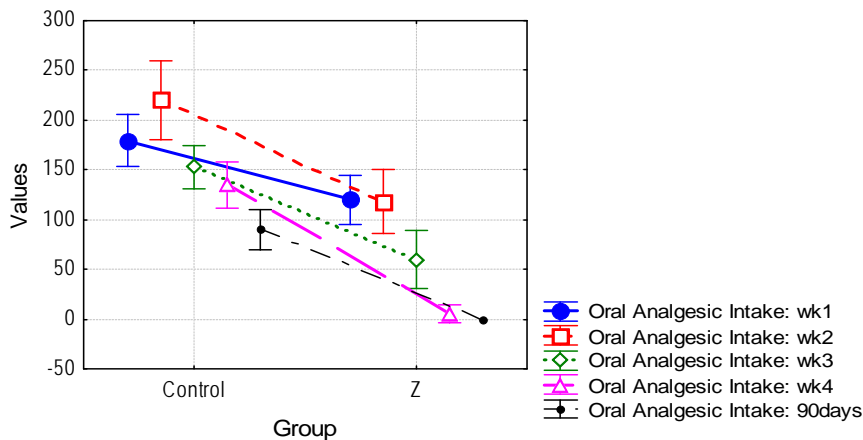
The results for Pain Assessment (Refer Table 1) show that there was no significant difference between the mean measures of the two groups in the first two weeks of the post-operative test period. However, the difference was significant from the third week up till day, 90 with Group Z reporting no pain from the week 4 and day 90 compared with the Control Group still experiencing pain, on average. The use of oral analgesics was significantly less for Group Z than for the Control Group across all post-operative test periods (Refer Table 2).



Table 2  
*Tukey HSD tests of Post-Operative Tests conducted on TKA Patients*  
 (\*=Significant Difference)

| Oral Analgesic Daily Dose Required | Control Group     |
|------------------------------------|-------------------|
| Week 1 – Days 6 to 13              | Group Z 0.001795* |
| Week 2 – Days 14 to 21             | Group Z 0.000435* |
| Week 3 – Days 22 to 29             | Group Z 0.000171* |
| Week 4 – Days 30 to 37             | Group Z 0.000161* |
| Day 90                             | Group Z 0.000161* |

Figure 2  
*Interactive plot of means for Oral Analgesic Intake*  
 (vertical lines: 95% confidence intervals)



Results for knee extension and flexion ROM tests were significantly different across all post-operative test periods for the two groups, with Group Z showing significantly greater knee extension and flexion than the Control Group (Refer Tables 4 & 5).

Table 3

Tukey HSD tests of Post-Operative Tests conducted on TKA Patients  
 (\*=Significant Difference)

| Knee Extension ROM     | Control Group | Group Z   |
|------------------------|---------------|-----------|
| Week 1 – Days 6 to 13  |               | 0.000704* |
| Week 2 – Days 14 to 21 |               | 0.000168* |
| Week 3 – Days 22 to 29 |               | 0.000162* |
| Week 4 – Days 30 to 37 |               | 0.000163* |
| Day 90                 |               | 0.000159* |

Figure 3

Interactive plot of means for knee extension (vertical lines: 95% confidence intervals)

