# DISUSE OSTEOPENIA STUDY

## CoRIPS 034

## REC ref: 09/H0202/64

# Interim report to the Society and College of Radiographers

## June 2011

**By**

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**Details of study**

| | |
|---|---|
| Full title of study: | A study into post-traumatic and post-surgical disuse osteopenia and its short- and long-term effects |
| Name of main REC: | Devon and Torbay |
| REC reference number: | 09/H0202/64 |
| Date of favourable ethical opinion: | 21st January 2010 |
| Sponsor: | University of Exeter |

**Commencement and termination dates**

Start date: February 2010
Estimated completion date: February 2013. Due to delays in recruitment, the anticipated completion date has been extended beyond the original date of October 2012. This remains well within the four year period allowed for completion of the PhD.

**Approved amendments**

1. Dated 6.4.10. Pedometers to be used in place of accelerometers for measurement of activity levels.

2. Dated 6.10.10. The fracture group participants have been difficult to recruit, in the main part due to low numbers of suitable fracture patients attending the Royal Devon and Exeter Hospital. Recruitment has been attempted from fracture clinic and accident and emergency, though numbers have been extremely low. Therefore, some mitigating measures are required to complete a study within the given time frame. Firstly, the two fracture patient groups, 'plaster of Paris' (POP) group and the 'internal fixation '(IF) groups, will be merged reducing recruitment from a total of 100 patients to 50 patients. If required, for the convenience of patients and to facilitate recruitment of this group, the period of 2 weeks between injury and baseline measurement may be extended to 3 weeks. 50 additional volunteers will be recruited who have sustained a leg/ankle fracture resulting in approximately 6 weeks of immobilization, post menopause and within the previous ten years. This will provide a cross-sectional arm to the study giving a comparison of bone changes due to previous immobilization in this group compared to the control group. This group will only be required to provide baseline data and will therefore only come for one visit and one set of scans.

**Recruitment of participants**

| Group | Recruited | Withdrawn/Did not attend | Total remaining |
|---|---|---|---|
| Controls | 46 | 1 | 45 |
| Total Knee Replacement | 19 | 5 | 14 |
| Recent Fracture | 9 | 1 | 8 |
| Longstanding fracture | 8 | 0 | 8 |
| TOTAL | 82 | 7 | 75 |

**Safety of participants**

There have not been any unexpected adverse events or serious breaches of the protocol during the study.

**Grant expenditure**

Summary: Appendix 1

**Conferences attended**

- National Osteoporosis Society Conference 2010
- Joint Meeting of the Bone Research Society and the British Orthopaedic Research Society Cambridge, 27-29 June 2011– Poster presentation: Appendix 2

NB. Conference fees and expenses have been met by The University of Exeter

**Results**

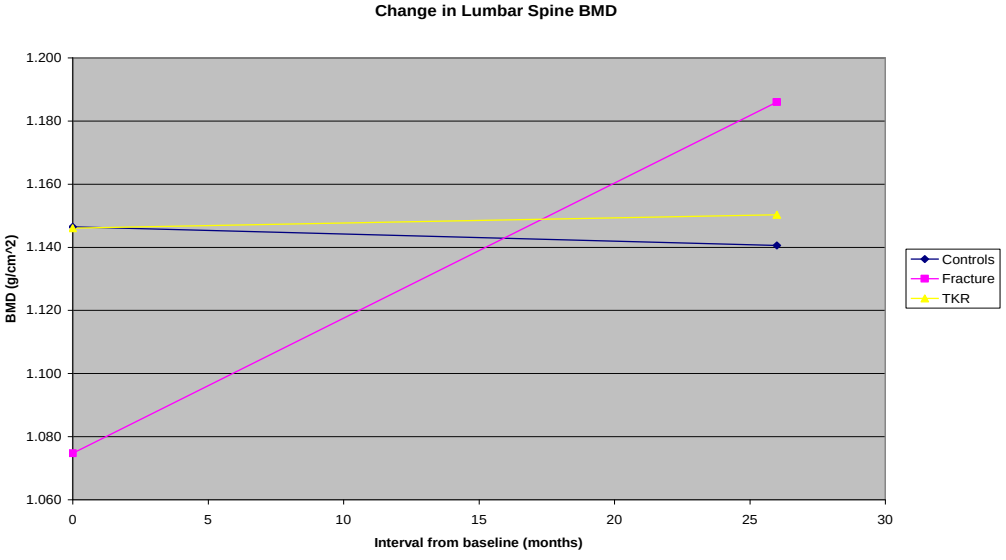
Due to the longitudinal methodology of the study, requiring participants to attend repeated visits over a period of one year, there are a limited number of completed data sets at the present moment. However, a basic preliminary analysis of the available data is summarised below. It should be noted that the number of participants analysed at each visit are not equal as not all have returned yet for the 6 month session. The group means are consequently not directly comparable and the graphs presented may only provide an indication of emerging trends.

