SUB-VASTUS APPROACH IS MORE EFFECTIVE THAN A MEDIAL PARAPATELLAR APPROACH IN PRIMARY TOTAL KNEE ARTHROPLASTY: A RANDOMIZED CONTROLLED TRIAL

Abstract

In a prospective single-center longitudinal randomized controlled trial 116 patients were allocated to the sub-vastus approach, and 115 to the medial parapatellar approach. At one week follow-up, compared to baseline, range of motion, Knee Society (KS) global, KS knee, and KS pain scores were significantly better in the sub-vastus group. At the one year follow-up WOMAC global and pain scores, SF36 physical function and role-physical scores, and EuroQol utility and pain score were significantly better in the sub-vastus group. The ease of exposure in the sub-vastus approach was significantly worse. There was no significant difference in length of stay or analgesia intake. The sub-vastus approach to total knee arthroplasty was more effective than a medial parapatellar approach at both one week and fifty-two weeks post-operatively, but surgeons reported a less easy exposure in the sub-vastus group.

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Keywords; total knee arthroplasty, sub-vastus approach, RCT, randomized, osteoarthritis

Running Title. Sub-vastus v Medial Parapatellar Approach in Total Knee Arthroplasty

Introduction

Knee arthritis is a common disabling problem and when advanced and following failure of conservative measures total knee arthroplasty is a recommended option [1,2]. In small randomized controlled trials patients who received a sub-vastus approach were reported to have better short-term functional outcomes than those treated with the traditional medial parapatellar approach [3,4,5,6]. The issue of best choice of surgical approach remains controversial [7]. In one survey, the medial parapatellar approach was reported to be used for the vast majority of total knee replacements [8]. Each approach has potential advantages and drawbacks, and to our knowledge there has been no reasonably sized comparison of the two approaches with a one-year follow-up.

We performed a single-center longitudinal, prospective, randomized controlled trial to compare the sub-vastus approach (the “intervention” group) to total knee arthroplasty with the medial parapatellar approach (the “control” group). We wished to determine the impact of these choices of sub-vastus or medial parapatellar approach on functional and clinical outcomes, up to one year after surgery.

Materials and Methods

Setting and Locations

The trial was approved by the local Ethics and Scientific Merit Committees. Seven accredited consultant surgeons in one English orthopaedic university-affiliated teaching hospital participated. Surgeons mainly consulted and operated at this hospital, but they also operated at another English university-affiliated teaching hospital forty miles from the main hospital, and at a local private hospital. Recruitment began in February 2001, and the last participant was recruited in August 2003. A Trial Steering Group chaired by a senior clinical researcher from another institution met on a six-monthly basis. An independent Data Monitoring Committee was chaired by a senior medical statistician who had no other involvement in this study. The decision to discontinue was only to be made if the results were likely to be convincing to our clinicians, participants in the trial and the general clinical community. A nominal significance level for stopping the trial was $p <= 0.02$ [9].

Eligibility Criteria

Eligible patients were those awaiting a primary unilateral total knee arthroplasty for any indication, who had not had or were not planned to have a major arthrotomy in the other knee within 12 months, who had not had previous open surgery in or around the knee in the previous 12 months, (e.g. high tibial osteotomy, femoral osteotomy, fracture fixation, patellar realignment, patellectomy and open meniscectomy), who had a valgus angle of $\leq$ 20°, and who had a surgeon who had no clear preference for either surgical approach.

Randomization

At the start of the trial, participating surgeons elected to randomize patients to be treated with either one of two approaches, the sub-vastus approach, or medial parapatellar

approach. Entry of a patient into the trial and treatment allocation were accomplished through a remote computer-based telephone service. The operating consultant surgeon telephoned the trials office to have the patient allocated to an approach, when their patient was escorted to the anaesthetic room immediately prior to surgery. Patients were allocated with minimisation on surgeon and gender [10].

Details of the Interventions

The two randomly allocated treatments were a medial parapatellar approach [11] and a sub-vastus approach [12] for total knee arthroplasty. The operating consultant surgeon responsible for the care of each patient ensured that all procedures were performed by surgeons who were competent to undertake the allocated procedure, and performed or directly supervised all operations. The Low Contact Stress (LCS®, Depuy) Mobile-Bearing Total Knee prosthesis was used in all procedures. Subsequent management followed the consultant orthopaedic surgeon's standard care pathway and practice, including if necessary the management of any complications.

Data Collection

Data were collected at five main time-points, on hospital admission prior to surgery, in hospital one-week post-operatively or at home if already discharged, and in the clinic at six weeks, 12 weeks, and one year following surgery. A blinded trained research physiotherapist or physiotherapy assistant recorded clinical measurements. The operating surgeon, who otherwise had no role in collecting or analyzing data, recorded surgical details and peri-operative measures. Questionnaires were given to patients, explained, and collected by a research nurse (GW). The nurse (GW) or research assistant (DC) ensured

data completeness. The nurse collected other clinical data from case-notes. Participants were blinded to approach.

Outcomes

The primary outcome measure for this study was change in Knee Society Score [13] at one year compared to baseline, with this measure a secondary outcome at other time-points 1, 6 and 12 weeks post-operatively. The Knee Society Clinical Rating System, is composed of a knee score and a functional score. The knee score is made up from components of pain, stability and range of motion, with deductions for flexion contracture, extension lag and **malalignment.** The pain component is measured on a 7 point scale from 0 points (severe) to 50 points (none). The functional score considers walking distance and stair climbing, with deductions for walking aids. Both the knee and functional scores range from 0 (worst) to 100 (best).