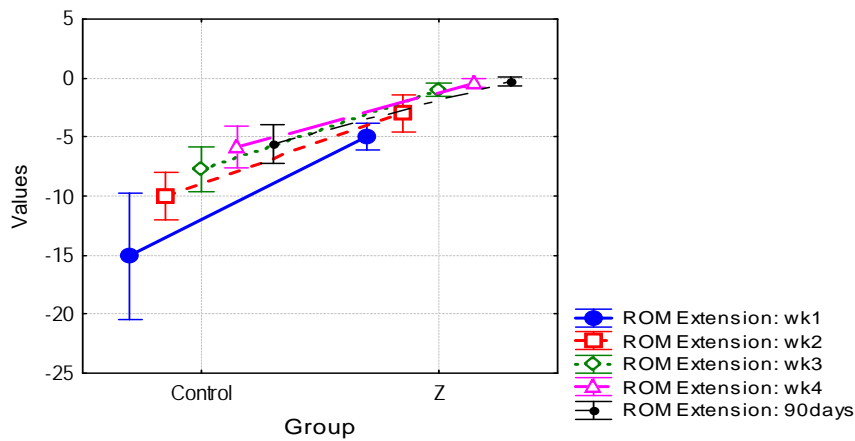


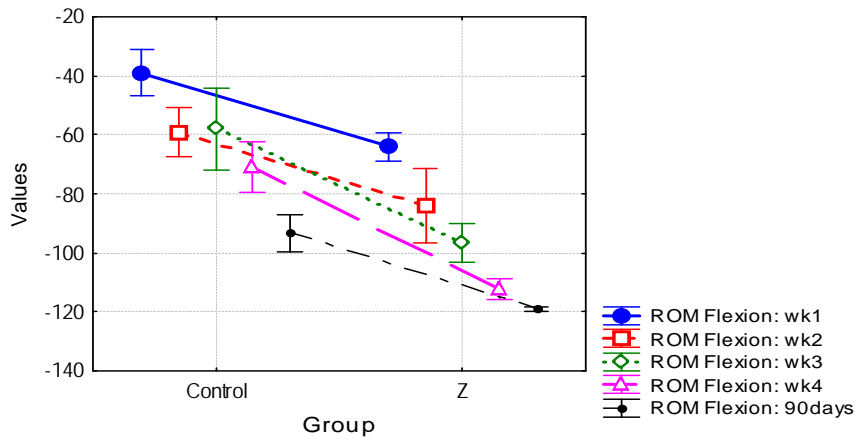
Table 4

Tukey HSD tests of Post-Operative Tests conducted on TKA Patients  
 (\*=Significant Difference)

| Knee Flexion ROM       | Control Group | Group Z   |
|------------------------|---------------|-----------|
| Week 1 – Days 6 to 13  |               | 0.00017*  |
| Week 2 – Days 14 to 21 |               | 0.00181*  |
| Week 3 – Days 22 to 29 |               | 0.00018*  |
| Week 4 – Days 30 to 37 |               | 0.000161* |
| Day 90                 |               | 0.000159* |

Figure 4

Interactive plot of means for knee flexion (vertical lines: 95% confidence intervals)



Results for the percentage of assistance required to ambulate more than 51ft and average gait distance in 10mins were also significantly different for the two groups. Group Z required significantly less assistance to ambulate more than 51ft across all post-operative test periods, and achieved a significantly greater gait distance in 10mins than the Control Group across all post-operative test periods (Refer Tables 5&6).

Table 5

Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)

| % of Assistance Required to Ambulate >51ft | Control Group |
|--|---------------|
| Week 1 – Days 6 to 13                      | 0.008095*     |
| Week 2 – Days 14 to 21                     | 0.000479*     |
| Week 3 – Days 22 to 29                     | 0.000161*     |
| Week 4 – Days 30 to 37                     | 0.000161*     |

Figure 5

Interactive plot of means for % assistance required to ambulate >51ft (vertical lines: 95% confidence intervals)

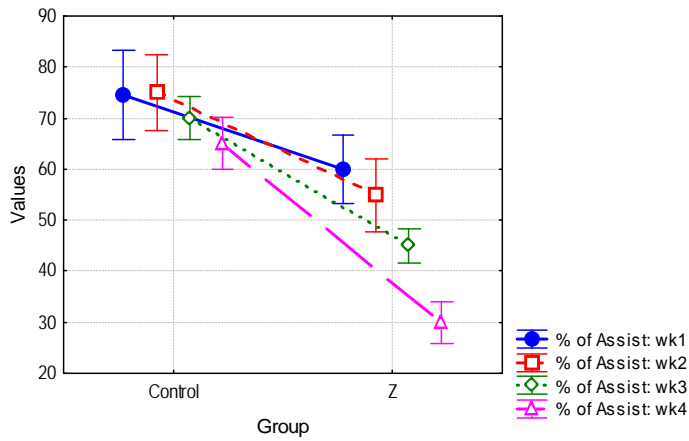


Table 6

Tukey HSD tests of Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)