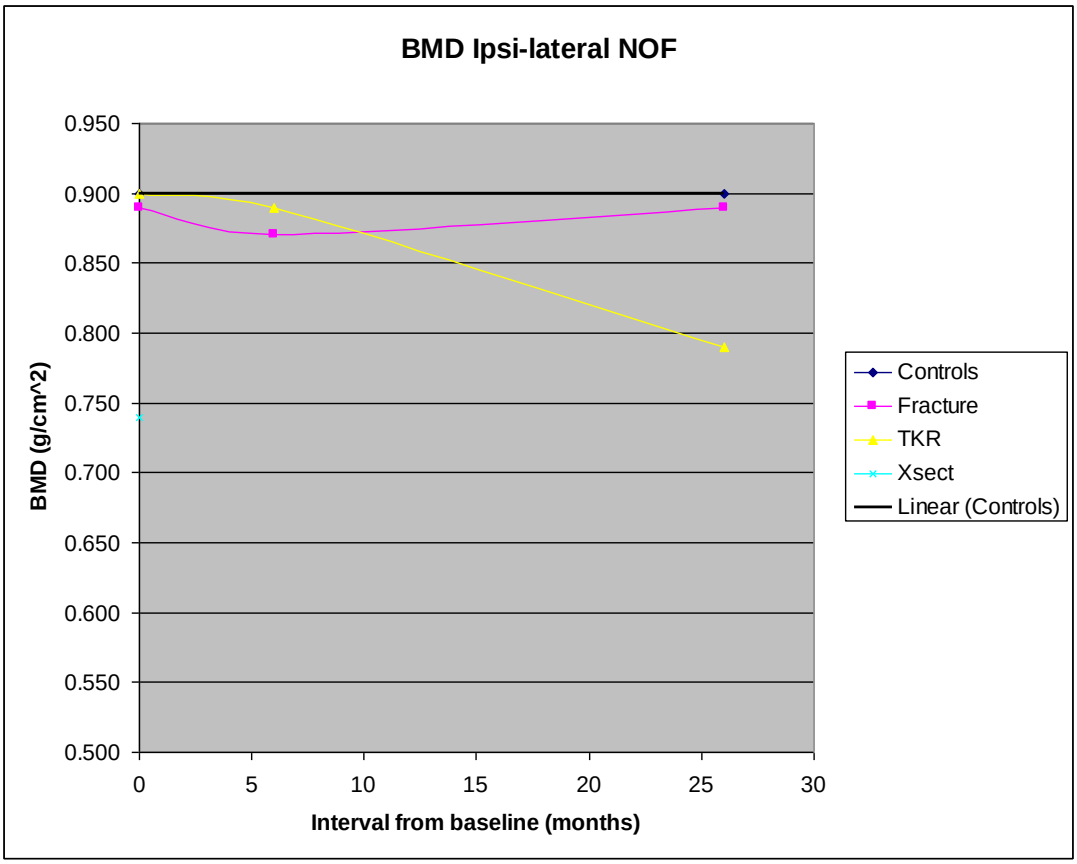
| **Participant Characteristics at Baseline – Means [Standard deviation]** | | | | | |
|---|---|---|---|---|---|
| Group | Controls | Total Knee Replacement | Fracture – internal fixation | Fracture – plaster only | Cross-sectional fracture group |
| Number analysed | 45 | 13 | 5 | 3 | 5 |
| Age at 1st visit (Years) | 64.3 [7.8] | 66.4 [8.9] | 65.5 [8.2] | 57.6 [3.8] | 61.1 [10.3] |
| Menopause age (Years) | 49.8 [5.5] | 49.0 [9.17] | 49.6 [5.6] | 46.7 [8.8] | 49.2 [4.7] |
| Menarche age(Years) | 12.85 [1.6] | 12.9 [2.2] | 12.2 [0.5] | 11.3 [1.5] | 13.1 [1.8] |
| Body mass index (BMI) Kg/m^2 | 25.7 [3.8] | 35.1 [7.6] | 24.9 [4.7] | 27.9 [1.9] | 28.0 [6.3] |
| BMI at age 21 Kg/m^2 | 21.9 [2.6] | 25.4 [6.8] | 20.4 [2.9] | 25.0 [1.3] | 21.24 [1.8] |
| Number of previous falls | 0.3 [0.6] | 0.9 [1.3] | 0.2 [0.4] | 0.3 [0.6] | 0.4 [0.9] |
| Number of co-morbidities detrimental to bone health | 0.8 [0.7] | 2.1 [1.4] | 0.6 [0.9] | 0.3 [0.6] | 1.0 [0.7] |
| Daily level of exercise * | 2.2 [0.7] | 0.9 [0.7] | 2.4[.9] | 2.7 [0.6] | 2.0 [1.0] |
| Past use of Hormone Replacement Therapy (months) | 27.9 [47.0] | 40.6 [81.2] | 11.0 [23.5] | 34.0 [44.2] | 24.4 [53.5] |

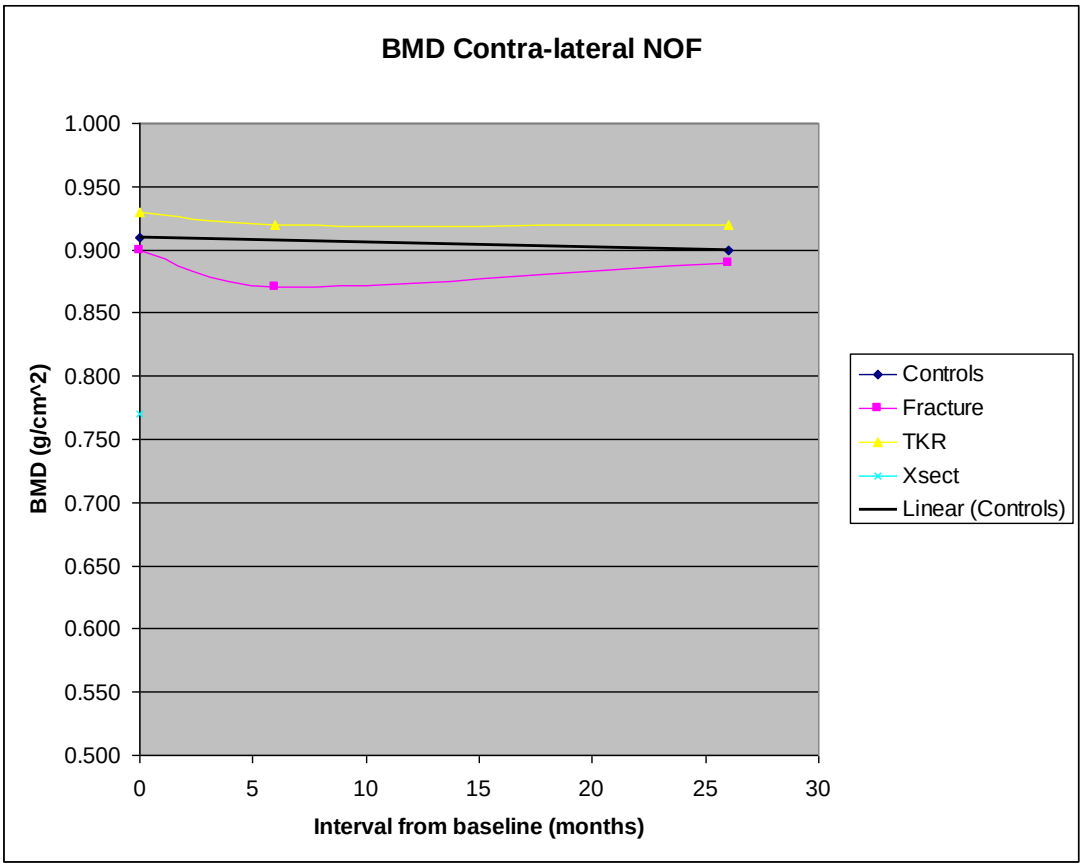
| | | | | | |
|---|---|---|---|---|---|
| Past use of Oral Contraceptive Pill (months) | 71.1 [80.1] | 3184.5 [11251.3] | 8.9 [11.3] | 139.3 [220.0] | 51.6 [105.6] |