The Western Ontario McMaster Osteoarthritis Index (WOMAC) [14], is a 24-item arthritis and lower limb specific measure of pain (5 questions), stiffness (2 questions) and physical functional difficulty (17 questions). It is available in two formats, visual analogue and Likert scales with similar metric properties [15]. We used the format with 5 Likert-boxes per item. We calculated a summary score for each dimension, with maximum scores of 20, 8 and 68 for the Likert version [14], with lower scores better. Its reliability, validity and responsiveness are well-established [16]. The pain component of the WOMAC ranges from 0 no pain on any question, to 20, extreme pain on each question.

The Medical Outcomes Study Short Form 36 (SF36) [17] is a self-completion questionnaire consisting of 36 items across eight components; physical function (10 items);

role limitation due to physical problems (4 items); bodily pain (2 items); general health (5 items); role limitation due to emotional problems (3 items); social function (2 items); mental health (5 items); energy/vitality (4 items). It is usually used to provide an eight-item profile of scores across the range of health domains, although physical and mental summary scores combining the first four, and last four items can also be used [18]. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. All scales were transformed to score between 0 (worst) and 100 (best).

The EuroQol [19] is a general measure of self-reported current health related quality of life that has been designed to complement other quality of life and disease specific measures [20]. It measures five dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, on three level scales (no symptoms or problems, moderate symptoms or some problems, and extreme symptoms or total inability), scored zero, one or two respectively. The descriptive data is used to generate a weighted health index, based on tables of values derived from general population samples. The EuroQol also provides a patient rated health status on a visual analogue scale from 0, worst imaginable health state, to 100, best imaginable health state.

Further outcome measures included; daily patient reported knee pain during the first post-operative week, measured on a visual analogue scale, from 0 (no pain) to 10 (worst possible pain); use of analgesia during the first post-operative week, from prescription charts; complications as recorded in medical records and as reported by patients at their research follow-up appointments; length of stay in hospital (days); surgeons ease of exposure measured with a Visual Analogue Score (VAS) ranging from 0 (easy) to 10 (extremely difficult), and proportion of patients who had a lateral release.

Sample size

In a group of 86 patients undergoing total knee arthroplasty the mean one-year post-operative Knee Society Score was 172.2 with a standard deviation of 20 and a range of 98-200 [21]. To detect a 5% increase in the post-operative Knee Society Score in the sub-vastus group compared to the medial parapatellar group with a two-sided significance level of 5% and a power of 90% a sample size of 105 patients was required in each group. An additional 10% were recruited to each group to allow for any patients lost to follow-up, giving a total sample size of 231.

Statistical Methods

Time was measured from baseline assessment of the outcomes which were usually made on the day before or day of surgery. Outcome variables were measured as differences (follow-up – baseline) at each time point, giving 4 differences (longitudinal repeated measures) for each patient. For example, the Womac outcome measures at weeks 1, 6, 12 and 52, were computed as:

d1 = Womac01-Womac0 (baseline)

d6 = Womac06-Womac0 (baseline)

d12= Womac12-Womac0 (baseline)

d52= Womac52-Womac0 (baseline)

An advantage of this method is that plots quickly reveal the underlying trends (between groups) with time. The plot will be flat if there is no change with time, while in/decreasing trends will reveal effects positive or negative depending on the definition of the original scores. **The outcome variables in the two groups were compared using t-tests, non-parametric methods and the multiple logistic function using the SPSS software**

package. The latter technique takes the correlation between the repeated measures into account by regarding the analysis as a comparison between the two treatment groups using the four repeated outcome measurements (d1, d6, d13 and d52). More detailed adjusted analyses were also conducted using a linear mixed model approach [30] which took into account: (a) previously selected baseline factors, (b) the trend over time (c) the correlation between the repeated measures, and (d) random error. These latter analyses were carried out using the S-Plus software package. Non-parametric trend lines were computed to show the average evolution in the difference from baseline in each treatment group

The primary analysis was by intention to treat, and involved all patients who were randomly assigned. The trial protocol has been described in more detail elsewhere [22].

Results

(a) Data Acquisition

Patient recruitment and follow-up is summarised in a flow-diagram (Fig 1). Two hundred and thirty-one patients were enrolled in the study, 116 were randomized to the sub-vastus (SV) approach, and 115 were randomized to the medial parapatellar (MP) approach. Twenty-three eligible patients declined to participate.

In four (3.5%) patients allocated the SV approach, the MP approach was performed. In three patients, a SV approach was attempted but the operation was completed through an MP approach; in one patient the surgeon stated the shape of the leg was a problem; in a second patient the approach was deemed too difficult; and in a third the leg was too bulky. In one patient, the surgeon carried out an MP instead of SV approach by mistake.

In the MP group 17/575 (3.0%) planned assessments (one at one, six at six, six at 12, and four at one year) were missed in 14 patients; in two instances because a patient elected not to have two interim assessments, in three because of death, in two illness, and in 10 for unknown reasons. In the SV Group 20/580 (3.1%) planned assessments (four at one, six at six, seven at 12, and three at one year) were missed in 12 patients; in seven instances because of death, in two illness, in two early hospital discharge, in one a long patient holiday, in one relocation, and seven for unknown reasons. In addition, 50 assessments were missing for the Knee Society Score, five at baseline, 36 at one week, four at six weeks, three at 12 weeks and two at one year, the great majority because of research physiotherapist unavailability. In one instance, a Knee Society Score was taken at one week, but other assessments were not taken because of patient illness.

(b) Baseline characteristics

A randomization check showed no significant difference between age and sex of the two groups (Table 1). Two-hundred and ten patients were retired, 17 were employed, three were house-wives, and one was seeking employment. Three (2.6%) of the MP group, and six (5.2%) of the SV group had rheumatoid arthritis, the remainder had osteoarthritis.

