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Title Page:

“Does body mass index affect the outcome of unicompartmental knee replacement?”

Authors:

Prof. DW Murray^{a,b}, Mr H Pandit^{a,b}, Mr JS Weston-Simons^a, Mrs C Jenkins^b, Dr HS Gill^c, Dr AV Lombardi^d, Mr CAF Dodd^{a,b}, Dr KR Berend^d

^a The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Headington, Oxford, UK

^b The Nuffield Orthopaedic Centre, Headington, Oxford, UK

^c Department of Mechanical Engineering, University of Bath, Bath, UK

^d Joint Implant Surgeons, Inc, 7277 Smith's Mill Rd, Ste 200, New Albany, OH 43054, USA

Corresponding Author:

Professor DW Murray
The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
The Nuffield Orthopaedic Centre,
Windmill Road,
Headington,
Oxford OX3 7LD
United Kingdom

Tel: 00 44 1865227457

Fax: 00 44 1865227671

E-mail: barbara.marks@ndorms.ox.ac.uk

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Abstract

Background: Obesity is considered to be a contraindication for unicompartmental knee replacement (UKR). The aim was to study the impact of BMI on failure rate and clinical outcome of the Oxford mobile bearing UKR.

Method: 2,438 medial Oxford UKRs were studied prospectively and divided into groups: BMI <25 (n= 378), BMI 25 < 30 (n= 856), BMI 30 < 35 (n= 712), BMI 35 < 40 (n=286), and BMI 40 < 45 (n= 126) and BMI \geq 45 (n=80).

Results: There was no significant difference in survival rate between groups. At a mean follow-up of 5 years (range 1-12 years) there was no significant difference in the Objective American Knee Society Score between groups. There was a significant ($p < 0.01$) trend with the Oxford Knee Score (OKS) and Functional American Knee Society Scores decreasing with increasing BMI. As there was an opposite trend ($p < 0.01$) in pre-operative OKS, the change in OKS increased with increasing BMI ($p = 0.048$). The mean age at surgery was significantly ($p < 0.01$) lower in patients with higher BMI.

Conclusions: With increasing BMI neither did the failure rate increase nor did the benefit of the operation decrease. Therefore, a high BMI should not be considered a contra-indication to mobile bearing UKR.

Level of Evidence: IV

Introduction

Unicompartmental knee replacement (UKR) is being used increasingly for the treatment of end stage arthritis affecting one compartment in the knee. This is because clinical studies have shown that, if appropriate indications and techniques are used, UKR tends to give a faster recovery, lower costs, fewer and less severe complications and better function than a total knee replacement (TKR)¹⁻³. National joint registers support these conclusions as they demonstrate that, compared with TKR, UKR have shorter inpatient stays, lower mortality, lower incidence of major complications such as infection and better outcome scores, although adjusted change scores are similar⁴⁻⁶. They do however show that UKR have a higher revision rate than TKR. As the registers also show that UKR are associated with less poor outcomes than TKR, the higher revision rate is not because there are more patients with poor outcomes, instead it is probably because revision is simpler^{6,7}. There is, however, debate about the contraindications for UKR, in particular whether UKR should be offered to patients with a high body mass index (BMI).

The last few decades have seen a general increase in the number of obese patients being referred to orthopaedic surgeons for the treatment of end stage knee arthritis and this trend is likely to continue⁸. Some surgeons have reservations in offering a knee replacement to obese and morbidly obese patients because of a fear of an increased risk of peri-operative complications and poor survival due to early implant failure secondary to component loosening and/or excessive wear. This concern is particularly relevant with UKRs because of the small area of the bone-implant interface and the potential for point loading, as seen with many UKR designs. Various arbitrary cut offs for weight or BMI have been suggested in the literature, but many have no supporting evidence⁹.

In 1989 Kozinn and Scott suggested that patients who “weigh more than 82 kg should ideally not be offered a UKR because of the fear of early implant failure”⁹. The cut off weight limit for UKR was broadened slightly by Deshmukh and Scott in 2001 to 90 kg¹⁰. In 2005, in a series of 73 fixed bearing, non-modular, all polyethylene tibial component UKRs it was found that, at a mean follow up of 40 months, a BMI >32 was associated with a four fold increase in the revision rate¹¹. More recent work, reviewing 40 fixed bearing UKRs with a BMI > 35, and a matched group with a BMI < 35, demonstrated higher revision rates in those with a BMI > 35¹². Conversely, Pandit et al. have shown that a weight > 82 kg was not associated with a higher failure rate using a mobile bearing UKR but they did not study the impact of BMI¹³.

