10. Appendices

Appendix 1 Registration form TKR, Norwegian Arthroplasty Register

Appendix 2 Clinical Investigation Plan

Appendix 3 KSS

Appendix 4 Explanations to the KSS

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Appendix 13 CT scan and radiography protocol

Appendix 14 Randomization procedure

Appendix 15 Patient form

The Norwegian Arthroplasty Register
Department of orthopaedic surgery, Helse Bergen HF
Haukeland University Hospital
Møllendalsbakken 11, N-5021 BERGEN
Telephone +47 55973742/55973743

Personal ID (11 digits):.....

Name:.....

(Write clearly, or use patient sticker – **specify hospital**)

Hospital:.....

KNEE PROSTHESES and other joints

Insertion, exchange or removal of one or more prosthetic parts

LOCALISATION

☐1 Knee ☐6 Wrist
☐2 Ankle ☐7 Finger (report joint)……
☐3 Toe (report joint)…….. ☐8 Other……
☐4 Shoulder ☐9 Back (report level)……
☐5 Elbow

HIP (one mark only) (Bilateral operations = two forms)

☐1 Right ☐2 Left

PREVIOUS OPERATION IN INDEX JOINT (more than one mark possible)

☐0 No
☐1 Osteosynthesis for intraarticular fracture
☐2 Osteotomy
☐3 Arthrodesis
☐4 Prosthesis
☐5 Synovectomy
☐6 Other (e.g. meniscal and ligament operations)……

DATE OF OPERATION (dd.mm.yy) |__|__| |__|__| |__|__|

INDEX OPERATION (one mark only)

☐1 Primary ☐2 Reoperation (previous prosthesis)

INDEX OPERATION (CHOOSE OPTIONS UNDER A OR B)

A . Primary operation because (more than one mark possible)
☐1 Idiopatisc arthrosis
☐2 Rheumatoid arthritis
☐3 Sequelae, fracture……
☐4 Ankylosing spondylitis
☐5 Sequelae, ligament tear
☐6 Sequelae, meniscal tear
☐7 Acute fracture
☐8 Sequelae,infection
☐9 Spondylosis
☐10 Sequelae, disc herniation surgery
☐11 Degenerative disc disease
☐12 Other ……

B . Reoperation because (more than one mark possible)
☐1 Loose proximal component
☐2 Loose distal component
☐3 Loose patella component
☐4 Dislocation of patella
☐5 Dislocation (not patella)
☐6 Instability
☐7 Malalignment
☐8 Deep infection
☐9 Fracture(near the prosthesis)
☐10 Pain
☐11 Defect polyethylene
Which part……
☐12 Other (e.g. prev. removed prosth.)……

TYPE OF REOPERATION (more than one mark possible)

☐1 Exchange of distal component
☐2 Exchange of proximal component
☐3 Exchange of all components
☐4 Exchange of patella components
☐5 Exchange of polyethylene (e.g. tibia, ulna, humerus)
☐6 Removal of prosthestic parts
Components:… ……..
……
☐7 Other ……
☐ Insert of patella comp.

BONE TRANSPLANT (more than one mark possible)

Proximal ☐0 No ☐1 Yes ☐2 Bone impaction
Distal ☐0 No ☐1 Yes ☐2 Bone impaction

SYSTEMIC ANTIBIOTIC PROPHYLAXIS

☐0 No ☐1 Yes, type (A).....

Dose (A).....Total number of doses.....Duration ……..hrs

Possibly in combination with (B).....
Dose (B).....Total number of doses.....Duration ……..hrs

OPERATION TIME (skin-to-skin) ……minutes

PEROPERATIVE COMPLICATION

☐0 No
☐1 Yes, which .....

THROMBOSIS PROPHYLAXIS

☐0 No ☐1 Yes, which type……
Dosage day of operation……First dose given preop. ☐0 No ☐1 Yes
Later dosage……Assumed duration……days
Possibly in combination with ……
Dosage…… Assumed duration……days
Stocking ☐0 No ☐1 Leg ☐2 Leg + Thigh Assumed duration……days
Mechanical pump ☐0 No ☐1 Foot ☐2 Leg Assumed duration……days

MINIMAL INVASIVE SURGERY (MIS) ☐0 No ☐1 Yes
COMPUTER NAVIGATION (CAOS) ☐0 No ☐1 Yes
Type of navigation ……

ASA CLASSIFICATION (see back of the form for a definition)

☐1 Normal healthy
☐2 Mild systemic disease
☐3 Severe systemic disease
☐4 Severe systemic disease that is a constant threat to life
☐5 Moribund

PROSTHESIS (specify accurate, or place sticker on back of the form)

KNEE

PROSTHESIS TYPE

☐1 Tricondylar ☐3 Unicondylar ☐4 Patellofemoral
☐2 Bicondylar ☐5 Bi-compartmental ☐6 Hinged
☐ Medial ☐ Lateral

FEMORAL COMPONENT

Name/Type/Size……
Catalogue number ……
Stem ☐0 No ☐1 Yes, length ……mm
Wedge ☐0 No ☐1 Yes
Stabilized ☐0 No ☐1 Yes, posterior ☐2 Yes, other
☐1 Cement with antibiotics – Name……
☐2 Cement without antibiotics – Name ……
☐3 Uncemented

TIBIAL COMPONENT (baseplate)

Name/Type/Size……
Catalogue number ……
Stabilized pegs ☐0 No ☐1 Yes, PE ☐2 Yes,metal ☐3 Yes,1 + 2
Extended stem ☐0 No ☐1 Yes, length…… ……mm
Wedge ☐0 No ☐1 Yes
☐1 Cement with antibiotics – Name……
☐2 Cement without antibiotics – Name ……
☐3 Uncemented

TIBIAL COMPONENT (polyethylene insert)

Name/Type/Size……
Catalogue number ……
Thickness…… mm
Stabilized ☐0 No ☐1 Yes, posterior ☐2 Yes, other

PATELLA COMPONENT

Name/Type/Size……
Catalogue number ……
Metal back ☐0 No ☐1 Yes
☐1 Cement with antibiotics – Name……
☐2 Cement without antibiotics – Name ……
☐3 Uncemented

CRUCIATE LIGAMENTS

Anterior, intact before operation ☐0 No ☐1 Yes
Anterior, intact after operation ☐0 No ☐1 Yes
Posterior, intact before operation ☐0 No ☐1 Yes
Posterior, intact after operation ☐0 No ☐1 Yes

OTHER JOINTS

PROSTHESIS TYPE

☐1 Total ☐2 Hemi ☐3 One component

PROXIMAL COMPONENT

Name/Type/Size……
Catalogue number ……
☐1 Cement with antibiotics – Name……
☐2 Cement without antibiotics – Name ……
☐3 Uncemented

DISTAL COMPONENT

Name/Type/Size……
Catalogue number ……
☐1 Cement with antibiotics – Name……
☐2 Cement without antibiotics – Name ……
☐3 Uncemented

INTERMEDIATE COMPONENT (e.g. caput humeri)

Name/Type/Size/Diameter……
Catalogue number ……

Doctor .....
Doctor that filled in the form (name will not be registered).

Protocol

1) Introduction: We will perform a prospective, randomised, clinically controlled RSA trial comparing:

a. Profix cemented bicompartmental knee prosthesis implanted with conventional intramedullary instruments
vs
b. Profix cemented bicompartmental knee prosthesis implanted with the use of computer navigation (from Brainlab)

The trial will take place at the orthopaedic departments in four hospitals: Haukeland university hospital, Haugesund hospital, Haugesund sanitetsforening rheumatism hospital and Lovisenberg diakonale hospital.The aim is to compare the technical results (implant positioning and stability) for the Profix knee prosthesis, the perioperative morbidity and the clinical and functional results comparing the two stategies. We will also evaluate the health economical aspect through a cost-effectiveness analysis. To complete the project we will analyse data from the Norwegian arthroplasty register with respect to the two different strategies. A doctoral fellowship is part of the project.

2) Background:
In arthroplastic surgery, scientific evidence is often lacking. Haukeland university hospital in Bergen and the Norwegian arthroplasty register are closely tied, and it is natural for us to critically evaluate the usefulnes and evidence of new implants and instrumentation. Computer assisted surgery is well documented in neurosurgery, but there have been a few trials in knee replacement surgery suggesting its usefulness. Some of these trials show a better alignment and positioning of the implants (1,10,12). In addition, retrospective trials have shown that the alignment is predictive of implant survival i.e. good alignment gives a better implant survival. (7,8,9) Indirectly that may indicate computer navigation is superior in regard to implant survival. Further one might assume that a better alignment gives a better functional outcome, and this new surgical technique may be less invasive, thus leading to a faster recovery. These questions still remain unanswered.

3)Challenges:
To date there are no long term studies confirming a definite association between computer navigation and better long term results for knee replacements. No trials have thoroughly investigated the possible change in functional outcome and morbidity after the introduction of computer navigation.

4)Objectives:
We seek to find the best treatment for gonarthitic patients in need of a knee replacement.

1. In this trial we investigate whether there is a definite correlation between computer navigated knee replacements and a better long term survival of the implants. Radiostereometric analysis (RSA) will reveal micromotion of the implants and from other trials we know this can predict the long term survival of the implants (19,20).
2. Some trials have reported a higher perioperative morbidity for patients treated conventionally, as opposed to those treated with the assistance of computer navigation (1,11). Intramedullary rods may increase bleeding, and may give a higher frequency of postoperative delirium from microemboli and metabolic disturbances (16). On the

other hand, the computer navigation is often more time consuming, and can lead to a higher risk of infection. The fixation of pin-fixators in femur and tibia for the reflection beads might weaken the bone and induce a fracture risk zone. We see that both positive and negative aspects of the computer navigation technique will be revealed in this trial.

3. The computer navigation software, hardware and surgical instruments add costs to the knee replacement procedure. Hence, it is important to evaluate the benefit as compared to the costs. We will analyse this using registry data and a Markov decision analysis.
4. The Norwegian arthroplasty register has data from all Norwegian hospitals. These data will be analysed and published with regard to computer navigated knee replacement.

5) Method:

We will randomise Profix cemented bicompartmental total knee implanted conventionally vs the same prosthesis implanted with the assistance of computer navigation. Profix is the standard implant in Helse Vest and it has good 5-year implant survival data in our Norwegian arthroplasty register (15).Tantalum markers will be injected into the bone and the implant for radiostereometric analysis (RSA). The radiographic technique is somewhat challenging and we have recruited specially trained and educated radiographers to obtain these images.The images allow us to localise every marker in a three dimensional coordinate system. Mathematic models will then calculate differences in position from one image to another. Micromotion down to 0,1mm and 0,2 degrees will be detected. Micromotions within the first two years correlate with long term implant survival. The radiation dose is low (10-20% of a regular x-ray of the knee). The image processing and the calculations are time consuming and expensive. Special software is needed and we therefore collaborate with Kompetansesenter for ortopediske implantater by Norges teknisk-naturvitenskapelige universitet (NTNU).
Prior to the inclusion of patients, every surgeon has performed more than 10 knee replacements with computer assistance. All surgeons are skilled and have performed more than 100 knee replacements with the conventional technique. A pilot study with 12 patients (6 in each group) will be performed. A total of 200 patients (100 in each group) will be included in the trial.
Only 60 patients will be included in the RSA part of the trial. The precision of the RSA will be evaluated by double investigations at a 1-year follow-up. The patient receives two images separated by a short period of time. The patient is first radiographed, then he/she takes a walk in the investigation room, and is then radiographed again. Micromotion between these two images is not real, so then we know the precision of our method. The limits for significant differences are calculated as 99% confidence intervals of absolute differences for the double investigation. The upper limits for ”mean error of rigid body fitting” and ”condition number” are set to 0,35mm and 130. These parameters describe the stability of the marker and the spreading, and expresses the precision of the software. At least 20 patients are needed in each group, but the technical demanding procedure has a drop-out risk, leading us to include 30 patients in each group (23).
We aim to reveal a difference of 0,5 degrees in the two groups with alignment in the frontal plane as measured on the CT-scan. Earlier research in this field indicates a greater variation in the conventional group (standard deviation=1,3) than in the computer navigated group (standard deviation=0,9) (10). With 80% statistical power and a significance level of 0.05, a power calculation suggests 79 patients in each group. Further, to be able to detect a difference of 10 units in our functional score (KOOS)(13) with a common standard deviation of 20 (14), our power calculations suggested 94 patients in each group to reach a power of 80% at a

significance level of 0,05. From these calculations we chose a study design with 100 patients in each group, assuming there will be some drop-outs. The study is recommended by the Regional ethics committee, Personvernombudet for forskning (Norsk samfunnsvitenskapelig datatjeneste) and Statens strålevern.