(c) Operative and Post-Operative Clinical Characteristics

Most patients had general anaesthesia, and 17/115 (14.8%) MP and 19/116 (16.4%) SV patients had epidural anaesthesia. The patella was replaced in 7/115 of the MP group (6.1%), and 10/116 (8.6%) of the SV group. Ease of exposure was recorded in 228/231 (98.7%) patients, with MP group mean 25.4 (SD 24.2) and SV group mean 32.8 (SD 26.4), a statistically significant difference of 7.4 (95%CI, 0.8 to 14.0, p = 0.028), favouring the MP group. A lateral release was performed in 14/115 (12.2%) of the MP group, and in 6/116 (5.2%) of the SV group. The difference between these proportions, 7%, is not statistically significant (95% CI: -0.5% to 14.5%, p=0.06).

There were no differences between groups in the pain or analgesic diaries, in either the total scores over seven days, or on an individual day basis. The median length of stay was eight days, with no difference between groups.

(d) Longitudinal Outcomes

Table 2 shows a cross-sectional summary of all mean outcome scores by group and time as an aid to interpretation of the formal longitudinal analyses. Table 3 shows a summary of the longitudinal outcomes, i.e. the between groups difference from baseline for each time period.

(d.i) Knee Society Clinical Rating System

There was a great improvement in pain with time in both groups, and a small improvement in range of motion which was lower than baseline until between the six and 12 week follow-up (Table 2). The functional score is lower than baseline at the one and six-week follow-ups. The total score, functional score and knee score all show considerable benefit of surgery at the one year follow-up in both groups.

At the one week follow-up, the SV group had a statistically significantly greater mean improvement in pain (5.7, Standard Error {SE} 2.74) and knee score (6.8, SE 3.33) compared to baseline, and less deterioration in range of motion (7.4, SE 3.59), and total Knee Society Score (9.9, SE 4.44). At six weeks the MP group had a non-statistically significant greater mean improvement in pain (4.8, SE 2.45) and knee score (5.5, SE 2.94). There were no significant differences at other time points. These results support a modest, but clinically significant benefit for the SV group at one week post-operatively, with no significant difference at other time points. A relative weakpoint of this measure compared to others, was 45 missing observations at the one week follow-up as the research physiotherapist was usually unavailable at one participating hospital during the early trial period. Further statistical analysis of this measure is presented in section (e).

(d.ii) WOMAC

In both groups the global, function and pain scores showed major improvement with time and at the one year follow-up outcome scores were 15 to 30% of their baseline values. The largest absolute improvement in scores occurred within a week of surgery (Table 2).

There were no statistically significant differences between groups at the one, six or 12 week follow-ups, although the improvement in pain in the SV group at one week tended to

be better than the MP group (-1.2, SE 0.6). At one year, the SV group had significantly greater improvement in pain (-1.6, SE 0.6), the SV group starting with an average pain score 0.7 units higher than the MP group and ending 0.8 units lower (tables 2 and 3). The SV group also had a significantly lower global score (-5.2, SE 2.4) at one year, attributable to greater improvements in both pain and function (-3.2, SE 1.9). Further statistical analysis of this measure is presented in section (e).

(d.iii) SF 36

In both groups physical function and social function dipped at one week, then improved to one year. Role-physical, and bodily pain showed continued improvement from one week to one year. There was little change in other measures.

At one year, the SV group showed statistically significantly greater improvements in physical function (7.8, SE 3.1), and role-physical (13.7, SE 5.9), and tendency for greater improvement in pain (6.3, SE 4.1). There were no significant differences in other outcomes, or at other time points. The benefit in physical function for the SV group at one year was corroborated by non-parametric testing but not by the multiple logistic function.

(d.iv) EuroQol

In both groups, there were improvements in pain, utility score and health status with time.

At one week, the SV group improved statistically significantly more in the utility score (0.093, SE 0.04), and tended to have improved more in the pain score (-0.18, SE 0.09). At six and 12 weeks there were no significant differences. At one year, the SV group had improved significantly more as measured by the utility (0.091, SE 0.04), and pain scores (-0.19, SE 0.09).

(e) Longitudinal Statistical Analysis

Figures 1 and 2 show for the Knee Society Score and the global WOMAC score, respectively, the longitudinal trends based on the four differences from baseline outcome measurements for each group. In both figures, the large amount of variation at each examination, which is not unusual, should be noted. The numbers in each group are approximately the same but, inevitably, the graphs show overprinting of symbols. The Knee Society results (Figure 1) show no average difference between groups over time, while the global WOMAC results show a small, persistent, benefit in favour of the SV group.

The repeated measures data presented in Figures 1 and 2 were analysed by fitting a series of models which took selected baseline covariates (age, gender, smoking status, baseline KSS and baseline WOMAC), the time trend, the treatment by time interaction and the correlation between repeated measures on the same subject into account.

In the case of the Knee Society data presented in Figure 1, in none of the models fitted was the treatment effect or the treatment by time interaction significant. In this analysis, we conclude that there is no significant difference in Knee Society Scores between the treatment groups studied.

In relation to the WOMAC score, the results are different. The model (A) fitting the treatment indicator alone is not statistically significant (treatment regression coefficient b_1=-2.59, **SE 2.18)**. A similar finding emerges when model (B) containing the treatment

indicator and the (linear) time trend is fitted (b_1=-2.65 , **SE 2.19)**. However, when the baseline WOMAC score is added (model C), the treatment effect becomes significant (b_1=-2.4 , **SE 1.17**), and, when the treatment by time interaction is added (model D), it too is significant (b_1=-2.44, se=1.19; interaction regression coefficient, b_2 =-1.53. **SE 0.67)**. Thus, when allowance is made for the baseline WOMAC score and time in the statistical model, a statistically significant difference emerges between the two groups. The SV procedure confers a greater reduction from baseline by approximately 2.5 WOMAC units of difference on average, and this benefit increases a little (but significantly) with time. These finding are broadly consistent with Figure 2 and Table 3. We noticed that the pain component of the Womac pain score differed significantly at one year between the groups. Pain was less in the SV group, the mean change from baseline to the 52 week examination was -10.61 (se=0.41) Womac pain units and in the MP group it was -8.99 (**SE 0.37)** units (t = 2.96, p=0.003).