* 1= None, 2= Some but less than half an hour, 3= Half to one hour, 4=More than one hour

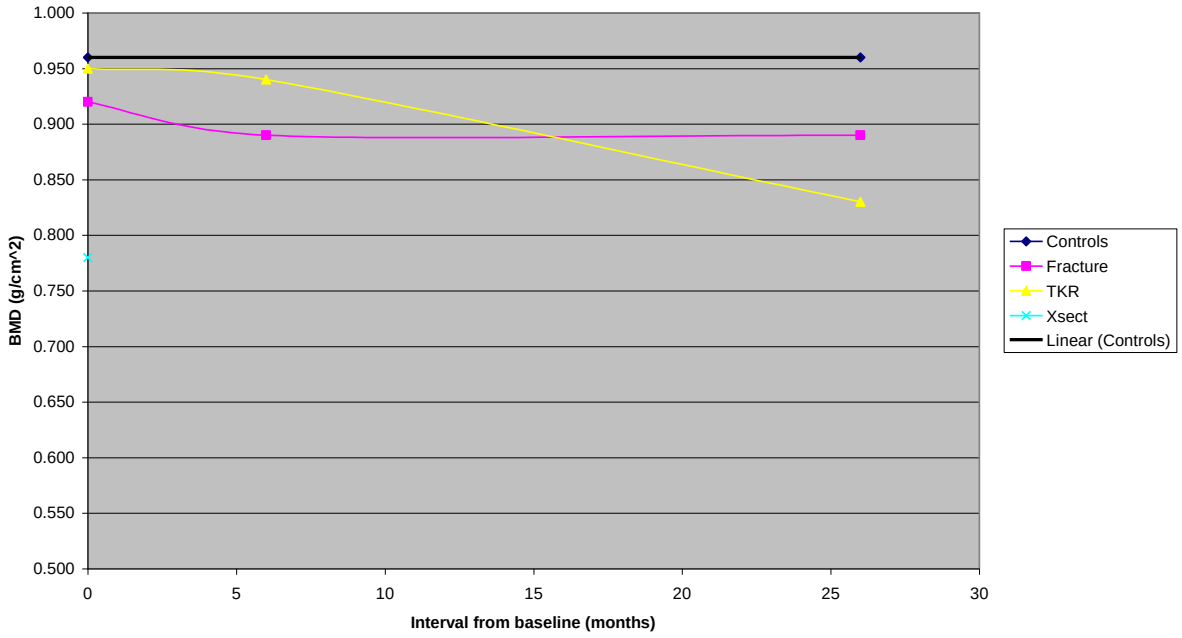
| **Baseline Bone Mineral Density (BMD)g/cm^2) – Means [Standard deviation]** | | | | | |
|---|---|---|---|---|---|
| Group | Controls | Total Knee Replacement | Fracture – internal fixation | Fracture – plaster only | Cross-sectional fracture group |
| Ipsilateral Neck of Femur (NOF) | 0.90 [0.14] | 0.90 [0.10] | 0.83 [0.11] | 0.97 [0.10] | 0.74 [0.10] |
| Contralateral NOF | 0.91 [0.13] | 0.93 [0.08] | 0.86 [0.12] | 0.98 [0.08] | 0.77 [0.07] |
| Ipsilateral Total Hip | 0.96 [0.15] | 0.95 [0.12] | 0.87 [0.14] | 0.99 [0.13] | 0.78 [0.114] |
| Contralateral Total Hip | 0.96 [0.15] | 0.97 [0.11] | 0.86 [0.13] | 0.97 [0.08] | 0.79 [0.7] |
| Lumbar spine (L1- L4) | 1.15 [0.19] | 1.15 [0.18] | 1.05 [0.05] | 1.12 [0.20] | 0.91 [0.14] |
| **Baseline Tissue mass (g) – Means [Standard deviation]** | | | | | |
| Lean – ipsilateral leg | 6324 [756] | 6489 [961] | 5783 [466] | 6423 [734] | 6187 [920] |
| Lean – contralateral leg | 6291 [781] | 6395 [788] | 6186 [681] | 6464 [593] | 6178 [908] |
| **Baseline Hip Strength Index (SI) – Means [Standard deviation]** | | | | | |
| Ipsilateral leg | 1.6 [0.41] | 1.26 [0.27] | 1.46 [0.18] | 1.71 [0.19] | 1.19 [0.43] |
| Contralateral leg | 1.65 [0.41] | 1.35 [0.37] | 1.53 [0.38] | 1.77 [0.26] | 1.34 0.71] |