6) Main activities and milestones:
Cost-effectiveness analysis 2009
Inclusion and surgery, 2009
Analysing CT scans and functional results, spring and summer 2010
Publication of 3 months follow-up winter 2010/2011
Analysing RSA results winter and spring 2012
Publication of RSA results summer and fall 2012
Register analysis, 2011

7)Scientific impact:
There are many new and expensive instrumentations and implants on the market today. In order for Norwegian hospitals to be able to offer a high international standard of treatment, we need to evaluate carefully before choices are made. To date, computer navigation in knee replacement surgery is not well documented to be recommended as a standard procedure at all Norwegian hospitals. Earlier studies are lacking in that they have not reported an impact on long term implant survival. This study is unique by using RSA to predict long term outcome. It is also large enough to evaluate functional results and morbidity. In addition, the register analysis will give us information that has not been published. It is important for the patient to be confident that he/she receives the best treatment available, and it is important for the health care providers and funding authorities to receive clear and accurate information when choosing between two different treatments, in order to gain the most benefit.

8)Dissemination of project results:
We will publish our results in high impact international medical journals to disseminate the results to colleagues around the world. Lectures and presentations in national and international congresses is a natural way to publish the results. An investigator education programme, PhD, is incorporated in the project, which includes presentations and posters in national and international congresses. The project will be registered in an international trial register, according to demands by many journals before publishing.

9) Budget:

Payroll and indirect expences for R&D personell:	**per year**	**3 years**
Doctoral research fellowship	641000,-	1923000,-
Project manager, 4 hrs/week, (0,0016*kr753500,-*192hrs)	77158,4,-	231475,-
Physiotherapist follow-up (200 patients*4 follow-ups*kr200,-)	53333,3,-	160000,-
Project secretarian 2hrs/week (,0016*220000,-*96hrs)	33792,-	101376,-
Office assistance (Innovest, 10% of sum total kr 4903400,-)	163446,6	490340,-
Total	968730,4	2906191,-

Procurement of R&D services:

Radiostereometric analysis, Trondheim (240 investigations*kr960,-)	76800,-	230400,-
Radiographer RSA, (240 investigations * kr430,-)	34400,-	103200,-

CT scan, X-ray (2000 investigations * kr900,-)	600000,-	1800000,-
Total	711200,-	2133600,-

Equipment:

Tantalum markers no.1000	5983,-	17950,-
2 injectors for tantalum markers	18000,-	54000,-
3 RSA-cages a kr 77000,-	77000,-	231000,-
Total	100983,-	302949,-

Other operating expences:

ICT, database	17000,-	51000,-
Total	17000,-	51000,-

Sum total (office assistance from Innovest included)	1797913,3	5393740,-

10) Project summary:

Background: Computer navigation in knee replacement surgery is increasingly being used around the world, but the documentation of its usefulness is lacking. In order to critically evaluate this new surgical method, we want to perform a prospective, randomised clinical trial.

Goal: We evaluate the need for these highly advanced techniques in knee replacement surgery, and the cost-effectiveness. Long term outcome for the patients will be predicted by using the radiostereometric analysis (RSA). Also, data from the Norwegian arthroplasty register will indicate any difference in long term survival of the implant. If there are any differences in the functional outcome or complication rate, between the two groups, this will be detected in this trial.

Method: Patients age 60 through 80 years old, with gonarthritis, in need of knee replacement, are included in the trial. Radiostereometric analysis (RSA), CT-scans, X-rays, clinical evaluation score systems and laboratory measures are used in the evaluation process. A cost-effective analysis is performed based on data from Norwegian life tables, data from SINTEF and from the Norwegian arthroplasty register. Data from the Norwegian arthroplasty register will be statistically analysed separately for all knee replacements done with computer navigation in Norway in the last 5 years. Four Norwegian hospitals will collaborate in this trial (Haukeland university hospital, Haugesund hospital, Haugesund sanitetsforenings hospital for rheumatic diseases and Lovisenberg diakonale hospital) and patients are recuited from all four hospitals.

Scientific impact/challenges: This trial will probably have great impact since good evidence supporting the use of computer navigation in knee surgery is lacking. It is important for the patient to be confident that he/she receives the best treatment, and it is important for the health care providers and funding authorities to have clear evidence when choosing between two different treatment techniques, in order for the patient to benefit.

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Pasientnummer:.....

American Knee Society Score (KSS)

Sett kryss ved svaret som best beskriver ditt kne

1.Hvor mye smerter har du fra kneet ditt når du går?	**2.Hvor mye smerter har du i kneet når du går opp eller ned trapper?**
☐ Ingen ☐ Lette/periodevise ☐ Moderate ☐ Svært store	☐ Ingen ☐ Lette/periodevise ☐ Moderate ☐ Svært store
3.Hvor mye smerter har du i kneet ditt når du er i ro? ☐ Ingen ☐ Lette ☐ Moderate ☐ Svært store	**4.Hvordan påvirker kneet gangfunksjonen din?** ☐ Jeg kan gå ubegrenset langt ☐ Jeg kan gå 1 – 2 km ☐ ½ til 1 km ☐ Jeg kan gå < 500 meter ☐ Jeg kan ikke gå utenfor huset ☐ Jeg kan ikke gå
5.Hvordan går du opp/ned trapper? ☐ Jeg går normalt opp og ned trapper, med en fot foran den andre ☐ Jeg går normalt opp, men må bruke rekkverket ned ☐ Jeg bruker rekkverket både opp og ned ☐ Jeg bruker rekkverket opp, kan ikke gå ned ☐ Jeg kan ikke gå i trapper	**6.Hvilken støtte bruker du når du går?** ☐ Ingen ☐ En stokk eller en krykke ☐ To stokker ☐ To krykker ☐ Rullator

Klinisk vurdering av kneet

7. **Grader bevegelse** (fra maksimal aktiv strekk til maksimal aktiv bøy) _____Grader
8. **Mangler på full aktiv strekk (extension lag)** _____Grader
9. **Mangler på passiv strekk (flexion contracture)** _____Grader

10.Medial/lateral stabilitet (20 grader fleksjon)	**11.Anterior/Posterior stabilitet (skuffetest)**
☐ 0-5 mm ☐ 5-10 mm ☐ >10 mm	☐ 0-5 mm ☐ 5-10 mm ☐ >10 mm

12.Akseavvik (Varus eller valgusfeilstilling i forhold til 0 grader mekanisk akse, klinisk bedømt)_____Grader

Kommentar og veiledning til kneundersøkelsen i KSS

Punkt 7:
Mål med goniometer fra mest laterale punkt/midt på trochanter, omdreiningspunkt på laterale epicondyl, og distale punkt på mest laterale punkt/midt på laterale malleol.

Punkt 8:
Mål med goniometer (som over) hvor mye som mangler på full strekk ved **akti**v ekstensjon.

Punkt 9:
Mål med goniometer (som over) hvor mye som mangler på full strekk ved **passivt** strekk.

Punkt 10/11:
Tas på øyemål, men gjerne med en finger i leddspalten. Det er slik vi måler grad 1, grad 2 og grad 3 instabilitet som tilsvarer de tre utfallene i KSS.

Punkt 12:
Mål på strakt kne (evt mest mulig strakt) på følgende måte:

1. Finn spina iliaca ant sup og gå to fingerbredder medialt.
2. Finn punktet midt mellom malleolene.
3. Legg goniometer midt på kneet med omdreiningspunktet i leddspaltenivå like i underkant (distalt) av patellaspissen.
4. Les av vinkelen.

Utregning av poeng i punkt 1. 2. og 3. i KSS

Ingen smerter: 1.1 + 2.1 + 3.1 = 50 p
Letter periodevise smerter:
1.2 = 45 p
3.2 = 45 p
1.2 + 3.2 = 45 p
Lette periodevise smerter, bare i trapper: 2.2 = 40 p
Lette periodevise smerter, trapper og gange: 1.2 + 2.2 = 30 p
Moderate smerter, periodevis:
1.3 = 20 p
2.3 = 20 p
1.3 + 2.3 = 20 p
Moderate smerter, kontinuerlig: 3.3 = 10 p
Svært store smerter:
1.4 = 0 p
2.4 = 0 p
3.4 = 0 p

Til punkt 6: 6.4 og 6.5: Begge punkt gir fratrekk på 20 poeng.
6.3 gir bare 10 poeng fratrekk.

Til punkt 10: 1mm tilsvarer 1 grad. Mediolateral instabilitet > 15 mm/grader mangler av en eller annen grunn i denne versjonen. Vi må sette > 10 mm/grader = 5 p også på de med instabilitet > 15 grader, siden vi nå har over 30 pasienter som ikke har med denne siste kategorien.

Missing data: (behandles som i KOOS, siden vi ikke har noen nærmere beskrivelse når det gjelder KSS)
Hvis bommet på boksen, brukes den boksen som er nærmest. Hvis to bokser er krysset av brukes den mest alvorlige kategorien. Hvis det mangler data innenfor en kategori, scores gjennomsnittsverdien (halvparten av max-verdi) for den aktuelle kategorien, feks er maks poeng 50 i kategori 1 (spsm 1), og gjennomsnittsverdi angis som 25 p.

VAS – Visual analogue scale

Merk av på linjen nedenfor hvordan du opplever smertene i kneet

Høyre kne:

Ingen smerte _____Uutholdelige smerter

Venstre kne:

Ingen smerte _____Uutholdelige smerter

EQ-5D

I de 5 neste spørsmålene ønsker vi å vite hvordan livssituasjonen din er NÅ.
Sett ring rundt det svaret som passer best:

1. Hvordan opplever du gangevnen din?

1 Jeg har ingen problemer med å gå omkring
2 Jeg har litt problemer med å gå omkring
3 Jeg er sengeliggende

2. Hvordan klarer du personlig stell?

1 Jeg har ingen problemer med personlig stell
2 Jeg har litt problemer med å vaske meg eller kle meg
3 Jeg klarer ikke å vaske meg eller kle meg

3. Hvordan klarer du dine vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- og fritidsaktiviteter)?

1 Jeg har ingen problemer med å utføre mine vanlige gjøremål
2 Jeg har litt problemer med å utføre mine vanlige gjøremål
3 Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerter eller ubehag?

1 Jeg har verken smerte eller ubehag
2 Jeg har moderat smerte eller ubehag
3 Jeg har sterk smerte eller ubehag

5. Angst eller depresjon?

1 Jeg er verken engstelig eller deprimert
2 Jeg er noe engstelig eller deprimert
3 Jeg er svært engstelig eller deprimert

User Guide

Prepared by:

Mark Oppe
Rosalind Rabin
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On behalf of the EuroQoL Group

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1. Introduction

This guide has been developed in order to give users of EQ-5D basic information on how to use EQ-5D. Topics include administering the instrument, setting up a database for data collected using EQ-5D as well as information about how to present the results. Also included are some frequently asked questions dealing with common issues regarding the use of EQ-5D and a list of currently available EuroQoL products.

EuroQoL Group

- The EuroQoL Group is a network of international multidisciplinary researchers devoted to the measurement of health status. Established in 1987, the EuroQoL Group originally consisted of researchers from Europe, but nowadays includes members from North America, Asia, Africa, Australia, and New Zealand. The Group is responsible for the development of EQ-5D, a preference based measure of health status that is now widely used in clinical trials, observational studies and other health surveys.

- The EuroQoL Group has been holding annual scientific meetings since its inception in 1987.

- The EuroQoL Group can be justifiably proud of its collective scientific achievements over the last 20 years. Research areas include: valuation, EQ-5D use in clinical studies and in population surveys, experimentation with the EQ-5D descriptive system, computerized applications, interpretation of EQ-5D ratings and the role of EQ-5D in measuring social inequalities in self-reported health.

- The EuroQoL Group's website (www.euroqol.org) contains detailed information about EQ-5D, guidance for users, a list of available language versions, EQ-5D references and contact details.

EQ-5D

EQ-5D is a standardised measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal[1]. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys (Figure 1).

EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. It is cognitively undemanding, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire.

EQ-5D essentially consists of 2 pages - the EQ-5D descriptive system (page 2) and the EQ visual analogue scale (EQ VAS) (page 3). The EQ-5D descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, severe problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. **It should be noted that the numerals 1-3 have no arithmetic properties and should not be used as a cardinal score.** This current 3-level, 5-dimensional format of EQ-5D will remain unchanged for the immediate future. However a EuroQoL task force is developing a 5-level version. This should become available around 2009.

The EQ VAS records the respondent's self-rated health on a vertical, visual analogue scale where the endpoints are labelled 'Best imaginable health state' and 'Worst imaginable health state'. This information can be used as a quantitative measure of health outcome as judged by the individual respondents.