(f) Adverse Events

Overall, the number and type of adverse events recorded was similar between groups.

Six deaths were recorded within one year of surgery. One SV patient died the day after surgery from malignant hypertension during her general anaesthetic followed by an intra-cerebral haemorrhage a few hours later. Other deaths within one year of surgery appeared coincidental, with two SV deaths from cardiac failure, and three in the MP group from cancer, stroke, and an unknown cause.

Peri-operative adverse events were recorded in three MP patients, namely excessive bleeding, a dysplastic knee led to difficulties sizing a prosthesis, and an anterior femoral cut damaged the lateral aspect of the femur.

In the SV group there was one joint infection, two deep incisional infections, three superficial incisional infections (one of whom was allocated the SV approach but received an MP approach), and two patients consulted their general medical practitioner with wound problems but were not referred to a surgeon. In the MP group there were three joint infections (one of whom had a revision joint arthroplasty), three superficial incisional infections, and seven patients consulted their general medical practitioner with wound problems.

One SV patient had a partially retained wound drain, left in situ. Two SV and three MP patients underwent knee manipulation for stiffness. One MP patient had a patellar dislocation at six weeks, managed with manipulation and cast immobilisation. One MP patient at one year had had a positive bone scan for persisting pain, and was awaiting radiologist review.

There was one pulmonary embolus in the SV group, and three in the MP group. There was one confirmed and one possible but unconfirmed deep venous thrombosis, both in the SV group. Two SV and one MP patients had a urinary tract infection at one week. Two SV and one MP patients developed a chest infection at 1 week postoperatively. One MP patient had a transient ischaemic attack at six weeks, and another atrial fibrillation.

Discussion

A novel finding of this study was that the group of patients who had their total knee arthroplasties' through a sub-vastus approach had, one year after their operations, significantly less pain measured by the WOMAC and EuroQol questionnaires, and significantly better global WOMAC score, EuroQoL utility score, and physical function and role-physical scores measured by the SF36 questionnaire. Sub-vastus patients also had significantly better scores one week post-operatively on the Knee Society overall, knee and pain scores, and range of motion. On average, surgeons found that the medial parapatellar approach gave a greater ease of exposure. Although other randomised studies comparing the two approaches have been reported, we believe that this investigation is the first to report follow-up at one year, and that the number of patients we recruited exceeds the combined total in the previous studies that we are aware of [3-6].

Care was taken to reduce bias by using minimization, by excluding participating surgeons from the collection of baseline and follow-up data and data analysis, and by blinding treatment allocation for both patients and the physiotherapists who took clinical measurements. The groups were similar at baseline, follow-up completion was good apart from Knee Society Score at one week post-operatively, the analysis was based on intention to treat, and the participants themselves assessed their outcomes with the use of standardized questionnaire instruments up to one year post-operatively.

The trial is relatively large for an orthopaedic trial. However, the estimated differences are statistically imprecise, and this is an important limitation. There were wide confidence intervals, indicating that the true differences could have been larger or smaller than those reported.

The longitudinal modelling approach avoids many of the issues of multiple testing and gives an overall synthesis of the trial results. Although such analyses are available for all of the outcome variables studied, in the interests of space, the discussion is limited to the Knee Society Score and global WOMAC the variables in which there was particular prior interest among the research group. In relation to the Knee Society Score, the main outcome variable in this study, these analyses conducted suggest that there is no difference between the two treatment groups, and the position is neatly summarized in Figure 1 which supports the formal statistical analysis. On the other hand, the findings in relation to the global WOMAC score show that the SV approach confers some benefit. In the SV group, Womac scores were statistically significantly lower (on average) by 2.5 units of change. This finding only emerged after adjusting for baseline WOMAC score, time, and the treatment by time interaction. The inclusion of the baseline WOMAC score in the statistical model is key to the adjustment process, as this had the effect of approximately halving the standard error of the treatment effect. Naturally, the evidence would have been more persuasive had the benefit been demonstrable without the necessity for an adjusted analysis. However, such adjustments are routine in the modern analysis of longitudinal trials, and overall the evidence suggests a modest benefit (as indicated in Figure 2).

An issue, at least to some extent, in all randomized controlled trials is their generalizability, as patients who are recruited differ from those who are not recruited, and it is then an issue of judgement of whether participants are sufficiently similar to patients treated by another clinician for the results to be generalized to that practice. Most patients at our hospital who were to receive a primary total knee arthroplasty were eligible for the trial, and only a

small proportion of eligible patients declined to participate. All surgeons were experienced in total knee arthroplasty, although they had all employed the medial parapatellar approach as standard prior to the trial. They therefore received additional training, supervised practice including video-analysis and feedback of their sub-vastus technique, prior to starting to recruit patients for the trial. The hospital standard knee arthroplasty was used throughout the study. Formal statistical analysis of the outcome of total knee arthroplasty using either approach per each surgeon showed no difference, confirming that all surgeons were able to obtain an equally acceptable clinical outcome whichever approach they were required to use by the randomization process.

The major criticisms of the sub-vastus approach have been poor and unpredicatable exposure, and difficulty with eversion of the patella [23,24], and our study did indicate that our surgeons found the ease of exposure less favourable with the sub-vastus approach.

An early post-operative advantage of the sub-vastus approach observed in this study in the Knee Society Score measures, has also been reported in several small trials using a variety of outcome measures [3-6]. This has been explained by less disruption of the extensor mechanism allowing better early rehabilitation [3-6]. The benefit of 7^0 greater range of motion for the SV group at one week post-operatively in this study, compares to a 23^0 benefit for an SV group reported in one trial [5], no difference between approaches in patients undergoing bilateral knee arthroplasty [4], and earlier bending to 90^0 reported in another trial [6]. An early pain benefit reported in the KSS pain item one week post-operatively is consistent with improved early pain reported elsewhere [6], but we did not observe different use of analgesics [3,5]. Roysam [5], reported 17 days in hospital for the sub-vastus group compared to 21 days for the medial parapatellar group, whereas in our

study we found no difference, with the length of stay of about a week being standard hospital practice in our participating hospitals and more determined by policy than difference in rehabilitation.