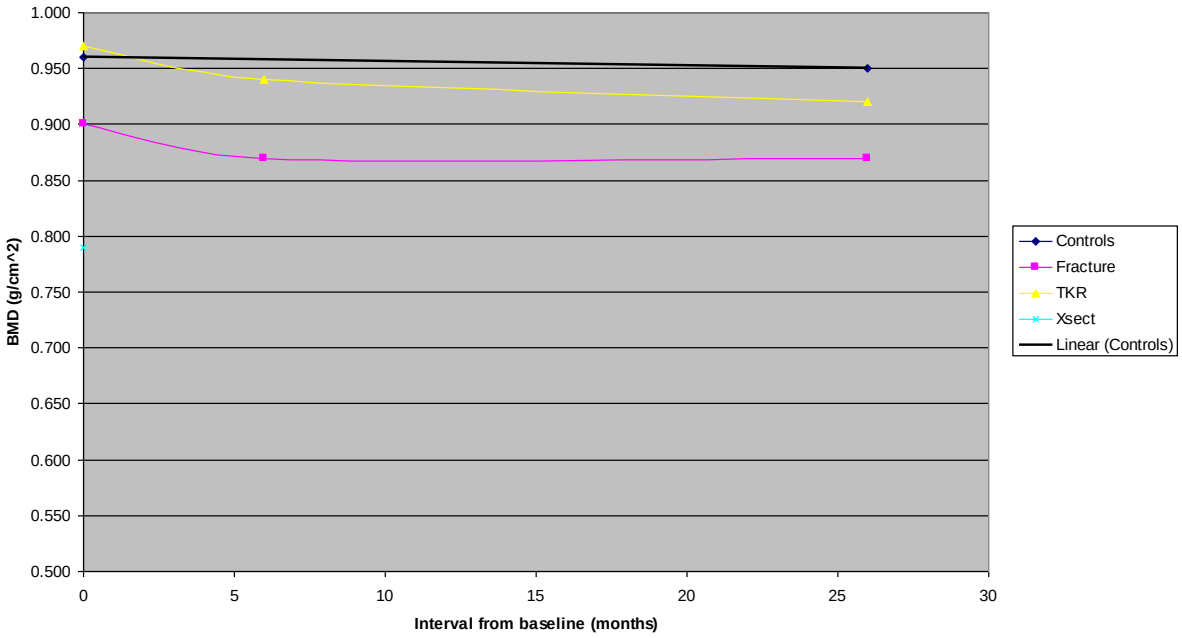

BMD Ipsi-lateral NOF
0.950
0.900
0.850
0.800
0.750
0.700
0.650
0.600
0.550
0.500
BMD (g/cm^2)
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)


BMD Contra-lateral NOF
1.000
0.950
0.900
0.850
0.800
0.750
0.700
0.650
0.600
0.550
0.500
BMD (g/cm^2)
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)