| Average Gait Distance in 10mins | Control Group |
|---------------------------------|---------------|
| Week 1 – Days 6 to 13           | 0.000211*     |
| Week 2 – Days 14 to 21          | 0.000161*     |
| Week 3 – Days 22 to 29          | 0.000161*     |
| Week 4 – Days 30 to 37          | 0.000360*     |

Figure 6

Interactive plot of means for Gait distance in 10 mins (vertical lines: 95% confidence intervals)

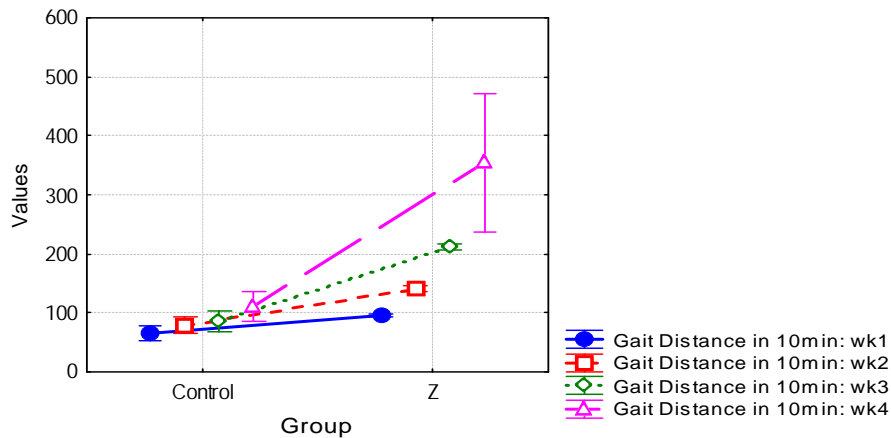


Table 7

*Tukey HSD tests Post-Operative Tests conducted on TKA Patients (\*=Significant Difference)*

| Tests:                            | Control Group |
|-----------------------------------|---------------|
| Dynamic Gait Index                | 0.000162*     |
| Tinetti Gait Assessment           | 0.000176*     |
| Number of days walking without AD | 0.004639*     |

Figure 7

*Interactive plot of DGI means (vertical lines: 95% confidence intervals)*

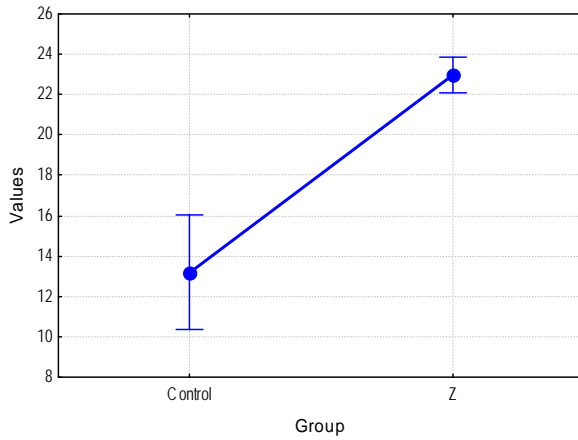


Figure 8

*Interactive plot of Tinnetti Gait means (vertical lines: 95% confidence intervals)*