The medial parapatellar approach does give excellent exposure of the knee joint in total knee arthroplasty, and is used in most operations [7]. Problems with this approach, however, particularly patellar complications, have been reported in up to 50% of patients [12,25-29], and may be one reason why a significant minority of patients do not appear to derive substantial benefit from their total knee arthroplasties. These problems motivated surgeons to search for other approaches, and Hofman [10] advocated the sub-vastus approach to avoid patellar complications through preservation of the extensor mechanism and less damage to the patella blood supply.

At a practical level, surgeons involved in this study, who previously did not use the sub-vastus approach, have introduced it as a frequently used option. Our study provides some evidence that, one year after a knee arthroplasty, patients who received a sub-vastus approach do better than those with a medial parapatellar approach. In this study, both the one week and one year outcome were better in the sub-vastus group on some measures compared to the medial parapatellar group. Longer term follow-up of patients in this study would allow identification of possible effects beyond the one year follow-up, and new trials in different settings with different surgeons and prostheses would be useful to see if our results are replicable in other settings.

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Fig. 1 Trial flowchart

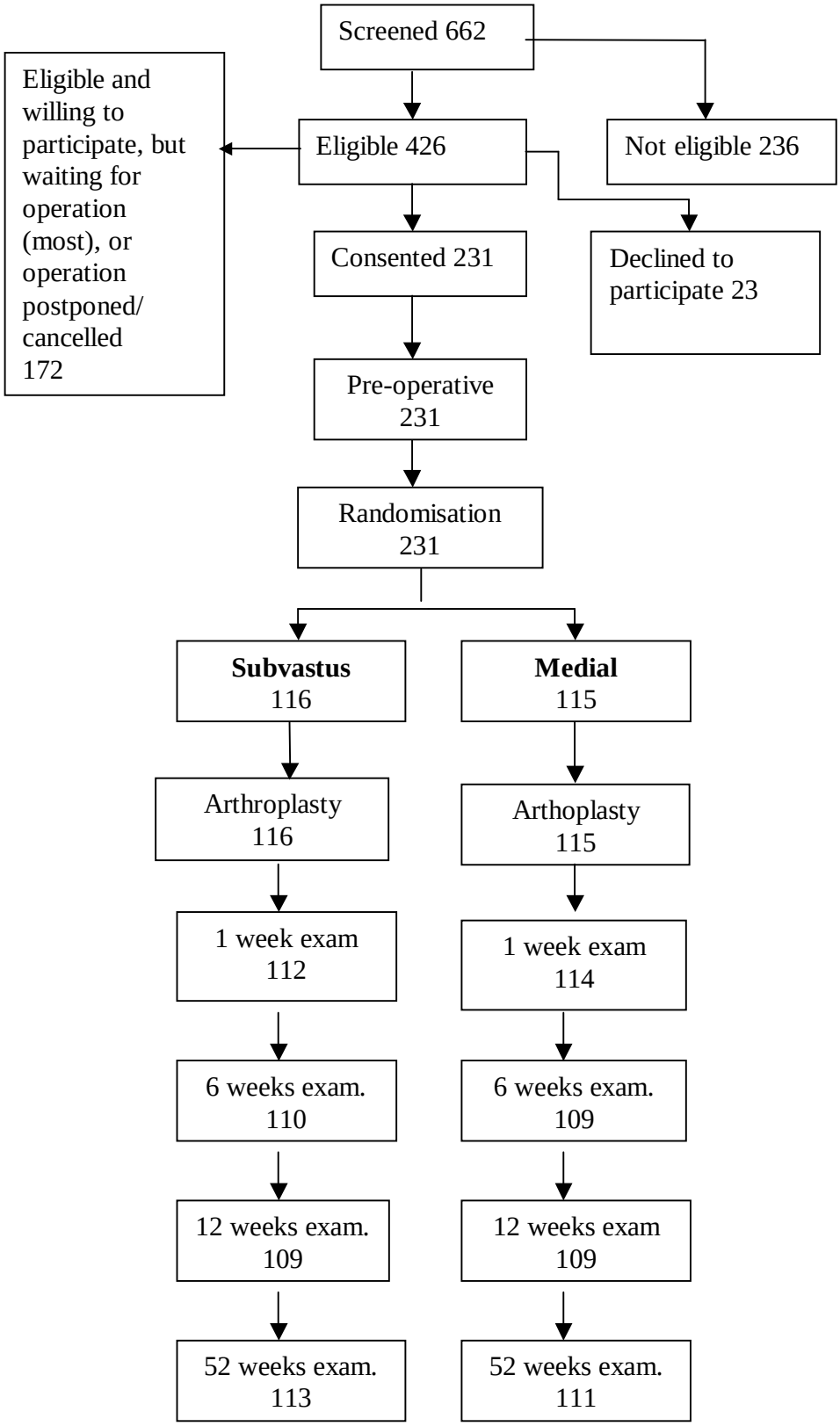
Screened 662
Eligible and willing to participate, but waiting for operation (most), or operation postponed/ cancelled 172
Eligible 426
Not eligible 236
Consented 231
Declined to participate 23
Pre-operative 231
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Table 1. Comparison of Factors at Baseline

Factors	Sub-vastus		Medial Parapatellar	
Categorical	n	%	n	%
Sex				
Male	60	(51.7)	59	(51.3)
Female	56	(48.3)	56	(48.7)
Total	116	(100)	115	(100)
Continuous	Mean	SD	Mean	SD
Age	70.1	(8.0)	70.9	(8.1)

NB: Comparison: Baseline check by multiple logistic function using 2 factors simultaneously - no evidence of imbalance.