This study aims to assess the impact of BMI on the clinical outcome and mid/long term survival of a large series of Oxford Phase 3 UKRs performed in two centres to determine if BMI should be considered to be a contraindication to UKR.

Methods

Between June 1998 and March 2010, 2438 cemented phase 3 medial Oxford UKRs (Oxford Knee, Biomet, Swindon, United Kingdom) were implanted at two institutes (centre 1 and centre 2) by four surgeons for anteromedial osteoarthritis or spontaneous osteonecrosis of the knee (SONK) as recommended by the Oxford Group^{14, 15}. No patients were excluded because of weight or BMI. All operations were performed using the standard minimally invasive surgical (MIS) technique¹⁴. Both centres are high volume users of the Oxford Knee and have similar selection criteria, surgical technique and post-operative regime. Pre-operative data including patient demographics as well as the patient’s height and weight were

recorded on dedicated databases. Data from centre 1 has already been used in a study of UKR on patients with weight above or below 82 kg and data from centre 2 has been used in a similar study with BMI above or below 32^{13,16}.

All patients, except those lost to follow-up, were contacted within two years of the cut off date for the study, (01/12/2010). In both the institutes the patients were asked about any complications encountered and whether they had undergone any further surgery. For patients who had died, this information was gathered from hospital notes, GP records and relatives to establish whether the patient had undergone any further surgery on the knee under investigation prior to their death. Four patients were lost to follow up in centre 1 and five in centre 2. Patients with a minimum of one year follow up were assessed with the Tegner Activity Score, American Knee Society Score Objective (AKSS-O), American Knee Society Score Functional (AKSS-F) and Oxford Knee Score (OKS)¹⁷⁻²⁰ at centre 1 and Objective and Functional American Knee Society Scores at centre 2.

Patients were classified into sub-groups based on their BMI at the time of surgery. The groups were BMI <25, BMI 25 to < 30 (overweight), BMI 30 to < 35 (obese), BMI 35 to < 40 (severe obesity), BMI 40 to < 45 (morbid obesity) and BMI \geq 45 (super obese)^{21,22}. The outcome data for the various sub-groups was compared to assess the effect of BMI on the clinical and functional outcome as well as implant survival. Survival was calculated with a failure defined as any operation in which a component was changed, a new component was added or where a bearing dislocation had occurred. Survival data was obtained by Kaplan-Meier analysis²³. Survival figures were only quoted when there were at least 12 knees at risk. The outcome scores and patient demographics for various groups were initially analysed to establish if the data were distributed normally or not. The survival rates were compared using the Log rank test²⁴. For normally distributed data, one way ANOVA and ANOVA for a trend

were performed to determine if the outcome changed with BMI. In centre 1, where the pre-operative OKS was available, the change in OKS was calculated. A significance level of $p < 0.05$ was used throughout. Additionally, BMI was analysed as a continuous variable using Linear regression to assess the relationship between BMI and change in OKS²⁴.

A power calculation ($\alpha = 0.05$, $\beta = 0.8$) suggests that the study has the necessary power to detect a standardised difference of about 0.5 between the outcome of the groups with very high BMI and the other groups. This would equate to about a 15% increase in failure rate which is half that seen with fixed bearing in the obese.

Results

There were a total of 2,438 knees identified with nine lost to follow-up. The mean age of the patients at the time of surgery was 64 years (range: 29 – 91 years). There were 63 re-operations that were classified as failures: 18 for unexplained pain, 18 for component loosening, eight for progression of osteoarthritis in the lateral compartment, eight for bearing dislocations, seven for infection (these include two culture negative infections), two for fracture, one for traumatic anterior cruciate ligament rupture (ACL) and one for avascular necrosis (AVN) of the lateral femoral condyle.

There was a significant negative correlation between the BMI at surgery and the patient's age at surgery with the patient needing a UKR at a younger age with increasing BMI ($p < 0.001$). The average age of patients, at surgery, with a BMI < 25 was 69 and with a BMI ≥ 45 was 59, (fig. 2).