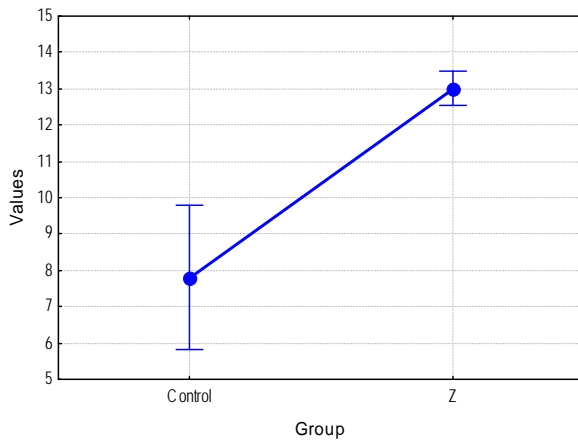
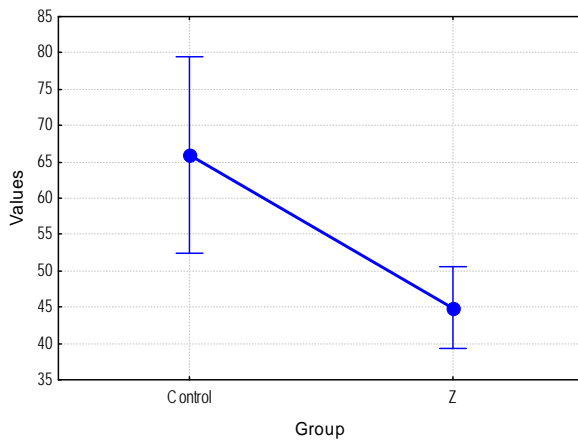


Figure 9

Interactive plot of #days walking without AD means (vertical lines: 95% confidence intervals)



Figures 7, 8 & 9 demonstrate the significant differences between the means for the two groups, with Groups Z showing that, on average, they are safe ambulators while the Control Group are at risk of falling, and that the Control Group required significantly more days to walk without an assistive device than Group Z.

The results shown in Table 8 do not show significant correlations between knee extension and flexion for the two groups at day 90, however, the negative correlation for the Control Group indicates that the greater the knee extension, the more likely the knee flexion will be smaller. The positive correlation for Group Z indicates that the greater the knee extension, the more likely the knee flexion will be greater.

Table 8

Pearson's Correlations (*r*) for 90-day Post-Operative Tests conducted on TKA Patients

| Group Variables:              | Knee Flexion |
|-------------------------------|--------------|
| Control Group: Knee Extension | -0.53        |
| Group Z: Knee Extension       | 0.22         |

\*Significance at  $p < 0.05$

Table 9

*Pearson's Correlations (r) for 90-day Tests conducted on TKA*

| Group Variables: |                | DGI    | Tinnetti Gait | Ambulate >100ft |
|------------------|----------------|--------|---------------|-----------------|
| Control Group    | Knee Extension | -0.38  | -0.13         | -0.12           |
|                  | Knee Flexion   | -0.78* | 0.49          | -0.09           |
| Group Z          | Knee Extension | 0.34   | -0.71*        | 0.21            |
|                  | Knee Flexion   | -0.34  | -0.16         | 0.27            |

\*Significance at  $p < 0.05$

Group Z data showed a significant negative correlation between knee extension and Tinnetti's gait assessment which implies that the greater the knee extension the more likely the subject is to be a safe ambulator; and the Control Group showed a significant negative correlation between knee flexion and the Dynamic gait index measures which suggests that the greater the less the knee flexion the more likely the subject is at risk of falling (Refer Table 9).

#### Summary

The outcome of the analyses confirm that the data showed sufficient evidence to conclude that Group Z reported significantly less pain and consequently used less oral analgesics than the Control Group. Also, Group Z had significantly greater knee extension and flexion than the Control Group, as well as requiring significantly less assistance to ambulate more than 51ft and having significantly greater gait distance after 10mins than the Control Group. The Control group was significantly more likely to be at risk of falling while Group Z could be described as safe ambulators when tested at 90 days post-operative. At day 90, Group Z required significantly less days to ambulate more than 100ft than the Control Group.