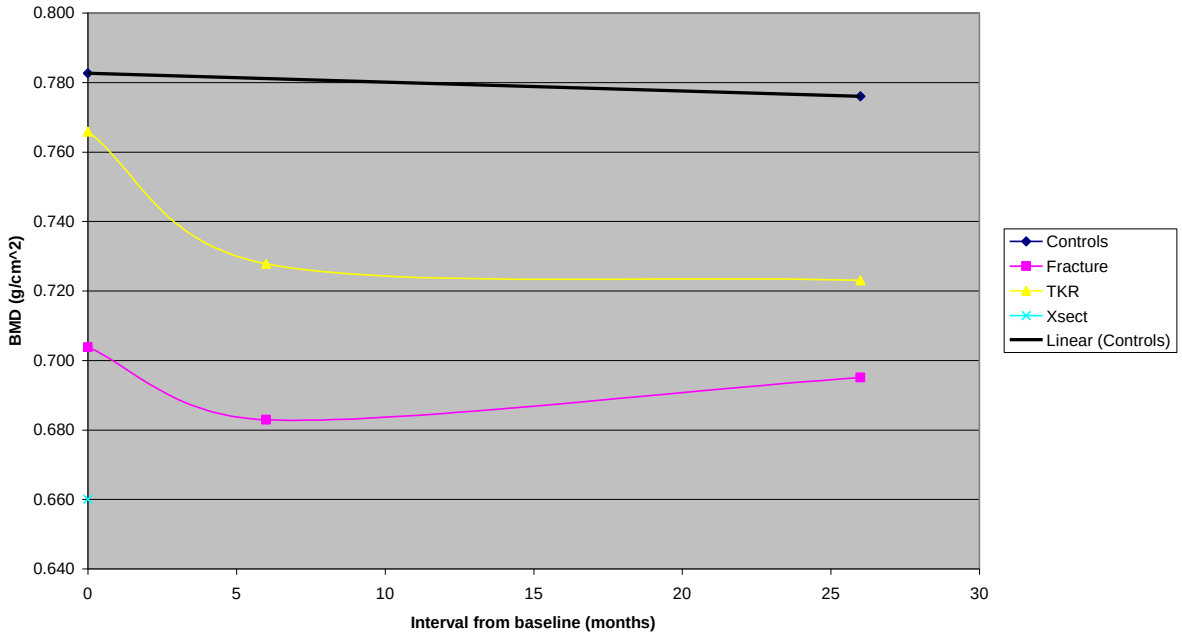
**BMD Ipsi-lateral Total Hip**



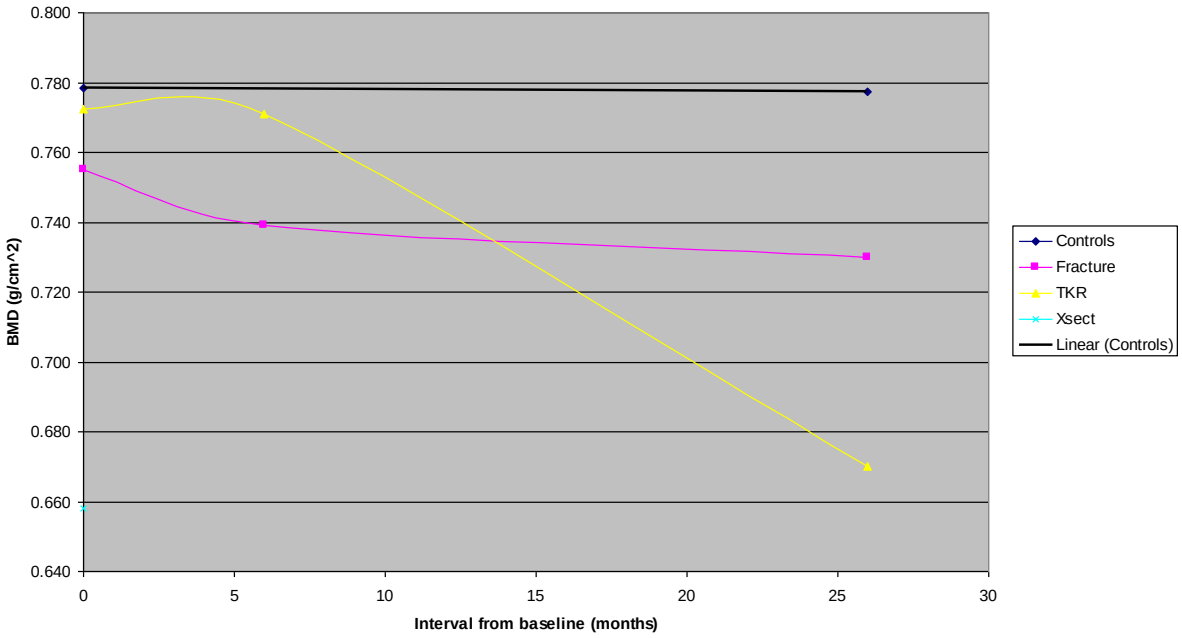

**BMD Contra-lateral Total Hip**

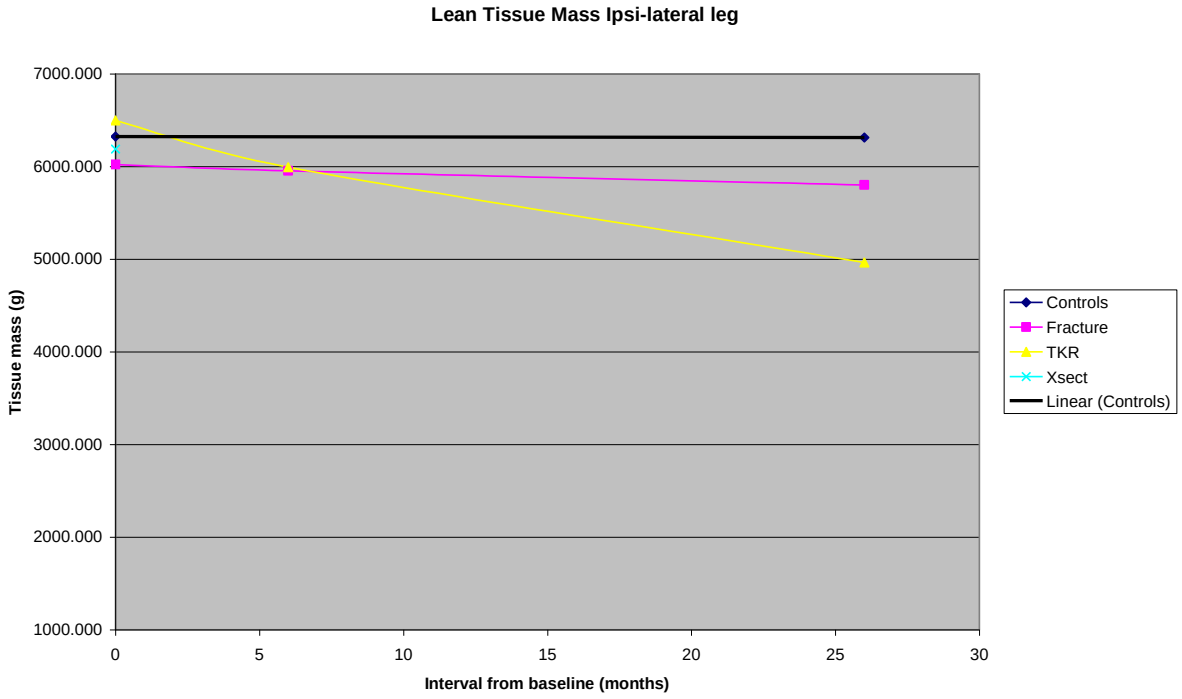


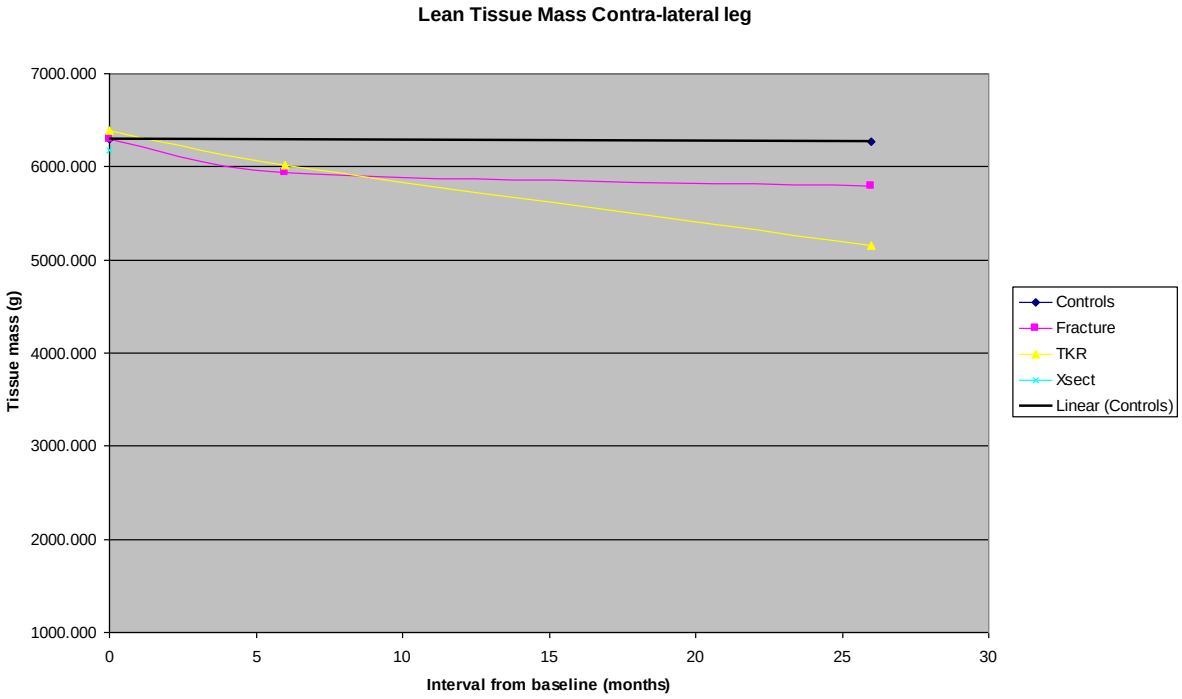
**BMD Ipsi-lateral Greater Trochanter**

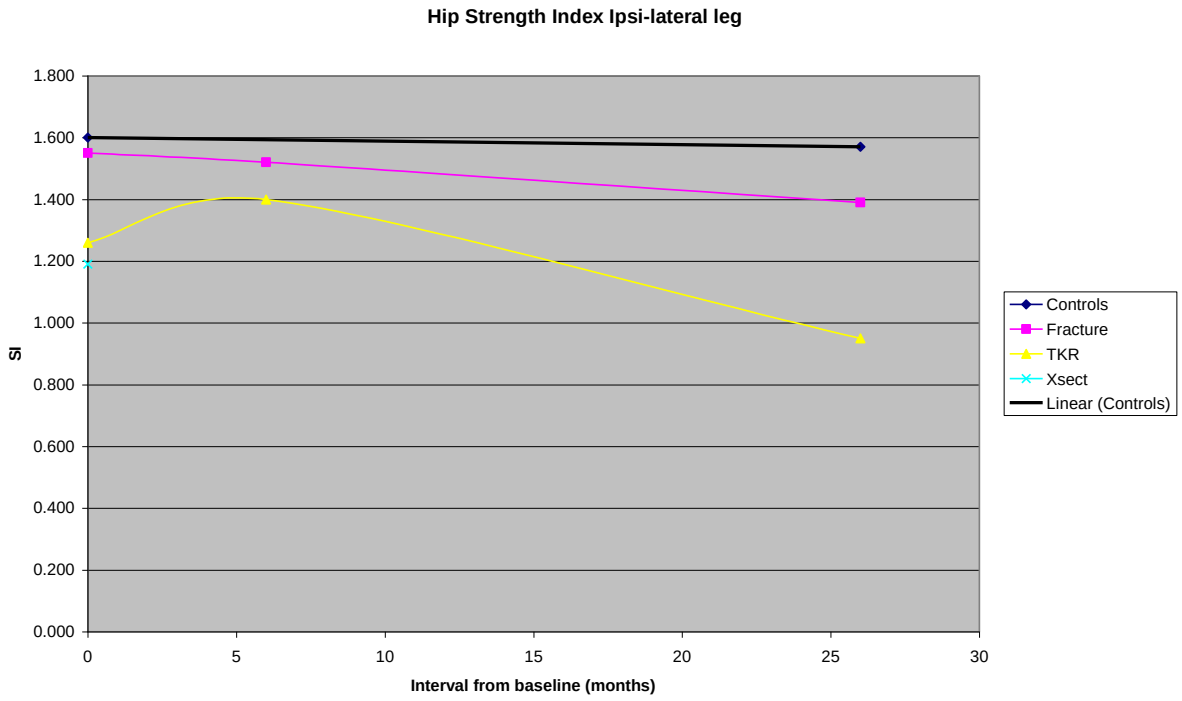


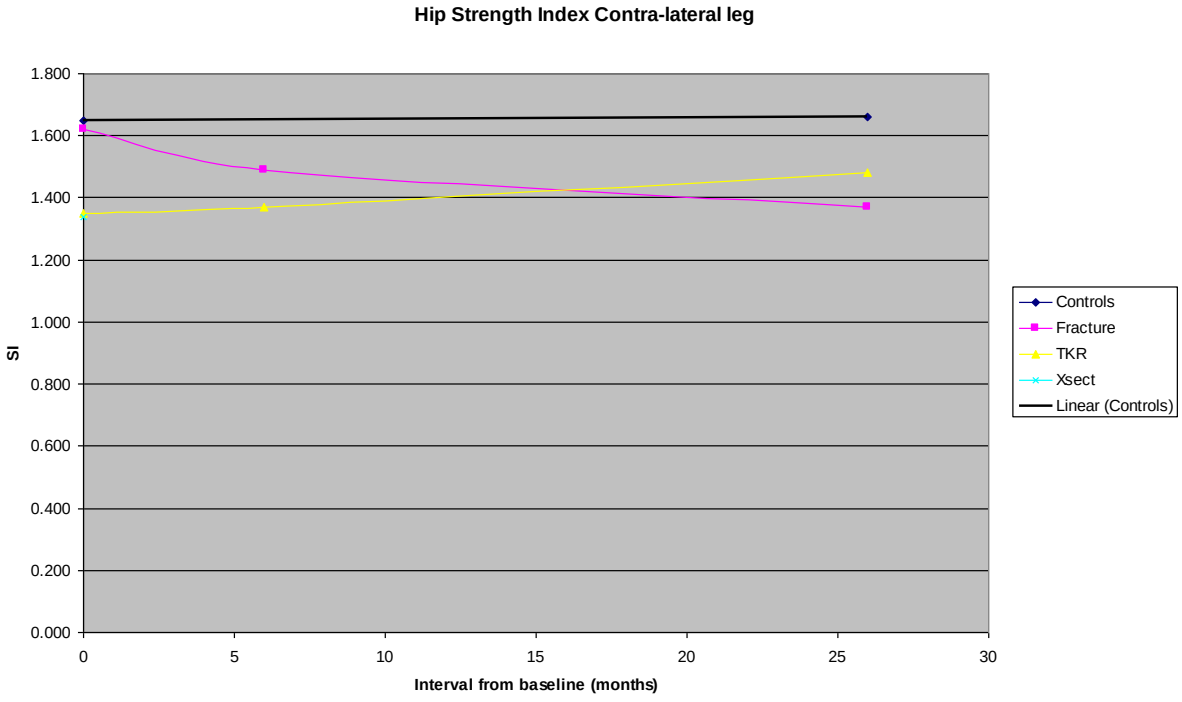