[1] EuroQoL Group. EuroQoL-a new facility for the measurement of health-related quality of life. Health Policy 1990;16:199-208

Figure 1: EQ-5D (UK English version)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

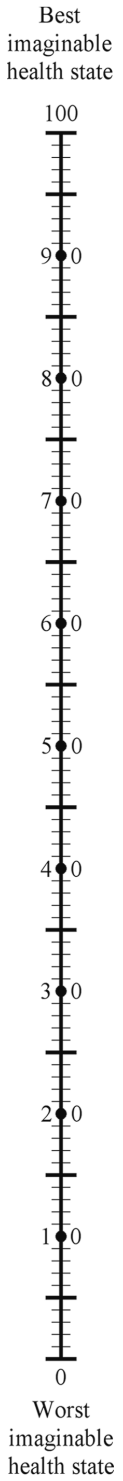
Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

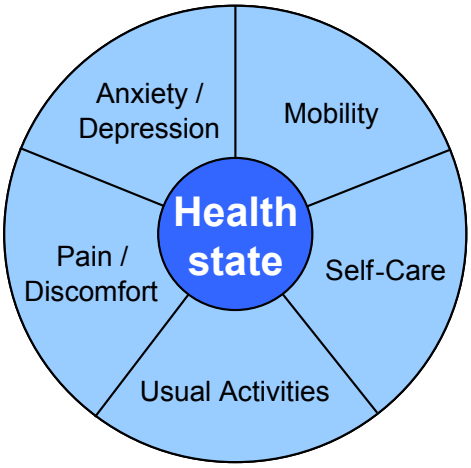


What is a health state?

Each of the 5 dimensions comprising the EQ-5D descriptive system is divided into 3 levels of perceived problems:

Level 1: indicating no problem
Level 2: indicating some problems
Level 3: indicating extreme problems

A unique health state is defined by combining 1 level from each of the 5 dimensions.



A total of 243 possible health states is defined in this way. Each state is referred to in terms of a 5 digit code. For example, state 11111 indicates no problems on any of the 5 dimensions, while state 11223 indicates no problems with mobility and self care, some problems with performing usual activities, moderate pain or discomfort and extreme anxiety or depression.

Note: Two further states (unconscious and death) are included in the full set of 245 EQ-5D health states, but information on these states is not collected via self-report.

Versions of EQ-5D

EQ-5D in different languages

Currently there are more than 100 translated versions of EQ-5D. If you want to know if there is an EQ-5D version appropriate for your country, please consult the website.

All translations/adaptations of EQ-5D are produced using a standardised translation protocol that conforms to internationally recognized guidelines. These guidelines aim to ensure semantic and conceptual equivalence and involve a forward/backward translation process and lay panel assessment. Only the EuroQoL Group Executive Office can give permission for a translation to be performed and translations can only be stamped as official if they are performed in cooperation with EuroQoL Group reviewers.

Alternative modes of administration

EQ-5D was primarily designed for self-completion by the patient or respondent. However the Group has brief guidelines for the following alternative modes of administration:

(i) Face-to-face
(ii) Self-completion in the presence of an interviewer
(iii) Telephone interview
(iv) Proxy (asking the proxy to rate how he or she, (i.e. the proxy), would rate the subject's health)

Guidelines for telephone and proxy use are available in a number of different languages.

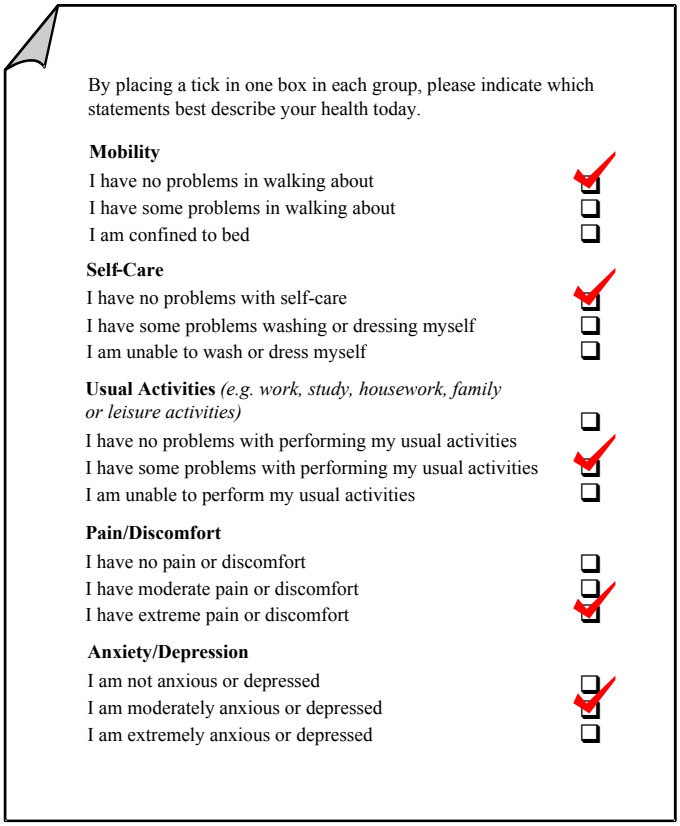
Child versions

EQ-5D is generally considered suitable for children aged 12 years and over (although this may vary in different countries). Currently a EuroQoL Group task force is developing a version for children between 7 and 12 years in international English. This version is being validated in Swedish, Italian, Spanish and German and these versions should become available in 2008.

Please check the EuroQoL website for up-to-date information on the availability of EuroQoL products.

2. Scoring the EQ-5D descriptive system

The EQ-5D descriptive system should be scored as follows:



By placing a tick in one box in each group, please indicate which statements best describe your health today.

Mobility
- I have no problems in walking about ☑
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care
- I have no problems with self-care ☑
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities *(e.g. work, study, housework, family or leisure activities)*
- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☑
- I am unable to perform my usual activities ☐

Pain/Discomfort
- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☑

Anxiety/Depression
- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☑
- I am extremely anxious or depressed ☐

Levels of perceived problems are coded as follows:

☑ ☐ ☐ Level 1 is coded as a '1'

☐ ☑ ☐ Level 2 is coded as a '2'

☐ ☐ ☑ Level 3 is coded as a '3'

NB: There should be only <u>one</u> response for each dimension.

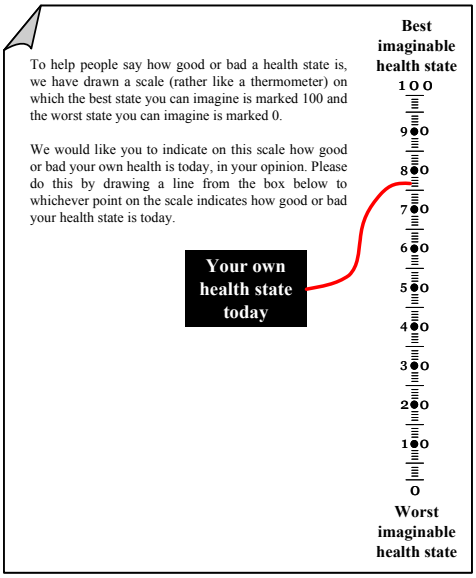
This example identifies the state 11232.

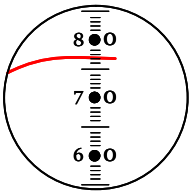
Missing values can be coded as '9'.

Ambiguous values (e.g. 2 boxes are ticked for a single dimension) should be treated as missing values.

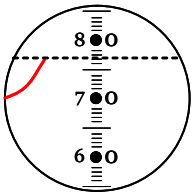
3. Scoring the EQ VAS

The EQ VAS should be scored as follows:





For example this response should be coded as 77



Even though the line does not cross the VAS this response can still be scored by drawing a horizontal line from the end point of the response to the VAS. In this example the response should be coded as 77

Missing values should be coded as '999'.

Ambiguous values (e.g. the line crosses the VAS twice) should be treated as missing values.

4. Converting EQ-5D states to a single summary index

EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension. The index can be calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). Information in this format is useful, for example, in cost utility analysis.

Value sets have been derived for EQ-5D in several countries using the EQ-5D visual analogue scale (EQ-5D VAS) valuation technique or the time trade-off (TTO) valuation technique. The list of currently available value sets with the number of respondents and valuation technique applied is presented in table 1. Most of the EQ-5D value sets have been obtained using a representative sample of the general population, thereby ensuring that they represent the societal perspective. For anyone working with EQ-5D data, an essential guide to the Group's available value sets can be found in: EuroQoL Group Monograph series: Volume 2: EQ-5D value sets: inventory, comparative review and user guide, recently published by Springer (see section 8 for more information).

Table 1: List of available value sets as of May 2007

Country	N	Valuation method
Belgium	548	EQ-5D VAS
Denmark	1179	EQ-5D VAS
Denmark	1332	TTO
Europe	6870	EQ-5D VAS
Finland	928	EQ-5D VAS
Germany	339	EQ-5D VAS
Germany	339	TTO
Japan	543	TTO
New Zealand	919	EQ-5D VAS
Netherlands	298	TTO
Slovenia	370	EQ-5D VAS
Spain	294	EQ-5D VAS
Spain	975	TTO
UK	3395	EQ-5D VAS
UK	3395	TTO
US	3773	TTO
Zimbabwe	2384	TTO

Documents containing the scoring algorithms, information on the valuation studies, tables of values for all 243 health states and SPSS and SAS syntax files can be ordered from the EuroQoL Executive Office (userinformationservice@euroqol.org).

5. Organising EQ-5D data

Data collected using EQ-5D can be entered in a database according to the following schema:

Variable name	ID	COUNTRY	YEAR	MOBILITY	SELFCARE	ACTIVITY	PAIN	ANXIETY
Variable description	patient ID number			1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value
Data row 1	1001	UK	2006	2	1	2	2	1
Data row 2	1002	UK	2006	1	1	1	1	1

Variable name	STATE	EQ_VAS	SEX	AGE	EDU	METHOD	SOC_ECON
Variable description		999= Missing value	1=male, 2=female, 9=Missing value	999= Missing value	1=low, 2=medium, 3=high, 9=Missing value	0=postal, 1=interview, 2=telephone, 9=Missing value	1=employed, 2=retired, ….., 9=Missing value
Data row 1	21221	80	1	43	1	0	1
Data row 2	21111	90	2	24	2	0	4

NB: The variable names are just examples. However, the variables for the 5 dimensions of the EQ-5D descriptive system should be named 'mobility', 'selfcare', 'activity', 'pain', and 'anxiety'. If they are given different names the syntax codes containing the value sets that are distributed by the EuroQoL Group will not work properly.

6. Presenting EQ-5D results

Data collected using EQ-5D can be presented in various ways. A basic subdivision can be made according to the structure of the EQ-5D:

1. Presenting results from the descriptive system as a health profile
2. Presenting results of the EQ VAS as a measure of overall self-rated health status
3. Presenting results from the descriptive system as a weighted index

However, the way results are presented is partly determined by what message you, as a researcher, wish to convey to your audience.

Health profiles

One way of presenting data as a health profile is by making a table with the frequency or the proportion of reported problems for each level for each dimension. These tables can be broken down to include the proportions per subgroup, such as age, before vs. after treatment, treatment vs. comparator, etc.

Sometimes it is more convenient to dichotomise the EQ-5D levels into 'no problems' (i.e. level 1) and 'problems' (i.e. levels 2 and 3), thereby changing the profile into frequencies of reported problems. This can be the case, for example, in a general population survey where the numbers of reported level 3 problems are very low. Tables 2 and 3 are examples of how to present EQ-5D data in tabulated form. The data for the tables originates from a general population survey in the UK[2].

[2]Kind P, Dolan P, Gudex C, Williams A. Variations in population health status: results from a United Kingdom national questionnaire survey Bmj 1998;316 (7133): 736-41.