There were 1,780 knees with a minimum one year follow-up. The outcome scores of these were assessed at a mean follow-up of 4.6 years (range 1 – 12 years). The data is summarised in Table 1.

BMI <25

There were 378 knees in this sub-group with a mean BMI of 23 (range 15 to 24.99). The mean age at the time of surgery was 69 years (range: 38 -91 years). Nine knees were revised: three for unexplained pain, two each for infection, and progression of osteoarthritis in the lateral compartment and one each for aseptic loosening and bearing dislocation. The implant survival at five and 10 years was 97.6% (CI: 95.8% to 99.3%) and 94.9% (CI: 90.8% to 99.1%) respectively (fig. 1).

Of the 378 knees, 319 had a minimum of one year follow-up. The mean outcome scores of the unrevised knees at the time of the last follow up were as follows: OKS 42 (SD: 6.8). Tegner 2.9 (SD: 1.3), AKSS-F 84 (SD 18.3), AKSS-O 91 (SD 10.0) (fig. 3).

BMI 25 to < 30

There were 856 knees in this sub-group with a mean BMI of 27. The mean age at surgery was 65 years (range 33 – 89 years). 25 knees were revised: seven for unexplained pain, five for aseptic loosening, four for infection (these include two culture negative infections), three each for progression of osteoarthritis and bearing dislocation and one each for traumatic ACL rupture, AVN of the lateral femoral condyle and fracture.

Of the 856 knees, 685 had a minimum of one year follow-up. The mean outcome scores of the unrevised knees at the time of the last follow up were as follows: OKS 41 (SD: 7.5). Tegner 3.0 (SD: 1.2), AKSS-F 86 (SD 19.0), AKSS-O 90 (SD 13.3) (fig. 3). The implant survival at five and 10 years was 96.8% (CI 95.4% to 98.2%) and 93.0% (CI: 89.0% to 97.0%) respectively (fig. 1).

BMI 30 < 35

There were 712 knees in this group with a mean BMI of 32. The mean age at the time of surgery was 61 years (range: 34 -88 years). 18 knees were revised: six for unexplained pain, five for aseptic loosening, three each for progression of osteoarthritis and bearing dislocation, and one for peri-prosthetic fracture. The implant survival at five and 10 years 95.3% (CI: 93.1% to 97.5%) and 95.3% (CI: 93.1% to 97.5%) respectively (fig. 1).

Of the 712 knees, 478 had a minimum of one year follow-up. The mean outcome scores of the unrevised knees at the time of the last follow up were as follows: OKS 39 (SD: 8.9). Tegner 2.7 (SD: 1.0), AKSS-F 81 (SD 21.0) and AKSS-O 90 (SD 13.8) (fig. 3).

BMI 35 < 40

There were 286 knees in this sub-group with a mean BMI of 37. The mean age at the time of surgery was 61 (range: 34 -87). Seven knees were revised: four for aseptic loosening and one each for unexplained pain, infection and bearing dislocation. The implant survival at five and 10 years was 93.8% (CI: 88.9% to 98.6%) and 93.8% (CI: 89.0% to 98.6%) respectively (fig. 1).

Of the 286 knees, 177 had a minimum of one year follow-up. The outcome scores of the unrevised knees at the time of the last follow up were as follows: OKS 39 (SD: 9.3). Tegner 2.3 (SD: 1.1), AKSS-F 77 (SD 24.4) and AKSS-O 91 (SD 12.5) (fig. 3).

BMI 40 < 45

There were 126 knees in this sub-group with a mean BMI of 42. The mean age at the time of surgery was 58 years (range: 41-87 years). Four knees were revised, two for aseptic loosening and one each for unexplained pain and infection. The implant survival at five years

was 95.2% (CI: 90.7% to 99.8%) (fig. 1). The number of knees at risk at 10 years was too few to have meaningful survivorship data. There were no failures between year five and year 10.

Of the 126 knees, 77 had a minimum of one year follow-up. The outcome scores of the unrevised knees at the time of the last follow up were as follows: OKS 39 (SD: 7.7). Tegner 2.5 (SD: 0.9), AKSS-F 76 (SD 20.8) and AKSS-O 91 (SD 14.4) (fig. 3).