**BMD Contra-lateral Greater Trochanter**

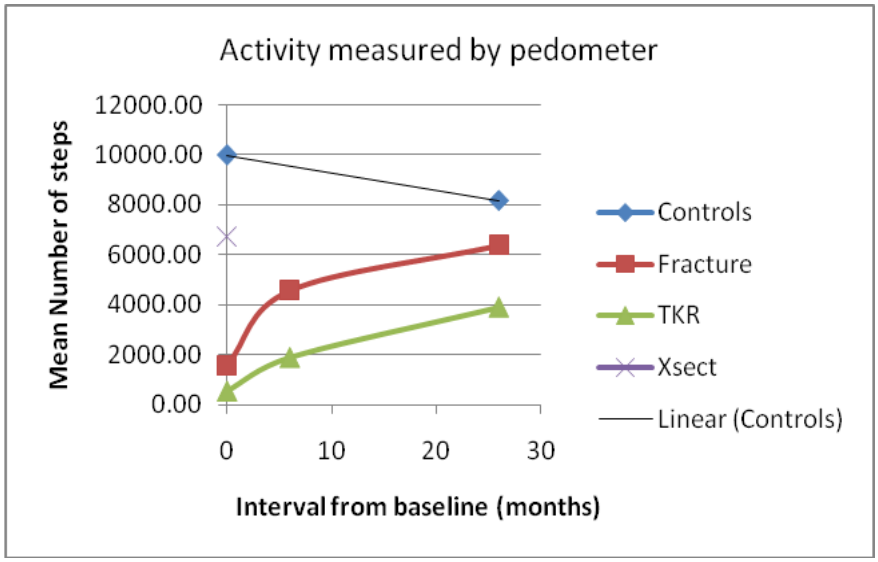


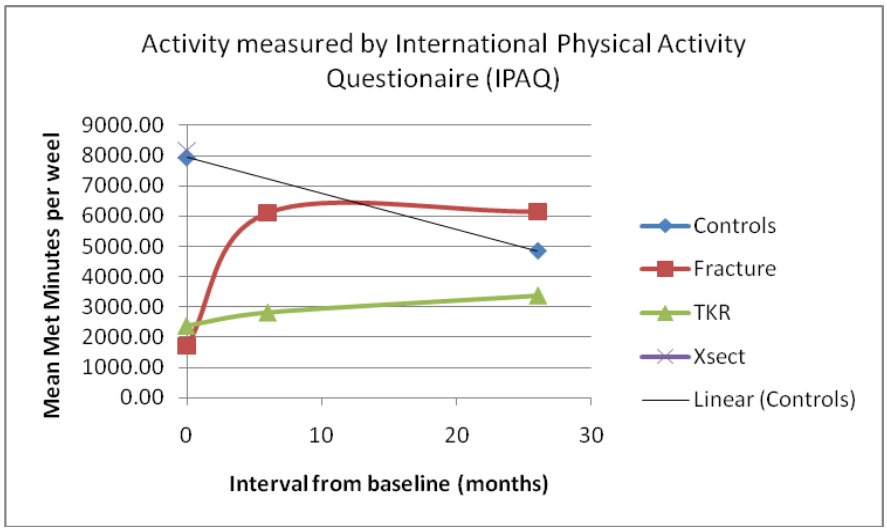

Lean Tissue Mass Ipsi-lateral leg
7000.000
6000.000
5000.000
4000.000
3000.000
2000.000
1000.000
Tissue mass (g)
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)

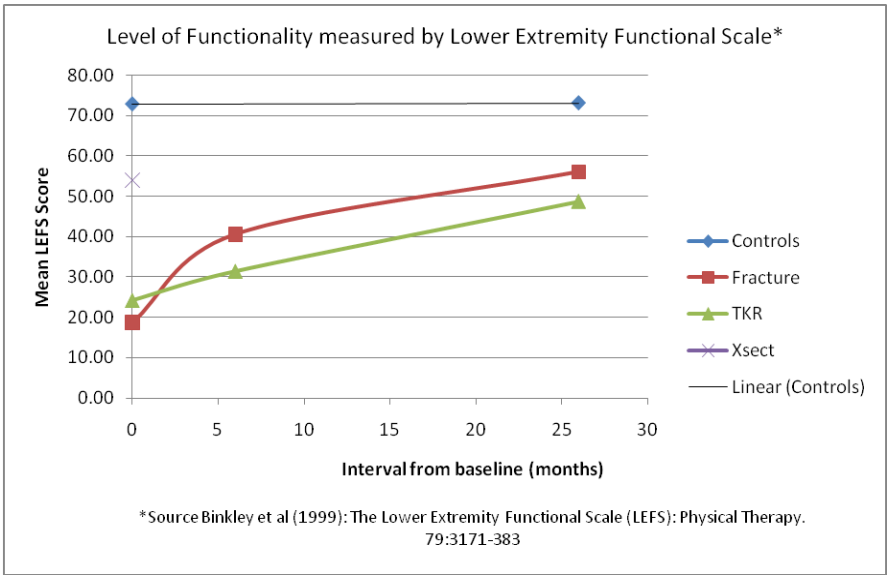