Table 2: Proportion of levels 1, 2 and 3 by dimension and by age group

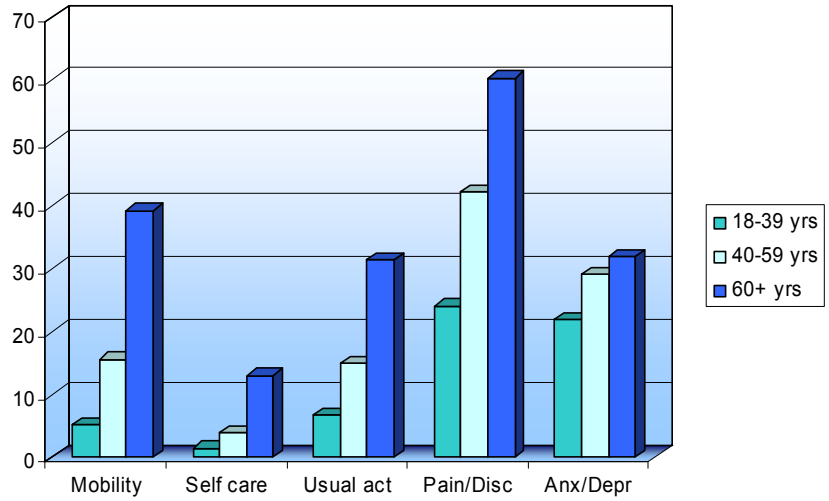
EQ-5D DIMENSION		AGE GROUPS 18-29	30-39	40-49	50-59	60-69	70-79	80+	TOTAL
MOBILITY	Level 1	95.4	92.2	89.7	78.1	70.7	60.2	43.3	81.6
	Level 2	4.6	7.6	9.9	21.9	29.3	39.8	56.7	18.3
	Level 3	0.0	0.1	0.4	0.0	0.0	0.0	0.0	0.1
SELF-CARE	Level 1	99.1	98.4	95.8	94.8	94.3	92.6	83.7	95.7
	Level 2	0.9	1.5	4.0	5.2	5.5	7.1	15.6	4.1
	Level 3	0.0	0.1	0.2	0.0	0.2	0.2	0.7	0.1
USUAL ACTIVITIES	Level 1	93.3	91.4	89.2	78.1	75.3	73.7	56.0	83.7
	Level 2	6.3	7.9	9.4	18.8	21.6	22.1	38.3	14.2
	Level 3	0.4	0.7	1.5	3.0	3.1	4.2	5.7	2.1
PAIN / DISCOMFORT	Level 1	83.9	80.7	74.1	56.3	53.8	44.0	39.7	67.0
	Level 2	15.8	17.7	22.8	38.1	40.6	48.4	49.6	29.2
	Level 3	0.3	1.6	3.1	5.6	5.6	7.6	10.6	3.8
ANXIETY / DEPRESSION	Level 1	86.5	82.6	81.3	72.8	72.0	74.7	75.2	79.1
	Level 2	12.6	16.4	16.9	24.4	25.1	22.6	24.1	19.1
	Level 3	0.9	1.0	1.8	2.8	2.9	2.7	0.7	1.8

Table 3: Frequency of reported problems by dimension and age group

EQ-5D DIMENSION		AGE GROUPS 18-29	30-39	40-49	50-59	60-69	70-79	80+	TOTAL
MOBILITY	No problems	643	631	489	362	339	246	61	2770
	Problems	31	53	56	101	140	162	81	625
SELF-CARE	No problems	668	673	522	439	452	378	119	3251
	Problems	6	11	23	24	27	30	23	144
USUAL ACTIVITIES	No problems	629	625	486	362	361	301	80	2842
	Problems	45	59	59	101	118	107	62	553
PAIN / DISCOMFORT	No problems	566	552	404	261	258	179	56	2275
	Problems	108	132	141	202	221	229	86	1120
ANXIETY / DEPRESSION	No problems	583	565	443	337	345	305	107	2684
	Problems	91	119	102	126	134	103	35	711

In addition to presenting the results in tabulated form, you can also use graphical presentations. Two or 3 dimensional bar charts can be used to summarise the results in 1 graph, (see figure 2). Figure 2 shows the sum of the proportion of reported level 2 and level 3 problems for each of the 5 EQ-5D dimensions for 3 distinct age groups. Older people reported more problems on all dimensions but the effect of age was strongest for mobility and weakest for anxiety/depression.

Figure 2: Profile of the population (% reporting problem)



EQ VAS

In order to present all aspects of the EQ VAS data, you should present both a measure of the central tendency and a measure of dispersion. This could be the mean values and the standard deviation or, if the data is skewed, the median values and the 25th and 75th percentiles. An example is presented in table 4. The data for the table originates from a general population survey in the UK[3].

Table 4: EQ VAS values by age – mean + standard deviation and median + percentiles

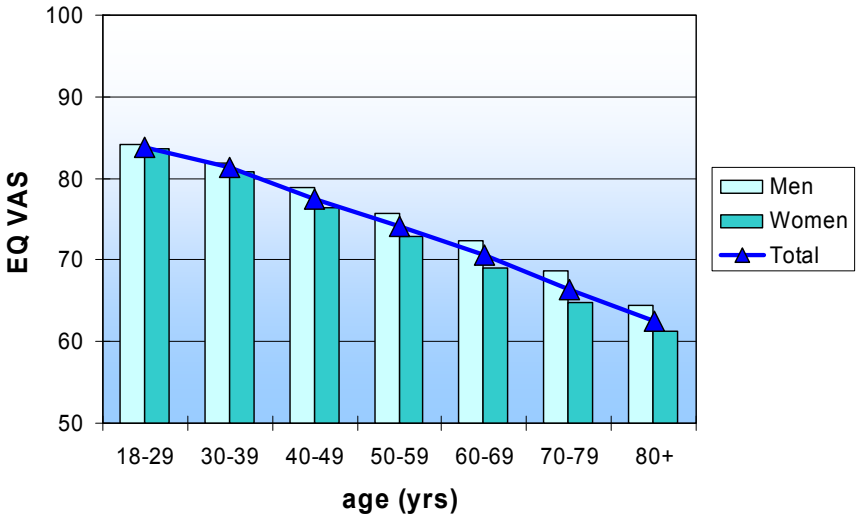
	AGE GROUPS							
EQ VAS	*18-29*	*30-39*	*40-49*	*50-59*	*60-69*	*70-79*	*80+*	*TOTAL*
Mean	87.0	86.2	85.1	81.3	79.8	75.3	72.5	82.8
- Std dev	13.8	14.6	15.5	46.8	17.5	18.5	18.2	23.1
Median	90	90	90	86	85	80	75	90
- 25th	80	80	80	70	70	65	60	75
- 75th	98	95	95	95	93	90	88	95

You can present a graphical representation of the data by using bar charts, line charts, or both (see figure 3). Figure 3 shows the mean EQ VAS ratings reported by

[3] Kind P, Dolan P, Gudex C, Williams A. Variations in population health status: results from a United Kingdom national questionnaire survey Bmj 1998;316 (7133): 736-41.

men, women and both for 7 distinct age groups. The mean EQ VAS ratings are seen to decrease with increasing age. Also, men of all age groups reported higher EQ VAS ratings than women.

Figure 3: Mean population EQ VAS ratings by age group and sex



EQ-5D index

Information about the EQ-5D index can be presented in much the same way as the EQ VAS data. This means that for the index, you can present both a measure of the central tendency and a measure of dispersion. This could be the mean values and the standard deviation (or standard error). If the data is skewed, the median values and the 25th and 75th percentiles could be presented. Tables 5 and 6 and figures 4 and 5 contain 2 examples of how to present EQ-5D index results. Table 5 and figure 4 present the results from a study where the effect of a treatment on health status is investigated. Table 6 and figure 5 show results for a patient population and 3 subgroups (the tables and figures are based on hypothetical data and for illustration purposes only).

Table 5: EQ-5D index values before and after treatment – mean + standard deviation and median + percentiles

EQ-5D index	before treatment	after treatment
Mean	0.59	0.76
- Std error	0.012	0.015
Median	0.60	0.70
- 25th	0.50	0.65
- 75th	0.70	0.80
N	120	110

Figure 4: EQ-5D index values before and after treatment – mean values and 95% confidence intervals

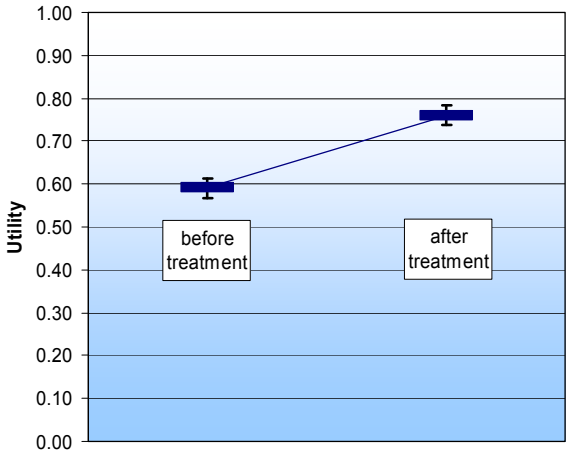
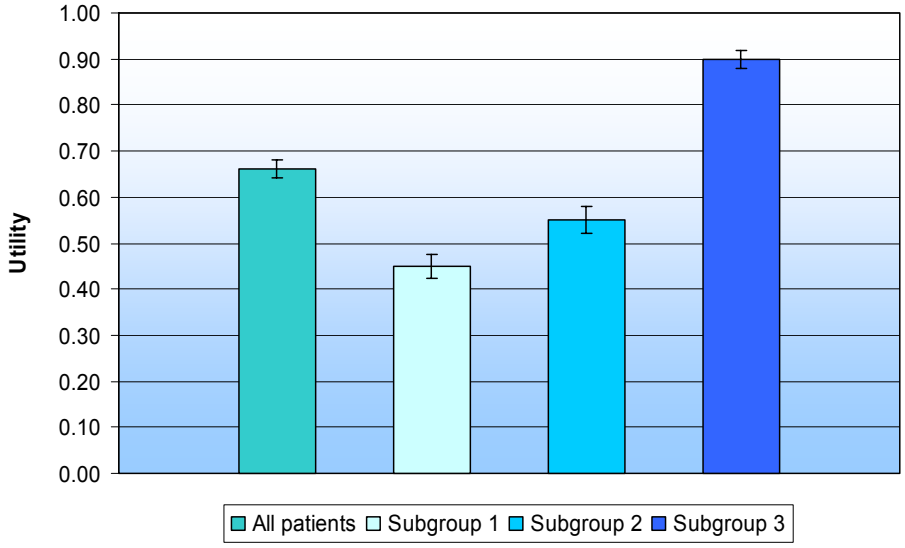


Table 6: EQ-5D index values of the total patient population and the 3 subgroups – mean + standard deviation and median + percentiles

EQ-5D-index	All patients	Subgroup 1	Subgroup 2	Subgroup 3
Mean	0.66	0.45	0.55	0.90
- Std error	0.010	0.013	0.015	0.010
Median	0.55	0.40	0.55	0.95
- 25th	0.50	0.30	0.50	0.80
- 75th	0.70	0.50	0.60	1.00
N	300	100	75	125

Figure 5: EQ-5D index values of the total patient population and the 3 subgroups – mean values and 95% confidence intervals



7. EQ-5D: Frequently asked questions

For what period of time does EQ-5D record health status?

Self-reported health status captured by EQ-5D relates to the respondent's situation at the time of completion. No attempt is made to summarise the recalled health status over the preceding days or weeks, although EQ-5D has been tested in recall mode. An early decision taken by the EuroQoL Group determined that health status measurement ought to apply to the respondent's immediate situation - hence the focus on 'your own health state today'.

General population value sets vs patient population value sets

If you want to undertake a utility analysis you will need to use a value set. Generally speaking utility analysis requires a general population-based value set (as opposed to a patient-based set). The rationale behind this is that the values are supposed to reflect the preferences of local taxpayers and potential receivers of healthcare. Additionally, patients tend to rate their health states higher than the general population because of coping etc, often underestimating their need for healthcare. The EQ-5D value sets are therefore based on the values of the general population.

Difference between the EQ-5D descriptive system and the EQ VAS

The descriptive system can be represented as a health state, e.g. health state 11212 represents a patient who indicates some problems on the usual activities and anxiety/depression dimensions. These health states can be converted to a single index value using (one of) the available EQ-5D value sets. These value sets have been derived using VAS or TTO valuation techniques, and reflect the opinion of the general population. The EQ VAS scores are patient-based and are therefore not representative of the general population. The EQ VAS self-rating records the respondent's own assessment of their health status. The EQ VAS scores however are anchored on 100 = best imaginable health and 0 = worst imaginable health, whereas the value sets are anchored on 11111 = 1 and dead = 0 and can therefore be used in QALY calculations.

Difference between the VAS and TTO techniques

The difference between the value sets based on TTO and those based on VAS is that the techniques used for the elicitation of the values on which the models are based differ. In the TTO task, respondents are asked, for example, to imagine they live in a health state (e.g. 22222) for 10 years and then asked to specify the amount of time they are willing to give up to live in full health instead (i.e. 11111). For example, someone might find 8 years in 11111 equivalent to 10 years in 22222. The VAS technique on the other hand, asks people to indicate where, on a vertical thermometer-like scale ranging from best imaginable health to worst imaginable health, they think a health state should be positioned.

Multinational clinical trials

Information relating to EQ-5D health states gathered in the context of multinational trials may be converted into a single summary index using one of the available EQ-5D value sets. There are different options available to do this using appropriate value sets-however the choice depends on the context in which the information will be used by researchers or decision makers. In cases where data from an international trial are to be used to inform decision makers in a specific country, it seems reasonable to expect decision makers to be interested primarily in value sets that reflect the values for EQ-5D health states in that specific country. So for example, if applications for reimbursement of a drug are rolled out from country to country, country-specific value sets should be applied and reported in each pharmaco-economic report. This is no different from the requirement to use country-specific costs. In the absence of a country-specific value set, the researcher should select another set of values for a population that most closely approximates that country. Sometimes however, information about utilities is required to inform researchers or decision makers in an international context. In these instances, 1 value set applied over all EQ-5D health states data is probably more appropriate.

The decision about which value set to use will also depend on whether the relevant decision making body in each country specifies any requirements or preferences in regard to the methodology used in different contexts (e.g. TTO, standard gamble (SG), VAS or discrete choice modelling (DCM)). These guidelines are the topic of an international ongoing debate but the EuroQoL website is planning to provide a summary of health care decision-making bodies internationally, and their stated requirements regarding the valuation of health states.

Detailed information regarding the valuation protocols, guidelines on which value set to use and tables of all available value sets has recently been published by Springer in: EuroQoL Group Monograph series: Volume 2: EQ-5D value sets: inventory, comparative review and user guide' (see section 8 for more information). Chapter 4 by Nancy Devlin and David Parkin will be of special interest to researchers pondering the issue of which value set to use.