BMI \geq 45

There were 80 knees in this group with a mean BMI 50 (range: 45 - 69). The mean age at the time of surgery was 59 years (range: 41 – 78 years). None of the patients in this sub-group underwent any revision surgery. The survivorship at five years was 100% (fig. 1). The number of knees at risk at 10 years was too few to have meaningful survivorship data. There were no failures between year 5 and year 10.

Of the 80 knees, 44 had a minimum of one year follow-up. The outcome scores at the time of the last follow up were as follows: OKS 41 (SD: 3.7). Tegner 2.3 (SD: 1.0), AKSS-F 73 (SD 22.8) and AKSS-O 89 (SD 13.8) (fig. 3).

Statistical Analysis

All data was normally distributed. There was no significant difference in the implant survival between various BMI groups (Log Rank test: Chi Square 3.872, significance level: $p=0.568$).

There were no significant differences between the BMI groups comparing AKSS-O scores ($p=0.943$). For the patient based clinical outcomes of Tegner activity score, AKSS-F and

OKS there was a significant difference between the BMI groups, ($p=0.02$, $p<0.01$ and $p=0.02$ respectively). For each score this was a manifestation of a trend with the scores being lower in patients with a higher BMI ($p = 0.01$, $p= 0.01$, $p= 0.01$ respectively).

The pre-operative OKS showed a significant trend ($p= 0.01$) with an increasing BMI being associated with a decreasing OKS. The change in OKS, (score at final review – pre-operative score), had a significant trend ($p = 0.048$) with increasing BMI being associated with a greater change in OKS (Fig 4). The mean change in OKS for BMI <25 was 16 (SD: 11.3) and for BMI ≥ 40 was 20 (SD: 7.5). Linear regression demonstrated that as BMI increased there was a significant, ($p=0.02$), association with an increased change in the OKS.

Discussion

This study suggests that a high BMI, even as high as 45 – 50, should not be considered to be a contraindication to mobile bearing UKR. The decision to perform a knee replacement in patients with a high BMI should be made with care because of the increased morbidity and mortality. Patients should ideally lose weight before they have surgery and be warned of the increased risks. However, the risks of serious complications, such as death or infection, are about half as high after UKR than a TKR, which is a significant advantage for UKR over TKR⁶, particularly in the obese. Furthermore, implanting a TKR in the obese is technically difficult, whereas, as the instrumentation for the UKR works from the front, the operation is no more difficult in the obese than in those not overweight.

The biggest concern with implanting a UKR in the obese is the risk of failure. The primary outcome measure in this study was therefore survival. Previous studies mainly of fixed bearing UKR have identified a decrease in survival associated with increased weight or BMI⁹⁻¹¹. There was no statistically significant difference in the implant survival between any

of the sub-groups. Interestingly, the group with the highest survival (100%) was those with a BMI ≥ 45 . The reason why the survival rate may improve with gross obesity is that the patients tend to be less active and surgeons may be less willing to re-operate. This study looked at only one design of UKR, the Oxford Knee, which has a fully congruent unconstrained mobile bearing. The mobile bearing ensures that there is little shear stress at the bone implant interfaces and a large area for load transmission to the bone beneath with the tibial base plate¹⁴, so the risk of loosening is low. In addition, the large area of contact with the polyethylene ensures minimal wear. This may explain, at least in part, why the failure rate increases with obesity with fixed bearing UKR¹¹ but does not with mobile bearings¹⁶, and hence why obesity is considered, by some, to be a contraindication to fixed bearing UKR^{11,12}.

The AKSS-O did not significantly ($p = 0.943$) change at different BMIs, presumably because the technical quality of the operation is independent of BMI. However, for other more functional outcome measures, (AKSS-F, OKS, Tegner), the results did significantly ($p = 0.01$, $p = 0.01$, $p = 0.01$) deteriorate with increasing BMI. Pre-operatively the OKS decreased with increasing BMI, (7 points worse with BMI ≥ 40 compared to BMI < 25 , Figure 4). This is probably in part because the operations are performed later due to the increased risks and in part because the obesity affects the function. Therefore, although the final outcome is worse in the obese ($p < 0.01$, 3 points worse with BMI ≥ 40 than < 25) the improvement resulting from the operation is actually better in those with a higher BMI ($p = 0.048$, 4 points better with BMI ≥ 40 than < 25).