Lean Tissue Mass Contra-lateral leg
7000.000
6000.000
5000.000
4000.000
3000.000
2000.000
1000.000
Tissue mass (g)
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)

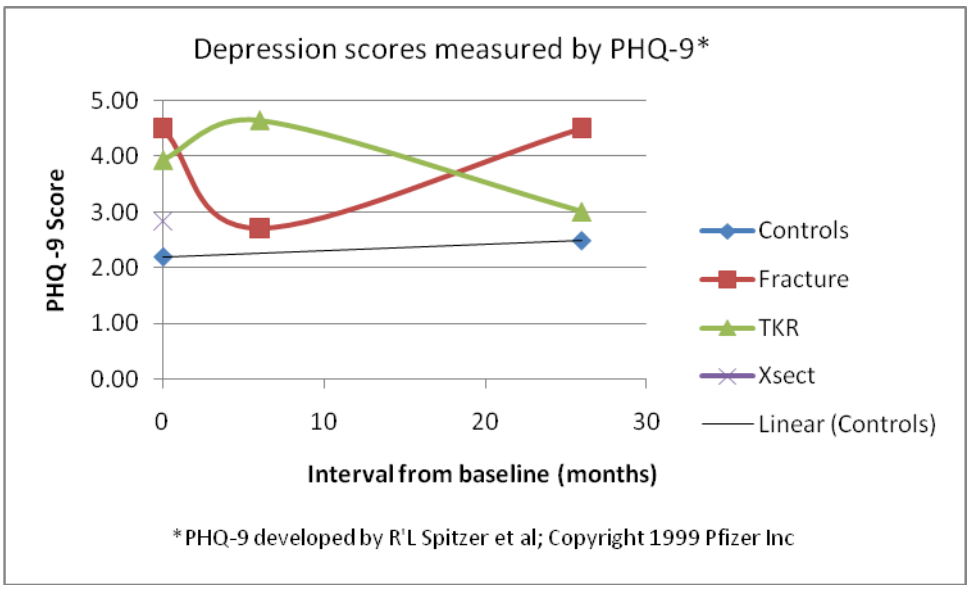

Hip Strength Index Ipsi-lateral leg
1.800
1.600
1.400
1.200
1.000
0.800
0.600
0.400
0.200
0.000
SI
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)