8. Additional information

Key EuroQol references

1. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

2. Brooks R (1996). EuroQol: the current state of play. Health Policy 37(1):53-72.

3. Dolan P (1997). Modeling valuations for EuroQol health states. Med Care 35(11):1095-108.

4. Roset M, Badia X, Mayo NE (1999). Sample size calculations in studies using the EuroQol 5D. Qual Life Res 8(6):539-49.

5. Greiner W, Weijnen T, Nieuwenhuizen M, et al. (2003). A single European currency for EQ-5D health states. Results from a six country study. Eur J Health Econ; 4(3):222-231.

6. Shaw JW, Johnson JA, Coons SJ (2005). US valuation of the EQ-5D health states: development and testing of the D1 valuation model. Med Care; 43(3): 203-220.

Referring to the EQ-5D instrument in publications

When publishing results obtained with the EQ-5D, the following references can be used:

1. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

2. Brooks R (1996). EuroQol: the current state of play. Health Policy 37(1):53-72.

If you used a value set in your study you can also include a reference to the publication regarding that value set. The appropriate references for the value sets can be found in the EQ-5D Value Sets Monograph and in the value set summary documents that can be ordered from the EuroQoL Executive Office.

Products available from the EuroQoL Executive Office

EQ-5D language versions/guidelines for different modes of administration

All language versions and guidelines for different modes of administration must be obtained exclusively from the EuroQoL Executive Office. Normally only the language(s) appropriate to the country where the research request originates will be supplied. They are distributed freely provided the research is not being funded by a commercial organization (e.g. a pharmaceutical or medical device company). In these latter instances, sponsorship is requested.

The Measurement and valuation of health status using EQ-5D: A European perspective. Eds Brooks R, Rabin R, de Charro F. Kluwer Acacemic Publishers, 2005

This book reports on the results of the European Union-funded EQ-net project which furthered the development of EQ-5D in the key areas of valuation, application and translation. The book can be obtained from Springer at www.springeronline.com at a cost of €107.95.

Measuring self-reported population health: An international perspective based on EQ-5D. Eds Szende A, Williams A. EuroQoL Group Monographs Volume 1. SpringMed publishing, 2004.

This booklet provides population reference data for a number of different countries and is available on request from the EuroQoL Executive Office.

EQ-5D concepts and methods: a developmental history. Eds Kind P, Brooks R, Rabin R. Springer, 2005.

This book is a collection of papers representing the collective intellectual enterprise of the EuroQoL Group and can be obtained from Springer at www.springeronline.com at a cost of € 85.00.

EQ-5D value sets: Inventory, comparative review and user guide. Eds. Szende A, Oppe M, Devlin N. EuroQoL Group Monographs Volume 2. Springer, 2006.

This book provides an essential guide to the use of the EuroQoL Group's value sets for anyone working with EQ-5D data and can be obtained from Springer at www.springeronline.com at a cost of € 49.95.

Future developments

Since 2002, the EuroQoL Foundation has provided modest funding for EuroQoL members to carry out innovative EQ-5D-related research. Since 2004, the Group has been establishing specific task forces to:

- Investigate the use of EQ-5D in different disease areas
- Develop a 5-level version of EQ-5D
- Explore different valuation methodologies for the 5-level version
- Develop an EQ-5D version for children aged 7-12 years in different languages
- Investigate the use of EQ-5D in population health

- Explore the use of electronic versions of EQ-5D in pc and web-based applications as well as palm pilots and (in the future) cell phones. This task force will also investigate the eliciting of values via the computer

Contact information:

For more information please look at the EuroQoL website at www.euroqol.org or e-mail us at userinformationservice@euroqol.org

Acknowledgements:

Part of this user guide was taken from and is based on the UK user guide that was developed by Professor Paul Kind from York University, UK in 1998.

```
*Syntax EQ-5D

COMPUTE raw_ind = 97.66.

IF (GANG_F eq 2) raw_ind = raw_ind -5.78.
IF (GANG_F eq 3) raw_ind = raw_ind - 16.03.

IF (STELL_F eq 2) raw_ind = raw_ind - 10.28.
IF (STELL_F eq 3) raw_ind = raw_ind - 13.67.

IF (GJOREMAAL_F eq 2) raw_ind = raw_ind - 2.31.
IF (GJOREMAAL_F eq 3) raw_ind = raw_ind - 7.54.

IF (SMERTER_F eq 2) raw_ind = raw_ind - 8.15.
IF (SMERTER_F eq 3) raw_ind = raw_ind - 14.35.

IF (ANGST_F eq 2) raw_ind = raw_ind - 7.81.
IF (ANGST_F  eq 3) raw_ind = raw_ind - 11.31.

IF (GANG_F  ne 1 or GJOREMAAL_F ne 1 or STELL_F ne 1 or SMERTER_F ne 1 or ANGST_F ne 1)
 raw_ind = raw_ind - 11.21.

IF (GANG_F  eq 3 or STELL_F eq 3 or GJOREMAAL_F eq 3 or SMERTER_F eq 3 or ANGST_F eq 3)
 raw_ind = raw_ind - 20.06.

missing values GANG_F (8,9,99,999) STELL_F (8,9,99,999) GJOREMAAL_F (8,9,99,999)
SMERTER_F(8,9,99,999) ANGST_F (8,9,99,999).
```

```
IF (missing(GANG_F ) or missing(GJOREMAAL_F) or missing(STELL_F) or missing(SMERTER_F) or missing(ANGST_F)) raw_ind = 999.

missing values raw_ind (999).



COMPUTE VAS_Findex = 100 * (raw_ind - 10) / (97.66 - 10).

IF (missing(raw_ind)) VASindex = 999.

missing values VASindex (999).


EXECUTE.


COMPUTE raw_ind = 97.66.


IF (GANG_E eq 2) raw_ind = raw_ind -5.78.

IF (GANG_E eq 3) raw_ind = raw_ind - 16.03.


IF (STELL_E eq 2) raw_ind = raw_ind - 10.28.

IF (STELL_E eq 3) raw_ind = raw_ind - 13.67.


IF (GJOREMAAL_E eq 2) raw_ind = raw_ind - 2.31.

IF (GJOREMAAL_E eq 3) raw_ind = raw_ind - 7.54.


IF (SMERTER_E eq 2) raw_ind = raw_ind - 8.15.

IF (SMERTER_E eq 3) raw_ind = raw_ind - 14.35.


IF (ANGST_E eq 2) raw_ind = raw_ind - 7.81.

IF (ANGST_E  eq 3) raw_ind = raw_ind - 11.31.
```

```
IF (GANG_E  ne 1 or GJOREMAAL_E ne 1 or STELL_E ne 1 or SMERTER_E ne 1 or ANGST_E ne 1)

 raw_ind = raw_ind - 11.21.


IF (GANG_E  eq 3 or STELL_E eq 3 or GJOREMAAL_E eq 3 or SMERTER_E eq 3 or ANGST_E eq 3)

 raw_ind = raw_ind - 20.06.


missing values GANG_E (8,9,99,999) STELL_E (8,9,99,999) GJOREMAAL_E (8,9,99,999)
SMERTER_E(8,9,99,999) ANGST_E (8,9,99,999).


IF (missing(GANG_E ) or missing(GJOREMAAL_E) or missing(STELL_E) or missing(SMERTER_E) or
missing(ANGST_E)) raw_ind = 999.

missing values raw_ind (999).


COMPUTE VAS_Eindex = 100 * (raw_ind - 10) / (97.66 - 10).

IF (missing(raw_ind)) VASEindex = 999.

missing values VASEindex (999).


EXECUTE.
```

KOOS – Spørreskjema for knepasienter.

DATO: _____

FØDSELSNR (11 siffer): _____

NAVN: _____

SYKEHUS:_____

KRYSS AV FOR RIKTIG KNE : ☐ **VENSTRE**

(NB. Et skjema for **hvert** kne) ☐ **HØYRE**

Veiledning: Dette spørreskjemaet inneholder spørsmål om hvordan du opplever kneet ditt. Informasjonen vil hjelpe oss til å følge med i hvordan du har det og fungerer i ditt daglige liv. Besvar spørsmålene ved å krysse av for det alternativ du synes passer best for deg (kun ett kryss ved hvert spørsmål). Hvis du er usikker, kryss likevel av for det alternativet som føles mest riktig.

Symptom

Tenk på de **symptomene** du har hatt fra kneet ditt den **siste uken** når du besvarer disse spørsmålene.

S1. Har kneet vært hovent?

Aldri	Sjelden	I blant	Ofte	Alltid
☐0	☐1	☐2	☐3	☐4

S2. Har du følt knirking, hørt klikking eller andre lyder fra kneet?

Aldri	Sjelden	I blant	Ofte	Alltid
☐0	☐1	☐2	☐3	☐4

S3. Har kneet haket seg opp eller låst seg?

Aldri	Sjelden	I blant	Ofte	Alltid
☐0	☐1	☐2	☐3	☐4

S4. Har du kunnet rette kneet helt ut?

Alltid	Ofte	I blant	Sjelden	Aldri
☐0	☐1	☐2	☐3	☐4

S5. Har du kunnet bøye kneet helt?

Alltid	Ofte	I blant	Sjelden	Aldri
☐0	☐1	☐2	☐3	☐4

Stivhet

De neste spørsmålene handler om **leddstivhet** . Leddstivhet innebærer vanskeligheter med å komme i gang eller økt motstand når du bøyer eller strekker kneet. Marker graden av leddstivhet du har opplevd i kneet ditt den **siste uken**

S6. Hvor stivt er kneet ditt når du nettopp har våknet om morgenen?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐0	☐1	☐2	☐3	☐4

S7. Hvor stivt er kneet ditt **senere på dagen** etter å ha sittet, ligget eller hvilt?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐0	☐1	☐2	☐3	☐4

Smerte

P1. Hvor ofte har du vondt i kneet?

Aldri	Månedlig	Ukentlig	Daglig	Hele tiden
☐0	☐1	☐2	☐3	☐4

Hvilken grad av smerte har du hatt i kneet ditt den **siste uken** ved følgende aktiviteter?

P2. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P3. Rette kneet helt ut

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P4. Bøye kneet helt

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P5.Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P6. Gå opp eller ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P7. Om natten i sengen (smerter som forstyrrer søvnen)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P8. Sittende eller liggende

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

P9. Stående

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

Funksjon i hverdagen

De neste spørsmål handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved følgende aktiviteter på grunn av dine kneproblemer.**

A1. Gå ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A2. Gå opp trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken.**

A3. Reise deg fra sittende stilling

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A4. Stå stille

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A5. Bøye deg, f.eks. for å plukke opp en gjenstand fra gulvet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A6. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A7. Gå inn/ut av bil

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A8. Handle/gjøre innkjøp

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A9. Ta på sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A10. Stå opp fra sengen

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A11. Ta av sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A12. Ligge i sengen (snu deg, holde kneet i samme stilling i lengre tid)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A13. Gå inn og ut av badekar/dusj

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A14. Sitte

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A15. Sette deg og reise deg fra toalettet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

Angi graden av **vanskeligheter** du har opplevd ved hver aktivitet den **siste uken.**

A16. Gjøre tungt husarbeid (måke snø, vaske gulv, støvsuge osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

A17. Gjøre lett husarbeid (lage mat, tørke støv osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

Funksjon, sport og fritid

De neste spørsmålene handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved følgende aktiviteter på grunn av dine kneproblemer.**

SP1. Sitte på huk

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

SP2. Løpe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

SP3. Hoppe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

SP4. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

SP5. Stå på kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐0	☐1	☐2	☐3	☐4

Livskvalitet

Q1. Hvor ofte gjør ditt kneproblem seg bemerket?

Aldri	Månedlig	Ukentlig	Daglig	Alltid
☐0	☐1	☐2	☐3	☐4

Q2. Har du forandret levesett for å unngå å overbelaste kneet?

Ingenting	Noe	Moderat	Betydelig	Fullstendig
☐0	☐1	☐2	☐3	☐4

Q3. I hvor stor grad kan du stole på kneet ditt?

Fullstendig	I stor grad	Moderat	Til en viss grad	Ikke i det hele tatt
☐0	☐1	☐2	☐3	☐4

Q4. Generelt sett, hvor store problemer har du med kneet ditt?

Ingen	Lette	Moderate	Betydelige	Svært store
☐0	☐1	☐2	☐3	☐4

Takk for at du tok deg tid og besvarte samtlige spørsmål!

KOOS *Manual scoring sheet*

Instructions:
Assign the following scores to the boxes!

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□
0	1	2	3	4

Missing data. If a mark is placed outside a box, the closest box is chosen. If two boxes are marked, that which indicated the more severe problems is chosen. Missing data are treated as such; one or two missing values are substituted with the average value for that subscale. If more than two items are omitted, the response is considered invalid and no subscale score is calculated.

