

Fracture of the proximal humerus

A randomized study of two surgical treatments:
Reverse Total Shoulder Arthroplasty
versus
angular stable device Philos

The DELPHI- trial

Othopaedic Department
Trauma
Oslo University Hospital

Tore Fjalestad
MD PhD



Fractures of the Proximal Humerus

Global perspective



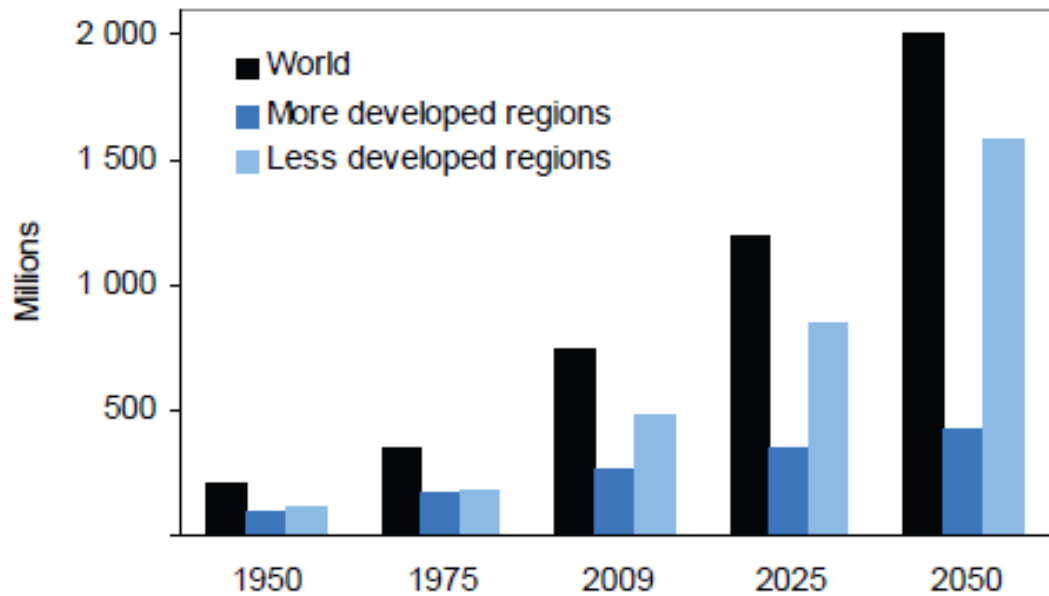
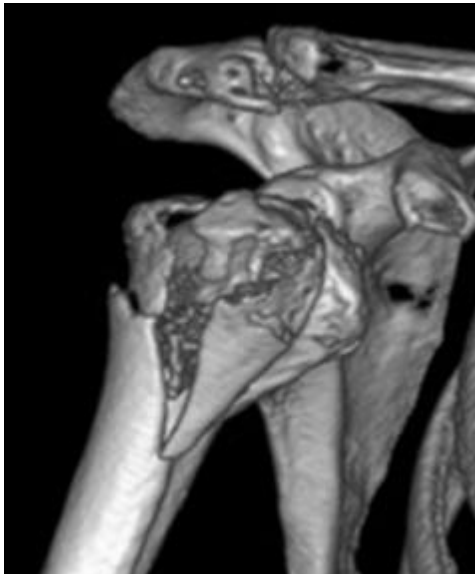
Proximal Humeral Fractures