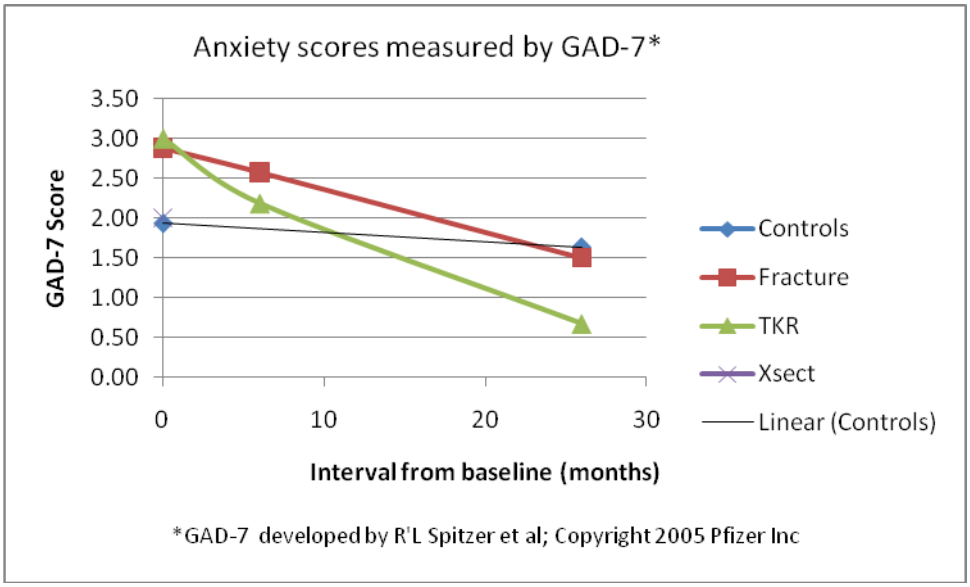

Hip Strength Index Contra-lateral leg
1.800
1.600
1.400
1.200
1.000
0.800
0.600
0.400
0.200
0.000
SI
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)


Activity measured by pedometer
Mean Number of steps
12000.00
10000.00
8000.00
6000.00
4000.00
2000.00
0.00
0
10
20
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)


Activity measured by International Physical Activity Questionaire (IPAQ)
Mean Met Minutes per weel
9000.00
8000.00
7000.00
6000.00
5000.00
4000.00
3000.00
2000.00
1000.00
0.00
0
10
20
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)


Level of Functionality measured by Lower Extremity Functional Scale*
Mean LEFS Score
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
5
10
15
20
25
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)
*Source Binkley et al (1999): The Lower Extremity Functional Scale (LEFS): Physical Therapy. 79:3171-383


Depression scores measured by PHQ-9*
PHQ -9 Score
5.00
4.00
3.00
2.00
1.00
0.00
0
10
20
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)
*PHQ-9 developed by R'L Spitzer et al; Copyright 1999 Pfizer Inc


Anxiety scores measured by GAD-7*
GAD-7 Score
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0
10
20
30
Interval from baseline (months)
Controls
Fracture
TKR
Xsect
Linear (Controls)
*GAD-7 developed by R'L Spitzer et al; Copyright 2005 Pfizer Inc

# Appendix 1

SPONSOR / TITLE: **SCoR**

START DATE: **01-Oct-09**

END DATE / EXTN: **30-Sep-12**

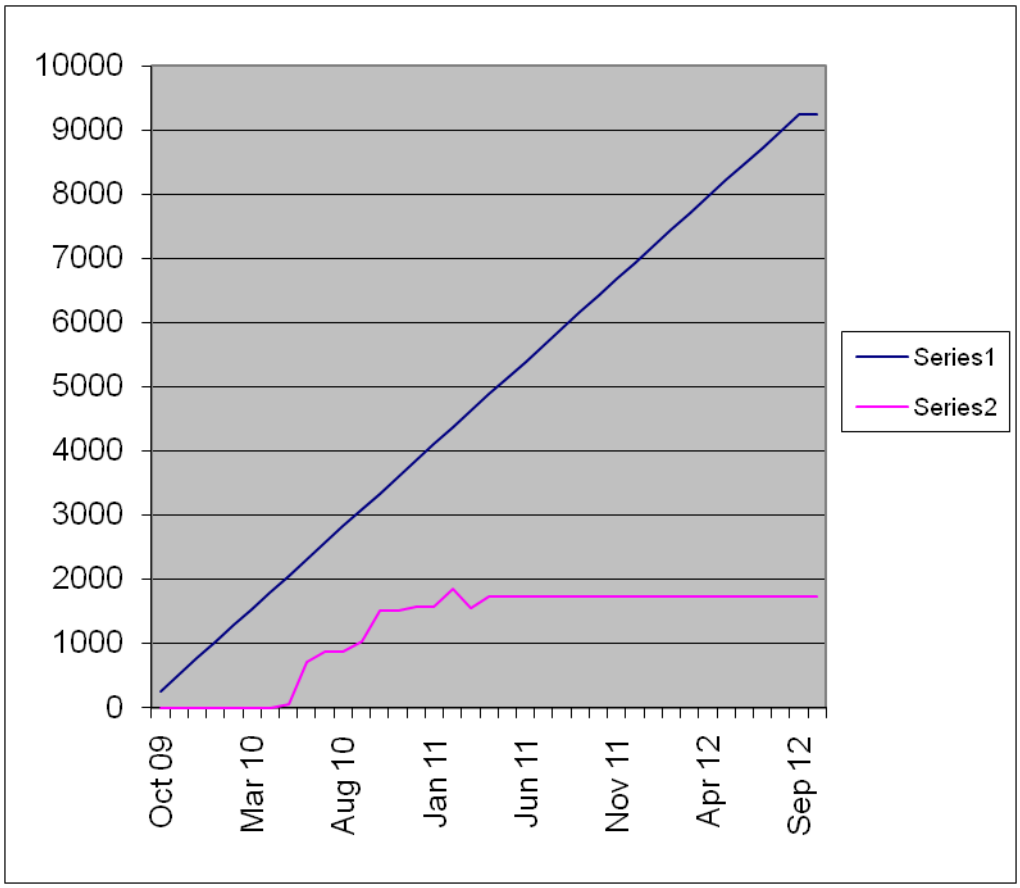
COST CENTRE: **1-SH-P-***-***-029-CZ-C1-04656**

LAST UPDATED: **06-May-11**

**Dr K Knapp**

COPIED TO: **Prof C Smith, Dr J Welsman, EMPS RA, D Watts, E Slater**

| | | Total Directly Incurred Budget (£) | Travel & Subsistence Budget (£) | Consumables Budget (£) | Conferences Budget (£) |
|---|---|---|---|---|---|
| Original 100% Directly Incurred Awarded Budget | | **9,250.00** | **7,200.00** | **1,050.00** | **1,000.00** |
| Expenditure to | *Current Quarter End Date* | **1,726.50** | **1,020.25** | **706.25** | **0.00** |
| Staff Commitments | | **0.00** | **0.00** | **0.00** | **0.00** |
| Non-Staff Commitments | For Details Refer to Commitments Tab | **0.00** | **0.00** | **0.00** | **0.00** |
| Remaining Directly Incurred Budget available | | 7,523.50 | 6,179.75 | 343.75 | 1,000.00 |



# Appendix 2