Sum up the total score of each subscale and divide by the possible maximum score for the scale. Traditionally in orthopedics, 100 indicates no problems and 0 indicates extreme problems. The normalized score is transformed to meet this standard. Please use the formulas provided for each subscale!

1. PAIN $100 - \frac{\text{Total score P1-P9} \times 100}{36} = 100 - \frac{\_\_\_\_\_}{36} = \_\_\_\_\_$

2. SYMPTOMS $100 - \frac{\text{Total score S1-S7} \times 100}{28} = 100 - \frac{\_\_\_\_\_}{28} = \_\_\_\_\_$

3. ADL $100 - \frac{\text{Total score A1-A17} \times 100}{68} = 100 - \frac{\_\_\_\_\_}{68} = \_\_\_\_\_$

4. SPORT&REC $100 - \frac{\text{Total score SP1-SP5} \times 100}{20} = 100 - \frac{\_\_\_\_\_}{20} = \_\_\_\_\_$

5.QOL $100 - \frac{\text{Total score Q1-Q4} \times 100}{16} = 100 - \frac{\_\_\_\_\_}{16} = \_\_\_\_\_$

WOMAC *How to score from the KOOS*

Assign scores from 0 to 4 to the boxes as shown above. To get original WOMAC scores sum the item scores for each subscale. If you prefer percentage scores in accordance with the KOOS, use the formula provided below to convert the original WOMAC scores.

$$\text{Transformed scale} = 100 - \frac{\text{actual raw score} \times 100}{\text{Possible raw score range}}$$

WOMAC subscores	Original score = sum of the following items	Possible raw score range
Pain	P5-P9	20
Stiffness	S6-S7	8
Function	A1-A17	68

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKT
Profix kneprotese, konvensjonell vs computernavigert.

De skal opereres med en kneprotese. Dette er en etablert behandling med gode resultater for de aller fleste pasienter. Operasjonen innebærer at man setter inn et kunstig kneledd av plast og metall som festes med bensement. Som annen medisinsk behandling er også kneprotesekirurgien i stadig utvikling, og man forsøker hele tiden å finne løsninger som ytterligere vil bedre behandlingsresultatene. Som ledd i vår søken etter bedre løsninger vil vi nå sammenligne kneproteser operert med vanlig, standard metode og kneproteser operert ved hjelp av såkalt computernavigasjon.
Profix-protesen er den protesen som brukes som standard i Helse Vest og på Lovisenberg Diakonale Sykehus, og den har gode resultater.
Computernavigasjon har de siste 5-6 år kommet for fullt inn i protesekirurgien. I Norge er det få sykehus som tilbyr slik behandling. Man har foreløpig begrenset dokumentasjon på nytten av dette nye operasjonsverktøyet. Man bruker et infrarødt kamera som sender og mottar signaler under operasjonen. Signalene overføres fra kneet til en computer som lager en modell av kneet ditt. Ut ifra denne modellen foretas visse beregninger som hjelper kirurgen å plassere protesen riktig. Standardmetoden i dag er å beregne protesens plassering ved hjelp av en siktepinne som settes i marghulen og visse anatomiske landemerker. Vi vil undersøke hvilken metode som gir best resultat med tanke på riktig plassering av protesen, som igjen har betydning for hvor lenge protesen varer før den evt må skiftes ut. Vi vil også undersøke hvilken metode som gir minst sykelighet og komplikasjoner etter operasjonen. Funksjon og livskvalitet vil bli vurdert, også i et helseøkonomisk perspektiv.

De blir herved forespurt om De vil delta i en studie som har til hensikt å sammenligne behandlingsresultatet med disse to metodene.

Hva innebærer deltakelse i studien?

Studien innebærer at man ved loddtrekning velger hvilken metode pasienten skal opereres med. Plassering av reflektorkuler for computernavigering innebærer to små (1cm) hudsnitt på leggen. Kulene festes med pinner som skrues fast i benet. Begge grupper vil få dette hudsnittet. Oppfølgingen vil også være den samme uavhengig av metoden. Pasienter som deltar i studien, vil under operasjonen få satt inn små metallmarkører (0,8-1mm) av metallet tantal i benet rundt protesen og i plastkomponenten. Disse metallmarkørene har vært benyttet til dette formålet internasjonalt i flere tiår og har ingen påviste bivirkninger. Ved hjelp av markørene og helt spesielle røntgenbilder kan man påvise mikroskopisk bevegelse av protesedelene og slitasje av plasten. Grad av bevegelse og slitasje sier noe om protesens stabilitet og derved kvalitet. Pasienter som deltar i studien vil få en ekstra nøye oppfølging med røntgenundersøkelser etter 3, 12 og 24 måneder, samt vanlig rtg. kontroll og undersøkelse etter 5 og 10 år. Det vil dessuten bli foretatt en CT-kontroll av kneet 3 måneder etter operasjonen for å sjekke protesens plassering. Dette medfører en strålebelastning på 1 mSv som tilsvarer 3 røntgenbilder av bekkenet.

Håndtering av opplysninger og Personvern

Deltagelse er frivillig, og De kan trekke dem fra studien, også etter operasjon. Dersom De velger ikke å delta i studien, vil dette ikke ha noen innvirkning på Deres behandling ved sykehuset, og De vil bli operert på vanlig måte med en standard Profix kneprotese.

De opplysninger og data som framkommer gjennom studien vil samles og databehandles. Dataene tas fra din vanlige pasientjournal fra opphold ved innleggelse for operasjon, påfølgende rtg. og polikliniske kontroller hos lege og fysioterapeut. Vi registrerer plassering av protesen, bevegelse av protese, grad av smerte, funksjon, andre sykdommer, evt. bivirkninger og bruk av medikamenter. I tillegg vil fysioterapeuten evaluere opptreningsperioden med et eget spørreskjema. Studien er et samarbeidsprosjekt mellom Haugesund sjukehus, Haugesund sanitetsforenings revmatismesjukehus, Lovisenberg Diakonale Sykehus og Haukeland Universitetssykehus. Opplysninger om enkeltpasienters identitet vil bli oppbevart ved hvert behandlende sykehus, mens data samlet inn i prosjektet vil bli utvekslet mellom sykehusene i avidentifisert form. Alle opplysningene vil bli behandlet konfidensielt. Prosjektet avsluttes år 2017, etter 10 års oppfølging av alle pasienter, og alle innsamlede forskningsdata vil da anonymiseres. Vanlige journalopplysninger vil ikke slettes.

Studien er klarert av Regional komité for medisinsk forskningsetikk Vest-Norge og meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Studien ledes av Klinikkoverlege professor dr. med. Ove Furnes, ved Ortopedisk avd. Haukeland Universitetssykehus.

Spørsmål vedrørende studien kan rettes til din behandlende lege, eller til legen som er ansvarlig for studien ved det sykehuset hvor De behandles.

Vennlig hilsen

Klinikkoverlege professor dr. med. Ove Furnes
Haukeland Universitetssykehus

Overlege Øystein Gøthesen
Haugesund Sjukehus

Overlege Herman Luhr
Haugesund sanitetsforenings revmatismesjukehus

Avdelingsoverlege Øystein Høvik
Lovisenberg Diakonale Sykehus

INFORMERT SAMTYKKE

Undertegnede har lest den vedlagte informasjonen og har diskutert studien med ansvarlig lege. Jeg er villig til å delta i studien.

_____	_____
Pasientsignatur	**Dato:** **(Pasienten skriver selv dato)**

Som ansvarlig lege bekrefter jeg at pasienten har fått muntlig og skriftlig informasjon om studien, og at pasienten har signert samtykke før prosjektspesifikke undersøkelser eller prosedyrer er påbegynt.

_____	_____
Ansvarlig leges signatur	**Dato:**

Revidert 2.august, 2010

Protocol - alignment and position

All angles are measured from the lateral side (coronal (frontal) view) or posteriorly (sagittal view).
All images in this protocol are from a right side knee.

Part 1. Computer tomography scans
Part 2. Full-length standing radiographs

Part 1. Computer tomography scans – method and definitions

Timing:
Performed at 3 months follow-up

Equipment:
A multi-slice scanner (64 slices) was used at 3 months follow-up at all hospitals involved in the trial, and the tomography was performed according to the Perth protocol [1].
Software for measurements of alignment: IMPAX Agfa version 6.4.0.4551. The images are analyzed using two computer screens facilitating cross-bearing in three dimensions, and data are registered directly into the database.

Positioning:

Patient in a supine position with toes pointing towards the roof. Ankles placed in a neutral position. Forefeet supported by taping/support if needed, to avoid outward rotation of the legs.

Definitions:

Mechanical axes of the knee replaced limb[2-4]:
Femur - coronal view: Axis from centre of hip to centre of femoral component
Femur - sagittal view: Axis from centre of hip to rotational centre of femoral component
Tibia - coronal and sagittal view: Axis from centre of tibial component to centre of ankle
Limb - coronal view: Femoral axis + Tibial axis

Centre of joints:
General principle: cross-bearing in three dimensions (Fig.A)

Hip:
Draw a circle to find centre of the femoral head (Fig.A1/A4)

Knee/Femoral component:
Coronal view: Point (on the joint line) where a perpendicular of the condylar tangent points towards the deepest part of the intercondylar groove (Fig.A2).
Sagittal view: Point (on the joint line) where a perpendicular of the condylar tangent points towards the deepest part of the intercondylar groove (Fig.A3).
Axial view: Mid-point of a line between the anterior faces of the pegs (Fig A8).

Centre of rotation/sagittal view: Draw circles to find a) the centre of the anterior part of the medial condyle, and b) the centre of the posterior part of the medial condyle (a typical J-shaped articulation). Centre of rotation of the knee is defined as the mid-point between these centres.(Fig.B)

Knee/Tibial component:
Coronal view: Mid-point of longest line from lateral to medial (Fig.C1).
Sagittal view: A line parallel and posterior to the stem crosses the upper surface of the tibial component. This crossing is defined as centre of the tibial component (Fig.C2).
Axial view: Mid-point of longest line from lateral to medial, crossing the centres of two oval shaped joint surfaces of the tibial component (Fig.C3).

Ankle (Fig.D):
Coronal view:
Middle of the ankle is defined as the mid-point of a line on the talus from medial to lateral.
Sagittal view:
Mid-point of the talar dome. (If the ankle is plantarly flexed, use the mid-point of the distal tibial joint surface)
Axial view:
Mid-point of a line from medial to lateral talar body.

Measures: Alignment and position of the implant:

1. Alfa1 (α1, Fig.E1): Alignment of the femoral component in the coronal view, referring to the mechanical axis of the "new" femur.
    a. The line between the pegs, adjusted with the tangent of the condyles, defines the line of the implant. This line is measured against the mechanical axis of the femur.
2. Beta1 (β1, Fig.E2): Alignment of the tibial component in the coronal view, referring to the mechanical axis of the "new" tibia.
    a. A line parallel to the upper surface of the tibial component, adjusted with a perpendicular line parallel to the stem, defines the line of the implant. This line is measured against the mechanical axis of the tibia.
3. Gamma (γ, Fig.E3): Alignment of the femoral component in the sagittal view, referring to the mechanical axis of the "new" femur.
    a. The mechanical axis in the sagittal plane is defined as the axis from the centre of the hip to the rotational centre of the femoral component. A line drawn parallel to the pegs adjusted by any of the backsides of the femoral component, defines the line of the implant. This line is measured against the mechanical axis of the femur.
4. Sigma (σ, Fig.E4): Alignment of the tibial component in the sagittal view, referring to the mechanical axis of the "new" tibia.
    a. A line parallel to the upper surface of the tibial component, adjusted with a perpendicular line parallel to the stem, defines the line of the implant. This line is measured against the mechanical axis of the tibia.
5. Lambda (λ, Fig.E5): The rotational position of the femoral component relative to the trans-epicondylar line. A line parallel to the posterior condyles, adjusted by a line between the pegs, defines the line of the implant. The perpendicular of this line is measured against the trans-epicondylar axis. The trans-epicondylar axis is drawn from

the most prominent part of the lateral epicondyle to the deepest point of the groove between the insertion of the superficial and the deep medial collateral ligament. (In cases with no groove, the most prominent part of the medial epicondyle is chosen as the reference point).

6. Mu (μ, Fig.E6): The rotational position of the tibial component relative to the anterior posterior axis (AP-axis). A line parallel to the posterior condyles defines the line of the implant. The AP- axis is defined as a line drawn from a point marking 1/3 of the medial tibial tubercle to a point representing the insertion of the posterior cruciate ligament. A CT slice where an S-shape is found at the back of the tibia is chosen, and the posterior point is marked where the concavity of the S turns into convexity.
7. Omega (ω, Fig.E7): The line of the femoral component in Lambda (λ) is superimposed on the line of the tibial component in Mu (μ). The angle between the two components represent a match/mismatch. Ideally this angle should be 10°, since the tibial component of the Profix prosthesis is supposed to be positioned in 10° internal rotation to achieve good bone coverage. (The polyethylene joint surface is externally rotated 10° to neutralize the rotation of the tibial component. Then the match between the polyethylene joint surface and the femoral component is zero degrees (perfect match)).
8. Chi1 (χ1), Hip-Knee-Ankle (HKA) angle: Alfa1 + Beta1

Part 2. Full-length standing radiographs

Timing:

Performed preoperatively and at 3 months follow-up.