501 Table 2a. Mean Values (SD) and numbers of patients for Longitudinal Outcomes for Medial ParaPatellar Group

Time	B	B	1	1	6	6	12	12	52	52
Variable	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Knee Society										
Total Score (0-200)	111	80.1 (23.1)	96	62.7 (25.3)	107	98.5 (28.9)	107	111.1(34.2)	107	125.8(31.1)
Function Score (0-100)	111	38.8 (16.6)	98	18.4 (12.6)	107	31.4 (18.7)	107	42.1(22.0)	108	50.6 (21.0)
Knee Score (0-100)	111	41.3 (13.9)	96	44.5 (18.1)	107	67.0 (18.4)	107	69.0 (19.8)	107	75.2 (17.6)
Range of Motion (^{0})	111	89.3 (21.9)	98	57.2 (17.4)	107	81.8 (17.2)	107	86.3 (19.6)	108	94.9 (15.5)
Pain (0- 50)	111	9.6 (10.2)	96	19.2 (15.6)	107	36.2 (15.0)	107	36.4 (16.5)	108	39.4 (15.7)
WOMAC										
Global (0-96)	115	44.5 (16.2)	112	20.3 (14.7)	108	11.3 (9.9)	107	11.9 (12.8)	111	11.5 (14.5)
Function (0-64)	115	28.5 (13.3)	112	10.2 (11.8)	108	5.7 (6.9)	109	7.2 (10.2)	111	7.3 (10.1)
Pain (0-20)	115	11.6 (3.3)	112	6.3 (3.9)	108	3.4 (3.5)	107	2.5 (3.1)	111	2.5 (3.9)
Stiffness (0- 8)	115	4.4 (2.2)	112	3.9 (2.0)	108	2.4 (1.8)	109	2.2 (1.8)	111	1.7 (1.9)
SF 36										
Physical Function	115	20.6 (20.0)	113	10.0 (14.7)	108	37.8 (23.4)	109	53.0 (26.2)	111	59.3 (25.6)
Role - Physical	115	4.2 (17.2)	112	29.2 (36.1)	108	53.0 (44.4)	109	61.2 (44.8)	111	67.1 (43.6)
Bodily Pain	115	37.8 (24.3)	112	52.0 (28.9)	108	75.2 (27.5)	109	74.8 (28.0)	111	78.7 (28.2)
Health Perception	115	73.5 (20.0)	113	77.1 (19.2)	108	81.2 (14.8)	109	79.4 (19.2)	111	74.2 (23.6)
Energy	115	44.1 (17.7)	112	42.8 (17.9)	108	49.4 (15.8)	109	54.4 (15.6)	111	52.4 (15.9)
Social Function	115	74.8 (38.4)	112	25.0 (34.2)	108	68.2 (41.2)	109	84.7 (31.1)	111	91.7 (20.7)
Role - Mental	115	94.2 (23.1)	112	89.0 (31.1)	108	96.3 (19.0)	109	92.0 (26.8)	111	98.2 (13.4)
Mental Health	115	77.3 (15.0)	112	79.0 (14.9)	108	79.0 (15.7)	109	76.8 (14.5)	111	75.9 (14.5)
EuroQol										
Health status (0-100)	115	73.4 (15.9)	113	72.0 (17.5)	108	79.8 (13.5)	109	79.1 (16.2)	111	79.6 (17.1)
Utility score (0- 1)	115	0.29 (0.27)	113	0.35 (0.19)	107	0.58 (0.24)	109	0.73 (0.29)	111	0.80 (0.26)
Pain (0- 2)	115	1.48 (0.52)	113	1.06 (0.50)	107	0.61 (0.54)	109	0.55 (0.60)	111	0.46 (0.57)

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506 Table 2b Mean Values (SD) and numbers of patients for Longitudinal Outcomes for Sub-Vastus Group

Time	B	B	1	1	6	6	12	12	52	52
Variable	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Knee Society										
Total Score (0-200)	115	80.2 (25.3)	91	71.0 (26.0)	108	95.6 (27.7)	108	111.0(31.5)	111	129.1(31.0)
Function Score (0-100)	115	37.4 (16.4)	91	19.7 (13.1)	108	32.7 (17.3)	108	42.8 (21.1)	111	52.3 (24.5)
Knee Score (0-100)	115	42.8 (16.3)	91	51.3 (20.4)	108	62.8 (20.4)	108	68.1(18.9)	111	76.8 (15.8)
Range of Motion (^{0})	115	87.0 (23.5)	91	61.2 (15.3)	108	80.8 (14.1)	108	87.1(17.7)	112	96.1 (14.9)
Pain (0- 50)	115	10.8 (11.5)	92	25.4 (17.9)	108	32.0 (17.8)	108	35.6(16.1)	111	41.1 (15.0)
WOMAC										
Global (0-96)	116	44.7 (17.5)	112	18.3 (13.9)	110	12.2 (12.2)	108	9.0 (9.3)	111	6.4 (9.7)
Function (0-64)	116	28.1 (13.7)	112	8.9 (11.4)	110	6.2 (8.9)	109	4.7 (7.0)	112	3.7 (6.7)
Pain (0-20)	116	12.3 (3.6)	112	6.0 (3.8)	110	3.8 (4.2)	108	2.4 (3.1)	111	1.7 (3.0)
Stiffness (0- 8)	116	4.4 (2.8)	112	3.3 (1.9)	110	2.2 (1.7)	109	2.0 (1.7)	113	1.1 (1.4)
SF 36										
Physical Function	116	20.8 (17.8)	112	11.7 (13.0)	110	39.6 (22.2)	110	56.5 (27.2)	113	67.3 (22.3)
Role - Physical	116	6.7 (23.6)	112	26.3 (29.6)	110	55.0 (44.4)	110	68.0 (42.3)	113	83.4 (36.5)
Bodily Pain	116	39.3 (23.1)	112	54.9 (27.8)	110	75.1 (27.2)	110	78.9 (27.0)	113	86.2 (24.2)
Health Perception	116	74.3 (21.8)	112	73.8 (20.7)	110	78.4 (19.4)	110	79.1 (18.6)	113	74.6 (21.4)
Energy	116	45.3 (17.6)	112	44.6 (17.6)	110	50.3 (18.3)	110	52.9 (18.5)	113	55.7 (15.7)
Social Function	116	73.6 (40.8)	112	35.7 (42.8)	110	67.1 (40.4)	110	87.8 (28.0)	113	94.2 (19.1)
Role - Mental	116	95.7 (20.4)	112	92.9 (25.1)	110	96.4 (18.8)	110	98.8 (10.0)	113	98.5 (11.3)
Mental Health	116	77.8 (14.4)	112	82.4 (11.8)	110	77.4 (14.8)	110	79.6 (12.8)	113	78.0 (12.3)
EuroQol										
Health status (0-100)	116	72.7 (16.6)	112	72.4 (16.9)	110	78.4 (16.8)	110	81.8 (13.4)	113	81.4 (16.3)
Utility score (0- 1)	116	0.27 (0.27)	112	0.42 (0.19)	110	0.61 (0.26)	110	0.77 (0.24)	113	0.87 (0.21)
Pain (0- 2)	116	1.52 (0.52)	112	0.93 (0.80)	110	0.72 (0.54)	110	0.54 (0.52)	113	0.31 (0.48)