EPIDEMIOLOGY

- ❑ 10% of all fractures
- ❑ 30% of fractures in patients > Age 60

UN Population Division 2009

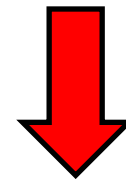
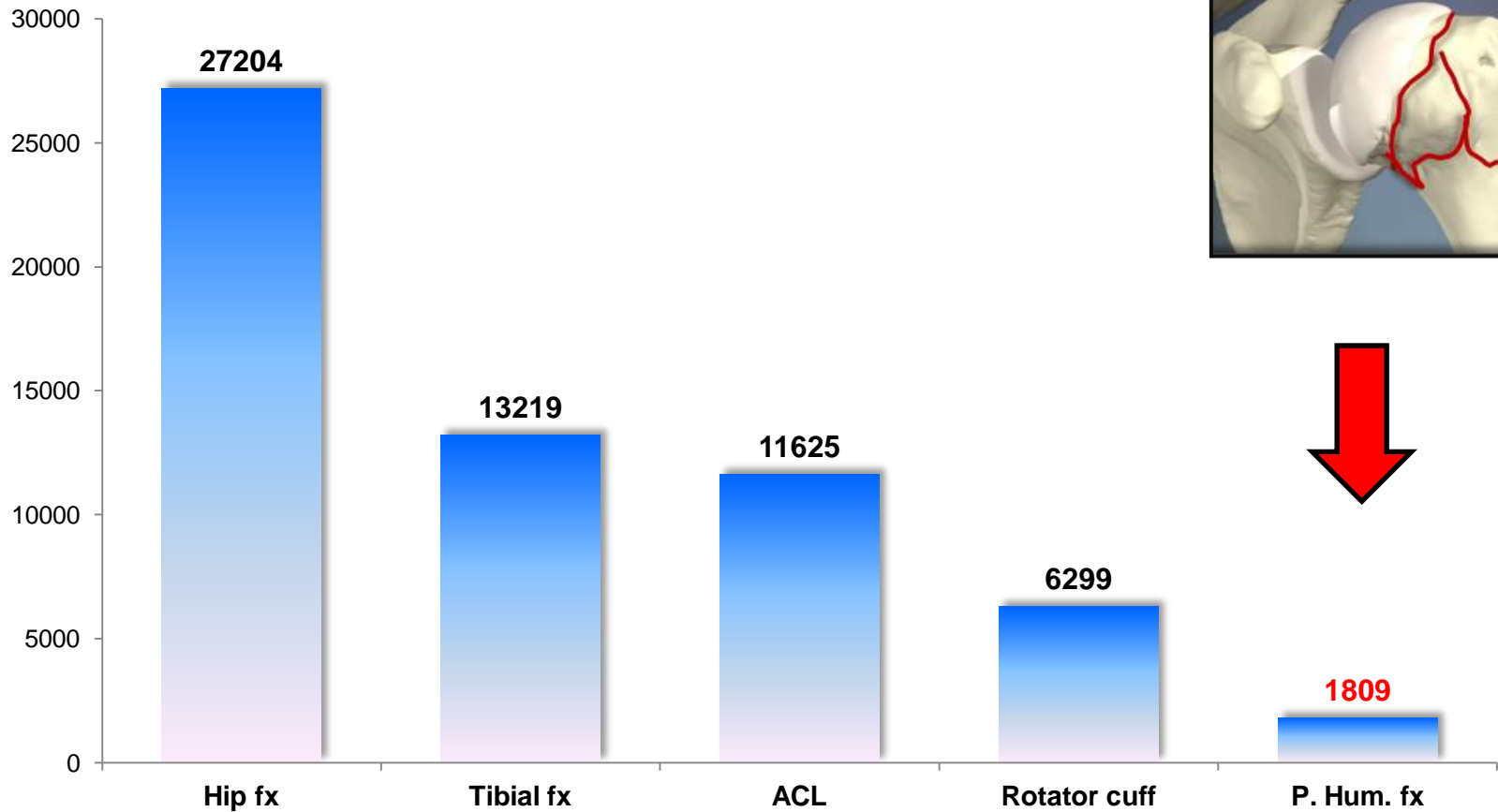
Population age > 60 during 1950 – 2050 ►



Fractures of the Proximal Humerus

PubMed 2011

Number of publications May 2011



COCHRANE CONCLUSIONS

There is an urgent need to define more clearly the role and type of surgical intervention in the management of proximal humeral fracture.

Cochrane Recommendations

Any trials must take account of the important issues of method of randomisation, blinding and duration of follow up. Such trials should use

- standard and validated outcome measures
- patient assessed functional outcomes
- resource implications

Fracture of the Proximal Humerus

COCHRANE Last updated 2010

TYPES OF STUDIES

- Conservative vs. conservative
- Conservative vs. surgery
- Surgery vs. surgery



THE COCHRANE
COLLABORATION®

| | Adequati | Allocatio | Blinding' | Blinding' | Incomple | Incomple | Free of s | Balance | Free from |
|--------------------|----------|-----------|-----------|-----------|----------|----------|-----------|---------|-----------|
| Agorastides 2007 | ? | ? | ? | ? | - | - | - | ? | ? |
| Bertoft 1984 | + | + | ? | + | ? | + | ? | ? | + |
| Fialka 2008 | ? | ? | - | ? | - | ? | ? | ? | + |
| Fjalestad 2010 | + | + | - | ? | + | + | ? | ? | + |
| Hodgson 2003 | ? | + | ? | ? | + | + | ? | ? | + |
| Hoellen 1997 | ? | ? | - | ? | - | ? | - | ? | ? |
| Kristiansen 1988 | ? | ? | - | ? | - | + | ? | + | ? |
| Kristiansen 1989 | ? | ? | ? | ? | - | - | ? | ? | ? |
| Lefevre-Colau 2007 | + | + | ? | ? | ? | ? | ? | + | + |
| Livesley 1992 | ? | + | + | ? | - | ? | - | ? | ? |
| Lundberg 1979 | ? | ? | - | ? | ? | ? | ? | + | + |
| Revay 1992 | ? | ? | ? | ? | - | ? | ? | ? | ? |
| Rommens 1993 | - | - | - | ? | ? | ? | ? | ? | ? |
| Stableforth 1984 | ? | ? | - | ? | - | ? | ? | ? | ? |
| Wirbel 1999 | ? | ? | - | ? | - | ? | ? | + | + |
| Zyto 1997 | ? | ? | - | ? | ? | - | - | + | + |

Fracture of the Proximal Humerus

Is surgical treatment better?