In some parts of the UK, knee replacement is not being offered to obese patients because they have worse outcomes than the non-obese. This study confirms that the outcomes scores are worse in obesity, however, it also shows that the improvement in score resulting from the

operation are better in obesity. Therefore there is no justification to restrict UKR in obesity. This raises the question as to which is more important: the final OKS or the change in OKS. Both are related to the pre-operative OKS: Higher pre-operative scores are associated with higher post-operative scores and lower change scores. We have recommended that both final and change scores are important as focusing on one may be misleading²⁰.

In this study, unlike the majority of previous studies, we have investigated BMI rather than patient weight. BMI is defined as the weight divided by the square of the height and thus it takes into consideration both height as well as weight. It is now routinely used to stratify levels of obesity. BMI rather than weight is likely to better represent the stresses to which the medial tibial plateau and tibial implant are likely to be exposed. Instead of using a single BMI cut off value of 32⁹, we have used the National Institute of Health classification^{21,22} which divides patients into groups based on BMI increments of five. Patients with BMI < 25 are considered to have normal weight, BMI 25 to < 30 overweight, BMI 30 to < 35 obese class I, BMI 35 to < 40 obese class II (severe obesity) and BMI > 40 obese class III (morbid obesity). We have further sub-classified the patients in obese class III as those with BMI 40 < 45 and those with BMI \geq 45 (super obesity) to find out if there is any upper limit of BMI to whom an Oxford Knee should not be offered. We were surprised to find that there was not.

The average age of patients requiring UKR decreased with increasing BMI. This is presumably because the increased stresses that the bones and cartilage are subjected to results in arthritis developing earlier. The difference in the mean age at surgery between the BMI groups of < 25 and > 45 is more than 11 years. As age and weight are closely linked, it is difficult to know if the differences seen between the BMI groups are a manifestation of the BMI or age. However, this is probably of little consequence as the question remains: Should patients with a high BMI, who are likely to be young, have a UKR? This study, because of

the patient demographics, has answered the question. With the general trend towards an increase in BMI in the general population²¹, more young and obese patients are likely to present to the treating clinicians with end-stage OA. As these obese patients are young their UKR will need to last for extended periods. The knees may fail in the long term and require conversion to a TKR, which should be relatively straight forward with a good outcome²⁵. The alternative would be to implant a primary TKR initially. However, the failure rate of TKR increases with BMI^{26,27} and revision of a failed TKR is more complex than that of a failed UKR and the outcome worse.

The main limitations of this study relate to the different data sets. In centre 1, although the follow up was long there were relatively few patients with very high BMI, whereas in centre 2 although there were many patients with very high BMI the follow up was relatively short. Furthermore the OKS was only collected in centre 1. As a result, there is limited long term data on those with a very high BMI. However, failures or poor outcomes in patients with a very high BMI tend to occur early¹¹ and the study is adequately powered to detect this. Indeed the study did demonstrate that the functional outcome was worse in patients with very high BMI. A further limitation is incomplete data. Nine patients were lost to follow-up, so it is not known whether their UKR failed. However, if a worst case survival analysis is undertaken, in which those lost to follow up are considered to have failed, there is still no significant difference in failure rate. On average for each outcome score 23% of patients did not have data, because of medical, social and geographic reasons. There is no reason to believe that this incomplete data would have affected the BMI groups differently so it should not affect the outcome of the study.

In conclusion, this study is more than an order of magnitude larger than previous studies of BMI in UKR. It demonstrates that survival rate of the Oxford Knee does not decrease with

increasing BMI, even with BMIs as high as 45-50. Therefore, a high BMI should not be considered to be a contraindication to surgery. The benefit, in terms of improved pain and function, resulting from a UKR, increases with increasing BMI. Therefore, obese patients should not be denied a UKR for fear of a poor outcome

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Conflict of Interest Statement

The author or one of more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other nonprofit organisation with which one or more of the authors are associated.