Positioning:

Patient standing with toes pointing in a straight forward direction and the knees in full extension

Definitions:

Mechanical axis of femur: Centre of hip to centre of prosthetic knee
Mechanical axis of tibia: Centre of prosthetic knee to centre of ankle

Centre of preoperative (native) knee (Figure F): A point between centre of femoral notch and tibial spines is extrapolated perpendicularly down to the joint line [5].

Centre of hip: Circles are used to identify the centre of rotation of the hip (Fig.G)
Centre of the prosthetic knee: A perpendicular of the femoral condylar tangent pointing to the deepest point of the intercondylar groove. The crossing of the perpendicular line and the tangent defines the prosthetic centre (Fig.G)
Centre of the ankle: Centre of a line from medial to lateral talar body (Fig.G)

Measures:

Alignment of the prosthetic knee

1. Chi2 ($\chi 2$), Hip-Knee-Ankle (HKA) angle: Angle between mechanical axes of femur and tibia (Fig.G)
2. Alfa2 ($\alpha 2$), Alignment of the femoral component: Angle between femoral condylar joint line and mechanical axis of the femur (Fig.H1)
3. Beta2 ($\beta 2$), Alignment of the tibial component: Angle between femoral condylar joint line and mechanical axis of the tibia (Fig.H2)

Alignment of the preoperative (native) knee (Fig.G)

4. Chi0 ($\chi 0$), HKA-angle: Angle between mechanical axes of native femur and native tibia.

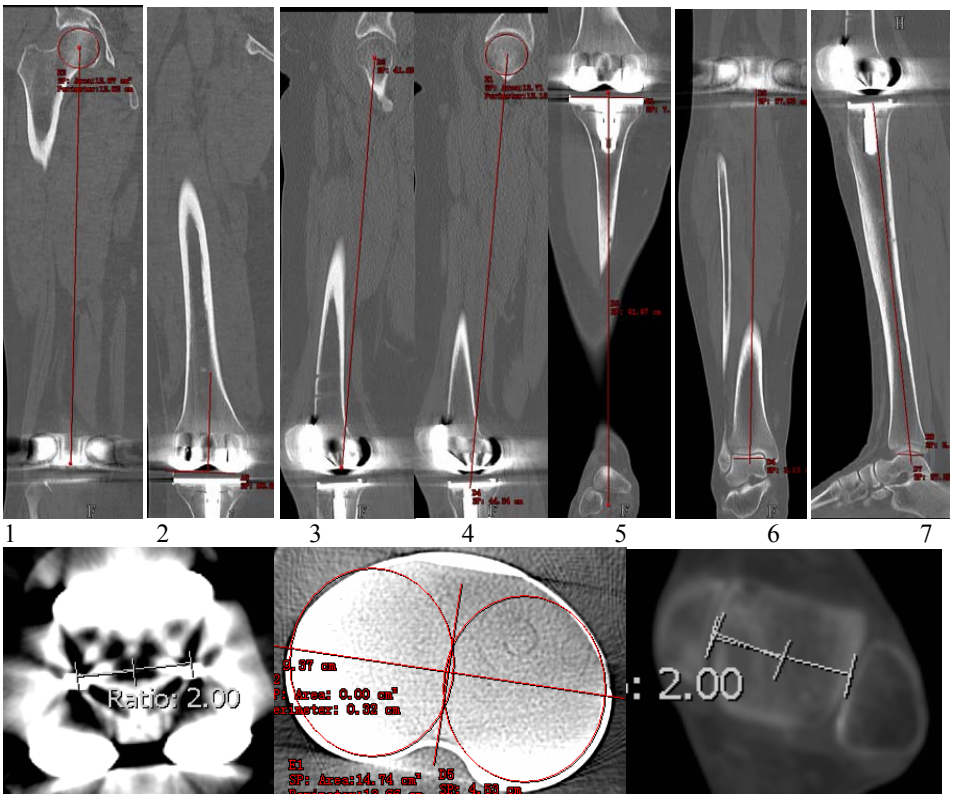


Figure A 1-10. Showing cross-bearing of coronal, sagittal and axial views to find mechanical axes of the prosthetic femur and tibia.

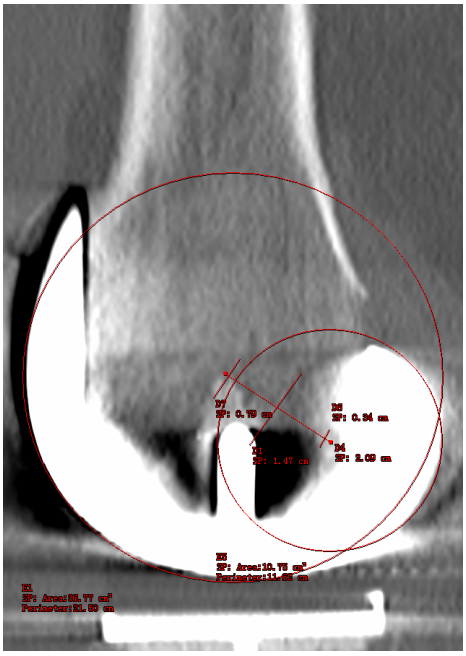
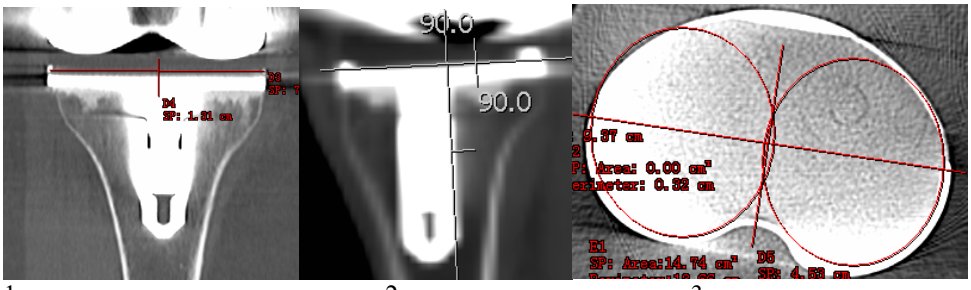
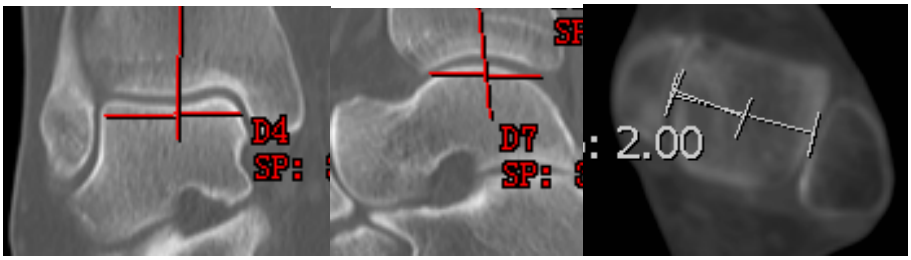


Figure B. Centre of rotation of the femoral component[6].



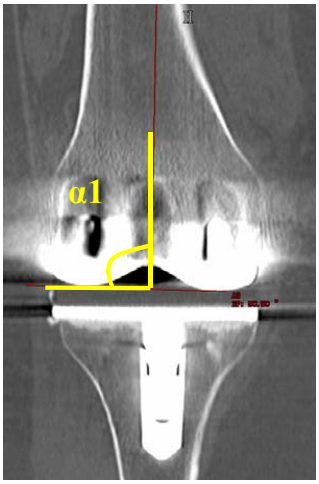
1 2 3

Figure C. The stem is somewhat medialized in the Profix tibia component, thus the centre of the component is somewhat lateral to the centre of the stem.

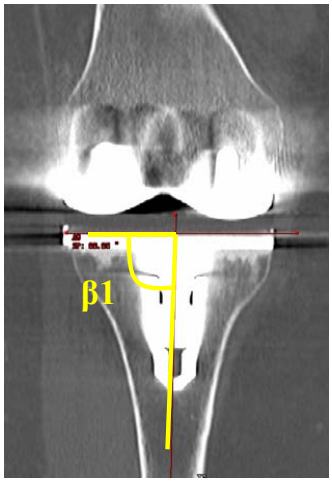


1 2 3

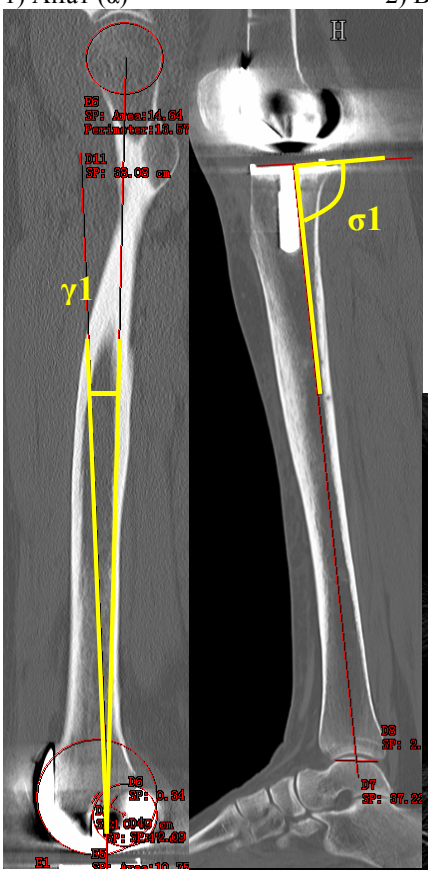
Figure D. Centre of the ankle in coronal (1), sagittal (2) and axial (3) views.



1) Alfa1 (α)

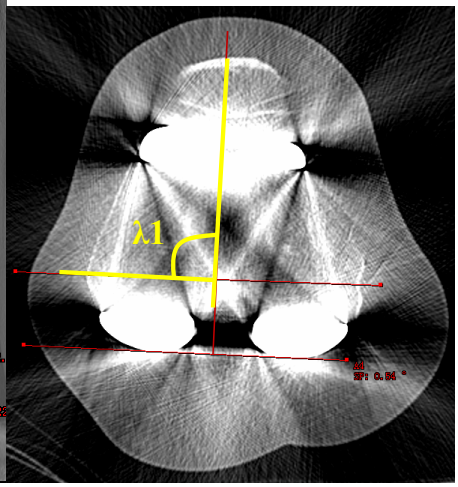


2) Beta1 (β)

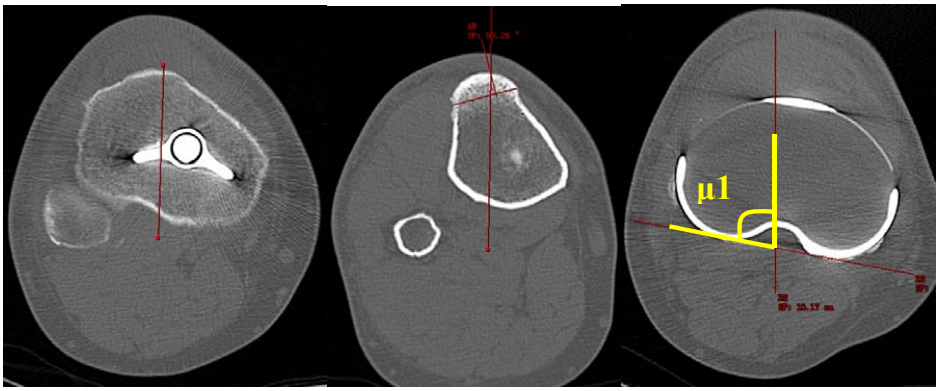


3) Gamma1 (γ)

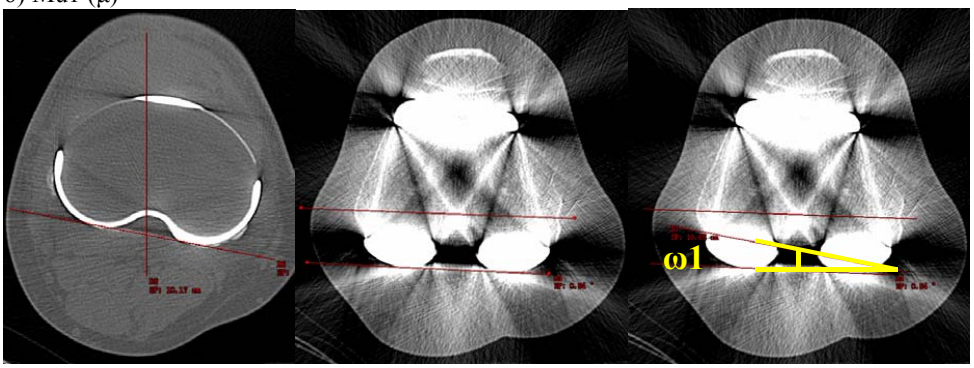
4) Sigma1 (σ)



5) Lamda1 (λ)



6) Mu1 (μ)



7) Omega1 (ω)

Figure E.1-7. Measuring the angles: alfa, beta, gamma, sigma, lambda, mu, and omega.