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Table 3. Differences in group averages (Sub-vastus group – Medial Parapatellar group) of change from baseline (follow-up – baseline), (95% CI, and p values from independent t test). Positive differences favour the sub-vastus group, except for all WOMAC and the EuroQol pain scores where negative differences favour the sub-vastus group.

Variable	One Week				6 Weeks				12 Weeks				52wks			
	Difference	95%CI		p	Differenc	95%CI		p	Difference	95%CI		p	Differenc	95%CI		p
Knee Society Score (KSS)																
Total Score	9.87	1.12	18.63	0.027	-2.84	- 4.80	10.50	0.46	-1.15	-9.72	7.42	0.79	1.92	-5.90	9.75	0.63
Function Sco'	3.30	- 1.43	8.03	0.17	2.64	- 7.24	1.96	0.26	1.17	-3.43	5.77	0.62	1.30	-4.10	6.70	0.64
Knee Score	6.78	0.20	13.36	0.043	- 5.49	-11.29	0.32	0.064	-2.32	-8.51	3.87	0.46	0.65	-4.63	5.93	0.81
ROM (^{0})	7.44	0.37	14.53	0.039	-0.22	- 6.71	6.26	0.95	3.79	-3.36	10.95	0.30	4.87	-1.11	10.85	0.11
Pain	5.70	0.31	11.10	0.038	-4.75	- 9.59	0.08	0.054	-1.94	-6.82	2.94	0.43	0.68	-5.07	3.72	0.76
WOMAC																
Global (0-96)	-2.21	2.96	-7.39	0.40	0.37	5.09	-4.35	0.88	-3.20	1.72	-8.12	0.20	-5.20	-0.49	-9.90	0.031
Functi' (0-64)	-0.52	3.67	-4.71	0.81	0.99	4.71	-2.72	0.60	-2.54	1.46	-6.54	0.21	-3.15	0.55	-6.84	0.095
Pain (0-20)	-1.17	0.08	-2.42	0.066	-0.57	0.70	-1.84	0.38	-0.93	0.31	-2.16	0.14	-1.62	-2.70	-0.55	0.003
Stiffness (0-8)	-0.53	0.24	-1.30	0.18	-0.05	0.68	-0.79	0.89	-0.24	0.49	-0.97	0.52	-0.56	0.16	-1.29	0.13
SF 36																
Physical Func'	1.65	- 3.94	7.23	0.56	1.97	- 4.39	8.33	0.54	3.43	-3.67	10.53	0.34	7.81	1.64	13.97	0.013
Role-Physical	- 5.58	-15.36	4.19	0.26	-0.66	-14.19	12.88	0.92	3.11	-9.40	15.63	0.62	13.71	2.13	25.29	0.020
Bodily Pain	1.69	- 6.91	10.29	0.70	-1.42	-10.12	7.26	0.75	2.84	-6.18	11.87	0.54	6.30	-1.71	14.31	0.12
Health Percep'	- 3.66	- 7.98	0.65	0.10	-2.12	- 6.86	2.61	0.38	-0.75	-5.38	3.89	0.75	-0.37	-5.94	5.19	0.90
Energy	0.71	- 4.78	6.20	0.80	-0.19	- 5.31	4.92	0.94	-1.68	-6.71	3.34	0.51	2.50	-1.99	7.00	0.27
Social Functi'	12.20	- 1.42	25.82	0.79	0.84	-14.10	15.79	0.91	5.06	-7.33	17.44	0.42	5.02	-5.50	15.87	0.36
Role - Mental	2.38	- 5.58	10.34	0.56	-1.56	- 9.56	6.44	0.70	5.17	-2.82	13.15	0.20	-1.25	-8.01	5.50	0.72
Mental Health	3.61	- 0.31	7.52	0.071	-1.30	- 5.88	3.29	0.58	1.85	-2.51	6.22	0.40	1.55	-2.98	6.07	0.50
EuroQol																
Health Status	1.15	- 3.95	6.25	0.66	0.23	-2.54	5.25	0.93	4.21	-2.54	9.22	0.10	3.39	-2.76	8.83	0.22
Utility Score	0.093	0.016	0.171	0.018	0.055	-0.035	0.145	0.23	0.068	-0.024	0.160	0.15	0.091	0.009	0.172	0.029
Pain	-0.18	0.00	-0.36	0.051	0.06	0.25	-0.13	0.53	-0.06	0.14	-0.25	0.58	-0.19	-0.01	-0.36	0.040