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Table 1: Summary of Statistics for BMI group within each centre for patients greater than 1 year

	BMI	Total Number of knees	Total lost to follow-up	Mean Age at Surgery (Range)	Sex (M:F) %	Mean Pre-op OKS (SD)	Mean Post-op OKS (SD)	Mean Post AKSS - O (SD)	Mean Post AKSS - F (SD)
Centre 1	BMI < 25	243	4	70 (42 - 87)	39 : 61	27 (9.2)	42 (6.8)	86 (9.9)	84 (18.5)
	BMI 25 – 30	422		66 (33 - 88)	59 : 41	25 (8.5)	41 (7.5)	85 (10.0)	86 (19.1)
	BMI 30 – 35	192		64 (40 - 87)	56 : 44	23 (7.9)	39 (8.9)	84 (14.9)	80 (21.2)
	BMI 35 – 40	44		63 (37 - 85)	39 : 61	19 (5.9)	39 (9.3)	82 (13.6)	69 (27.4)
	BMI 40 – 45	19		61 (41 - 77)	21 : 79	19 (8.4)	39 (7.7)	93 (6.1)	79 (21.1)
	BMI > 45	6		68 (63 - 75)	33 : 67	23 (6.2)	41 (3.7)	84 (19.8)	76 (13.6)
Centre 2	BMI < 25	76		66 (38 - 91)	30 : 70	N/A		94 (8.8)	85 (17.8)
	BMI 25 – 30	263	3	64 (38 - 89)	43 : 57			92 (13.8)	87 (18.8)
	BMI 30 – 35	286	2	62 (29 - 85)	58 : 42			91 (13.3)	81 (20.9)
	BMI 35 – 40	133		61 (34 - 87)	45 : 55			91 (12.3)	79 (23.1)
	BMI 40 – 45	58		58 (36 - 87)	40 : 60			91 (14.7)	76 (20.8)
	BMI > 45	38		76 (41 - 78)	37 : 63			89 (13.7)	73 (24.0)

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Error bars represent Standard Error.

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Figure 1:

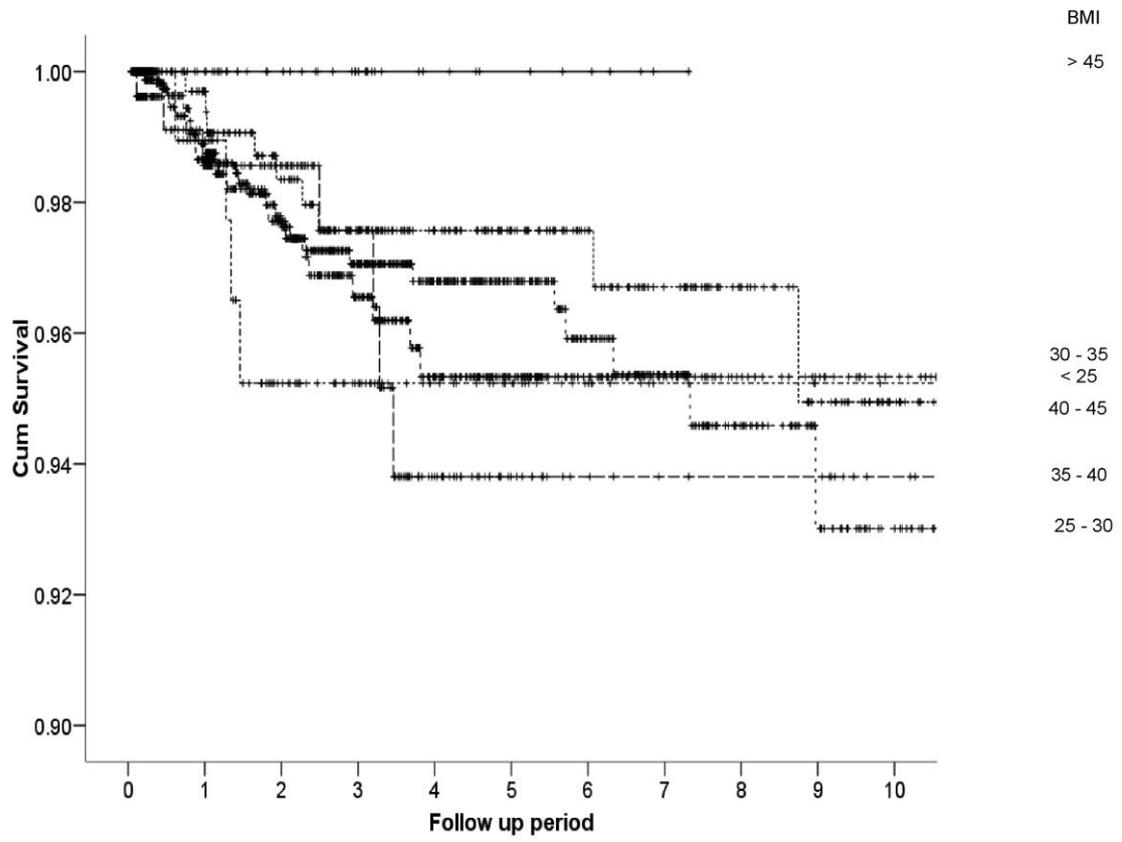
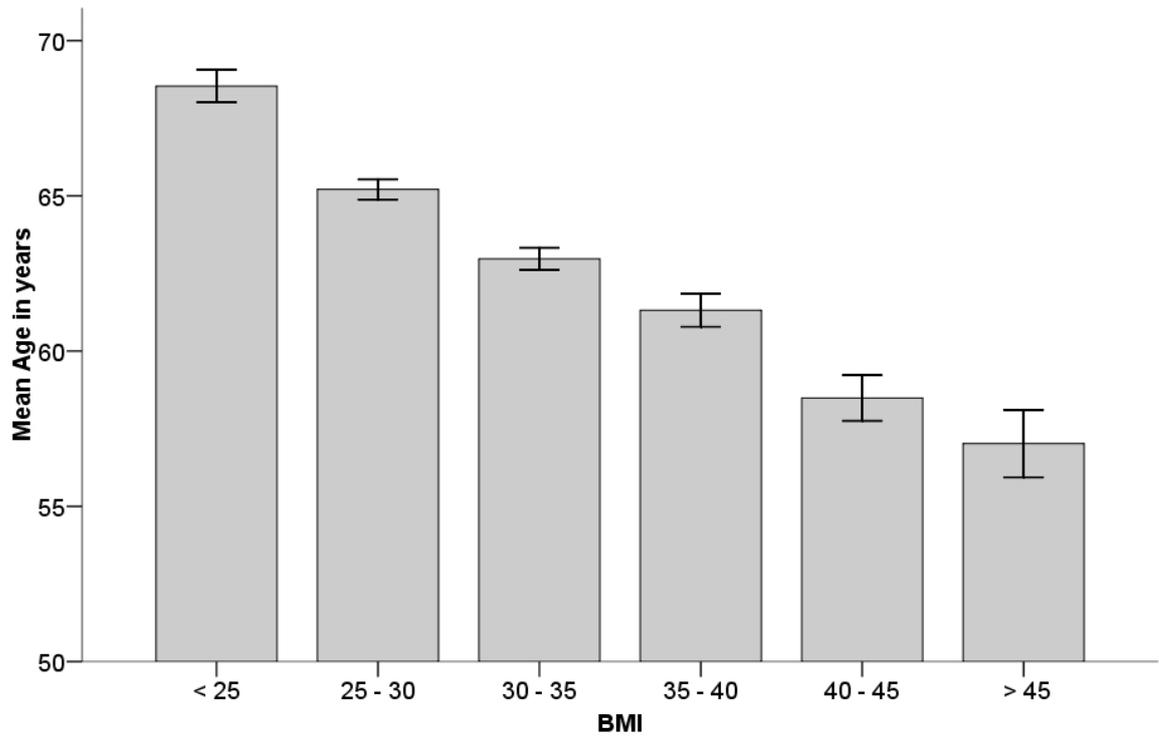
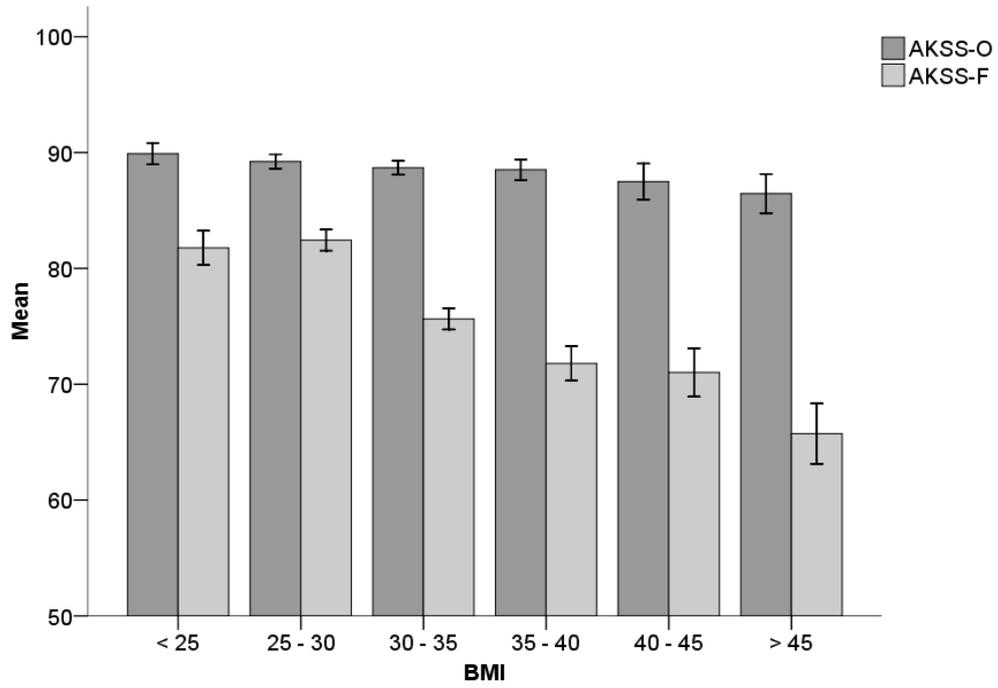