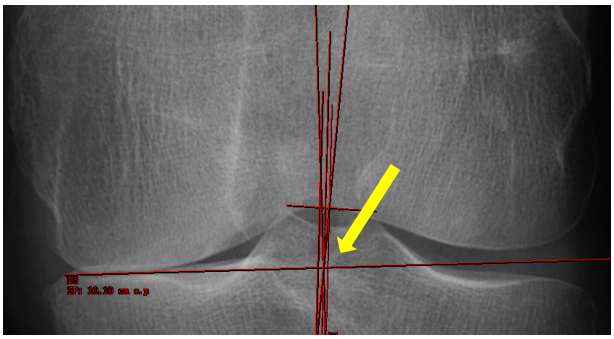


Figure F. Yellow arrow shows the centre of the native knee. A point between the centre of the femoral notch and the tibial spines is extrapolated perpendicularly down to the joint line.

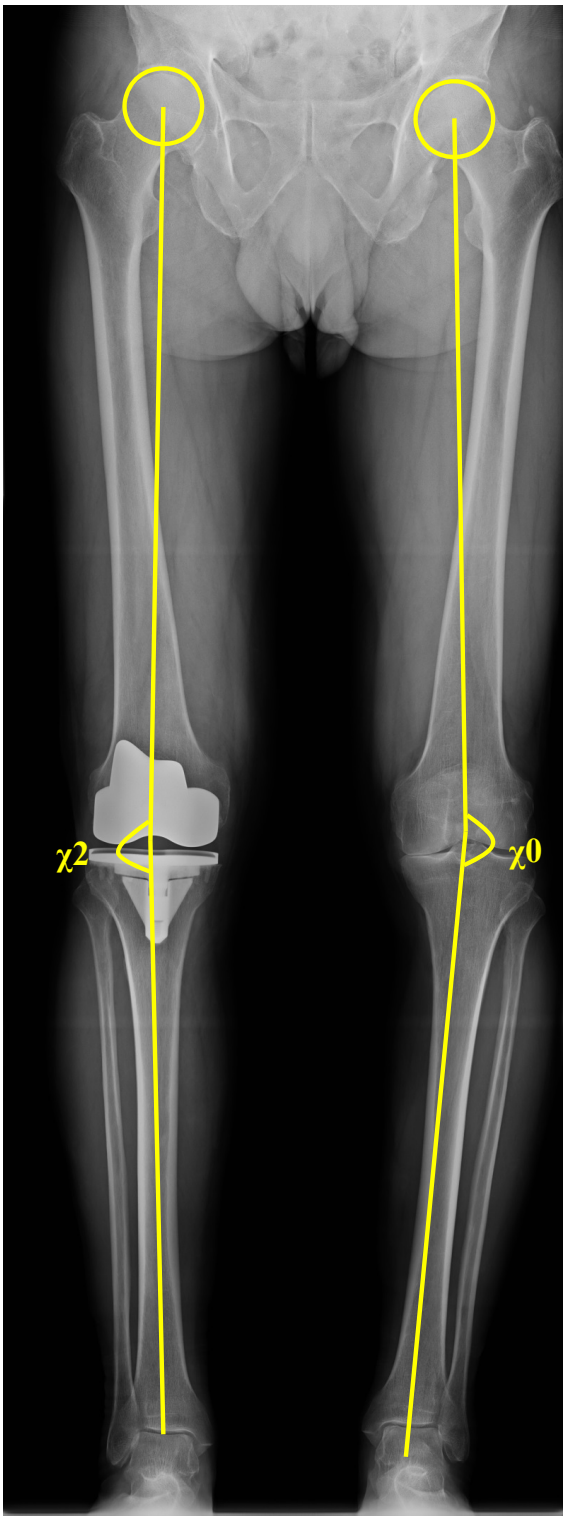
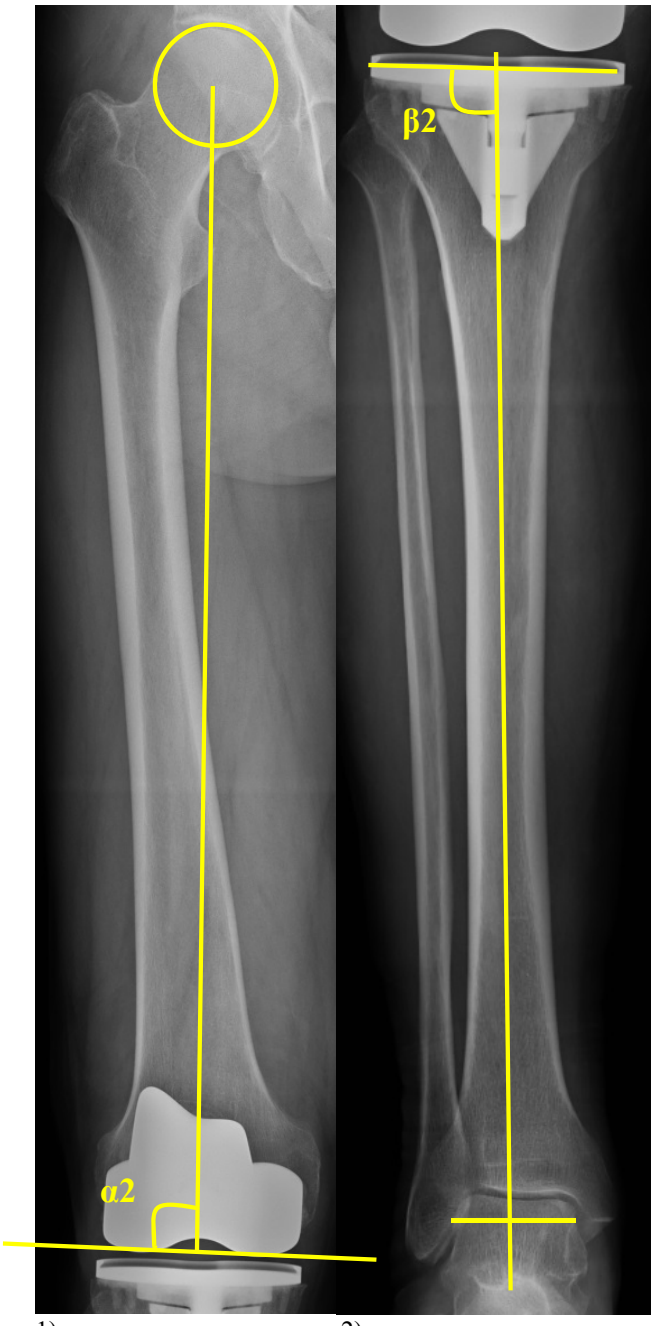


Figure G. The Hip-Knee-Ankle angle on full-length radiographs of a prosthetic knee ($\chi 2$) and a non-operated/native knee ($\chi 0$).



1) 2)

Figure H1-2. Alignment of the femoral component (α2) and the tibial component (β2) on full-length radiographs.

Reference List

(1) Chauhan SK, Clark GW, Lloyd S, Scott RG, Breidahl W, Sikorski JM. Computer-assisted total knee replacement. A controlled cadaver study using a multi-parameter quantitative CT assessment of alignment (the Perth CT Protocol). *J Bone Joint Surg Br* 2004; 86(6):818-823.

(2) Matziolis G, Krocker D, Weiss U, Tohtz S, Perka C. A prospective, randomized study of computer-assisted and conventional total knee arthroplasty. Three-dimensional evaluation of implant alignment and rotation. *J Bone Joint Surg Am* 2007; 89(2):236-243.

(3) Paley D, Herzenberg JE, Tetsworth K, McKie J, Bhave A. Deformity planning for frontal and sagittal plane corrective osteotomies. *Orthop Clin North Am* 1994; 25(3):425-465.

(4) Paley D, Pfeil J. [Principles of deformity correction around the knee]. *Orthopade* 2000; 29(1):18-38.

(5) Moreland JR, Bassett LW, Hanker GJ. Radiographic analysis of the axial alignment of the lower extremity. *J Bone Joint Surg Am* 1987; 69(5):745-749.

(6) The influence of femoral component position and tibial posterior slope on knee stability and range of motion after total knee arthroplasty. 70th Annual Meeting American Academy of Orthopaedic Surgeons; 03 Feb 13; 2003.

Randomization procedure

Patients are randomly parallel-group assigned to CAS or CONV (allocation ratio 1:1).

Separate randomization lists are created for each surgeon participating in the study using the statistical software PASW Statistics v 19 (IBM SPSS, Armonk, New York).

Block randomization with randomly varying block sizes of 2 and 4 is generated to achieve approximate equal numbers in the treatment groups at all times.

A central randomization office performs computer-generated allocation to trial group, with concealment by identical, opaque, sequentially numbered, sealed envelopes.

An investigator with no clinical involvement in the trial performs the randomization, and sequentially numbered envelopes are sent to an independent local contact/research assistant.

Initially 10 envelopes per surgeon are sent to the research assistant at the hospital.

The research assistant orders 10 more envelopes when needed, from the central randomization office.

When a patient has given consent to participate in the trial, the research assistant is given notice.

The envelope is opened as close to the operation as possible (normally the day before surgery), by the research assistant, who informs the surgeon about the result of the allocation assignment.

The randomization form is dated and the name of the patient is written on the form before filing.

A 4-digit number is given to all patients:

The first digit refers to the hospital; Haugesund (1), Haukeland (2) and Lovisenberg (3)

The second digit refers to the surgeon; Gøthesen (11), Luhr (12), Skredderstuen (21), Furnes (22), Hallan (23), Jacobsen (24), Petursson (31), Uppheim (32), Jervidalo (33).

The two last digits refer to the patient; i.e. the third patient of Gøthesen's is number 1103 and the fourteenth patient is number 1114.

PASIENTSKJEMA;

Computernavigasjon vs konvensjonell metode v/TKA.

⇨ **Pasientnummer:…….**

⇨ **Fødselsdato:.....**

⇨ **Kjønn: Mann____Kvinne___**(sett kryss)

⇨ **Diagnose:**

1. Primær gonartrose
2. Sequele fraktur
3. RA
4. Psoriasis / Bechterev
5. Annet. Presiser:…….

⇨ **Side:** Hø
Ve

⇨ **Charnley klasse:**

A -Unilateral knelidelse
B -Bilateral knelidelse
C -Multippel leddlidelse eller annen sykdom som nedsetter gangfunksjonen

⇨ **Status i kontralaterale kne:**

1. Normal funksjon
2. Moderat nedsatt funksjon
3. Alvorlig nedsatt funksjon

⇨ **Tidligere inngrep i aktuelle kne:**

1. Åpen/Artroskopisk meniskreseksjon/debridement
   a. 0-1 år siden
   b. >1 år siden
2. Osteosyntese etter fraktur:
   a. Patella
   b. Femur
   c. Tibia
   d. Kombinasjon av ovennevnte
3. Artroskopisk båndoperasjon
   a. ACL
   b. Annet (inkl pcl, mcl, lcl, menisksutur etc)

⇨ **Tidligere sykdommer:**

1. DVT i aktuelle underekstremitet
2. DVT i kontralaterale underekstremitet
3. Lungeemboli
4. Hjerteinfarkt
5. Atrieflimmer/flutter
6. Annen hjerterytmeforstyrrelse
7. Hjerteklaff-sykdom
8. TIA
9. Sequele etter hjerneslag/hjerneblødning
10. Revmatoid artritt
11. Psoriasis artritt
12. Polyartritt

⇨ **Allergier: penicillinallergi: Ja___Nei___**

⇨ **Medikamenter:**

Medikament	Dose (vedlikeholds-)	Sluttdato preop	Gjenoppstarts -dato postop	Pågående (ikke seponert preop – sett kryss)
1. Marevan	mg pr uke			
2. Albyl-E	mg pr dag			
3. Plavix	mg pr dag			
4. Ticlid	mg pr dag			
5. Persantin	mg pr dag			
6. **Annet antitrombotikum**	mg pr dag			

⇨ **Høyde (cm):_____**

⇨ **Vekt (kg):_____**

⇨ **Blodprøver:**

Preoperativt: Hb_____
Hct____
Postoperativt dag 2-3: Hb_____
Hct____

⇨ **Transfusjoner (totalt antall enheter a 250ml):_____**

⇨ **Operasjonsdato:**

⇨ **Operatør:**

⇨ **Blodtomhetstid (min):_____**

⇨ **Knivtid (min):_____**

⇨ **Anestesitype/postop sm.regime:**

1. **Spinal/epidural**
2. **Narkose/annet**

⇨ **Komplikasjoner/bivirkninger:**

1. Dyp infeksjon
2. DVT
3. Lungeemboli
4. Hjerteinfarkt
5. Hjerneslag
6. Fraktur
7. Utstyrssvikt (spesifiser!)
8. Annet

Signatur, ansvarlig lege……

Dato:……