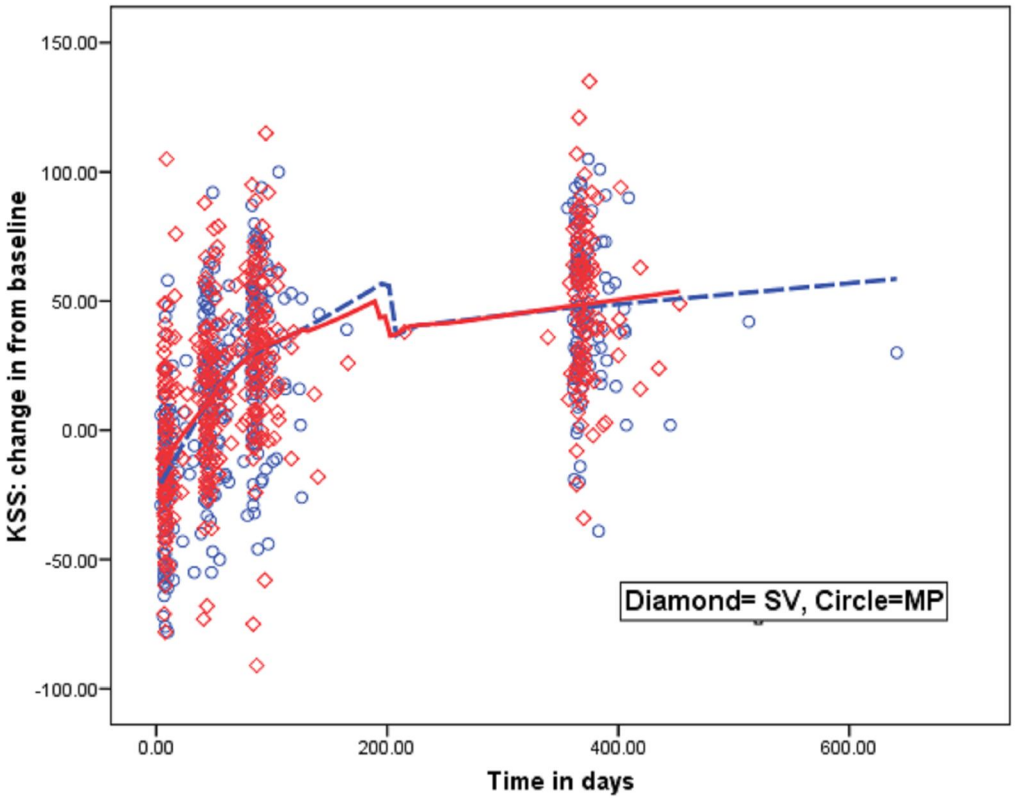

Figure 1: Total Knee Society Score by Time for each group: Diamonds = SV, Circles = MP; trend lines show average Evolution (solid line=SV, broken line=MP)

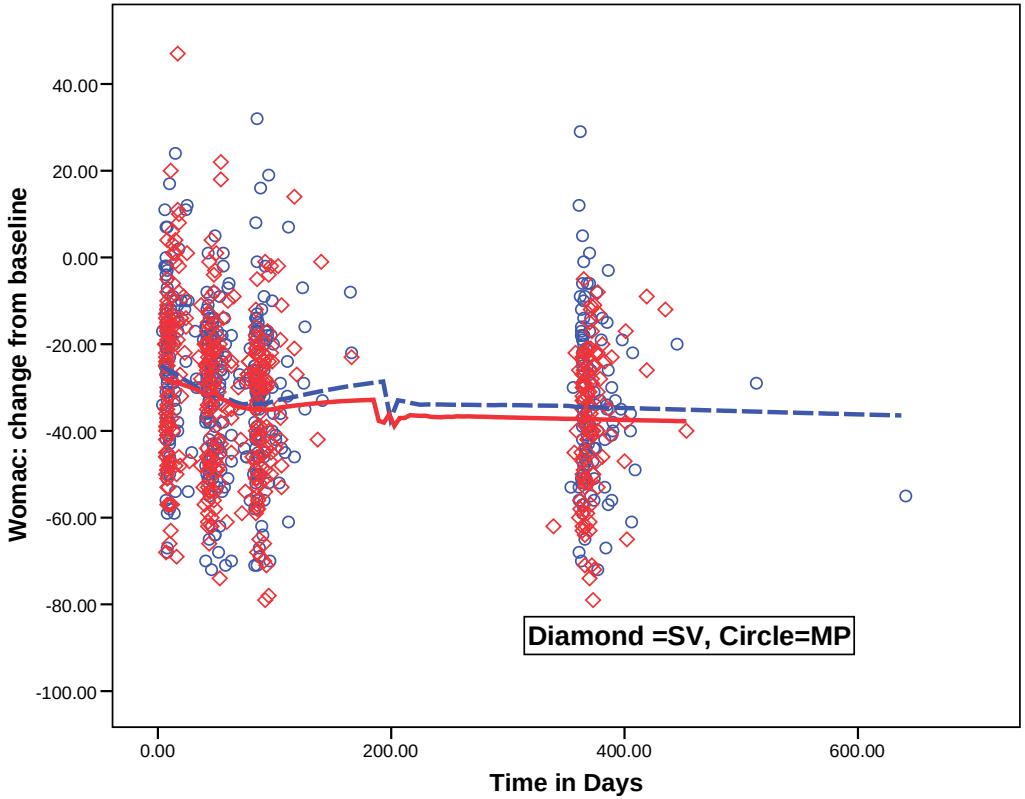

Figure 2: Total Womac Score by Time for each group: Diamonds = SV, Circles = MP; trend lines show average Evolution (solid line=SV, broken line=MP)