Figure 2:



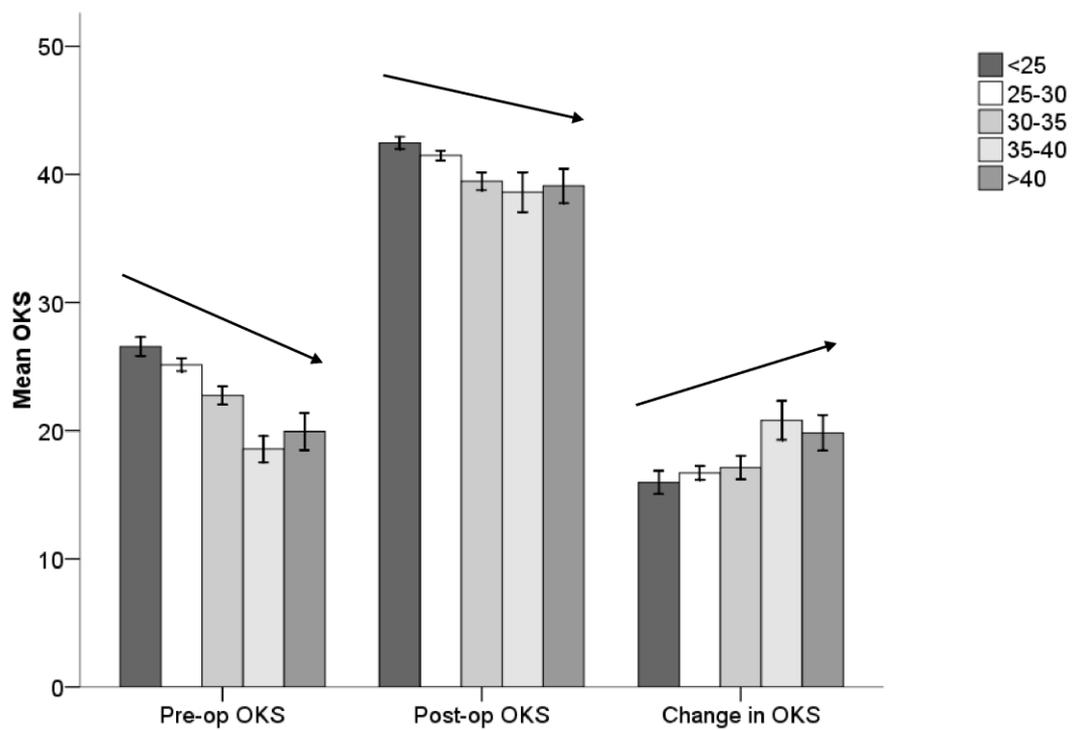
DRY

Figure 3:



DRY

Figure 4:



OKS