Surgical Treatment With an Angular Stable Plate for Complex Displaced Proximal Humeral Fractures in Elderly Patients: A Randomized Controlled Trial

Tore Fjalestad, MD, Margrethe Ø. Hole, PT,† Inger Anette Hynås Hovden, MD,‡
Judith Blücher, MD,§ and Knut Strømsøe, MD, PhD**



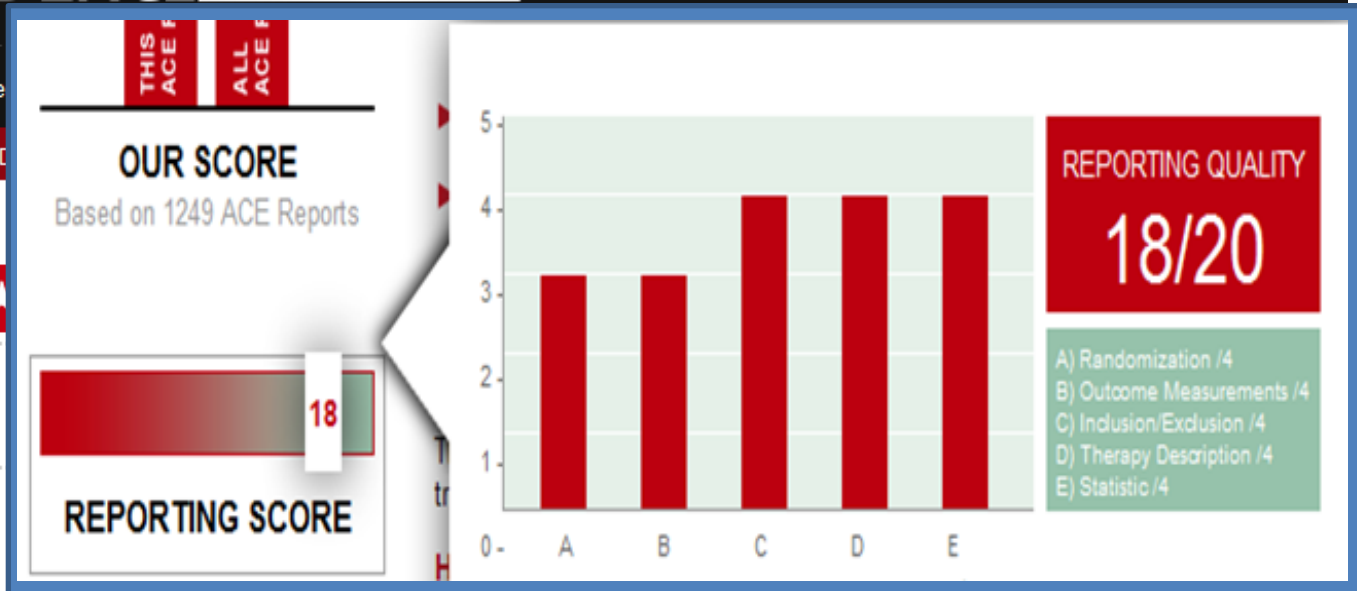
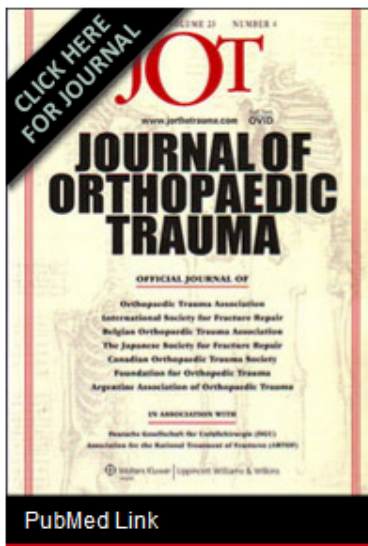
Fracture of the Proximal Humerus

REPORTING SCORE

OE ORTHOEVIDENCE™ EVIDENCE THAT MATTERS

me | ACE Reports | Video

OE ACE REPORT



Synopsis

50 elderly patients (>60 years) with displaced three or four part proximal humeral fractures were enrolled in this randomized clinical trial to compare fixation methods for humeral fractures in the elderly. Patients were randomized to fixation either surgically, using an angular stable implant, or a conservative approach. The results at 1 year follow-up indicate that functional results were similar between the surgical and conservative groups. Patient self-assessment was also similar between these groups at final follow-up, while radiographic outcomes were significantly better in the patients that underwent surgical reduction.

Funding: Non-Industry funded

Sponsor: Helse Sor-Ost

Conflicts: None disclosed



Fracture of the Proximal Humerus

www.clinicaltrials.gov

ClinicalTrials.gov
Protocol Registration System



Protocol Registration Receipt

01/12/2013

Displaced Proximal Humeral Fractures: Reversed Total Shoulder Arthroplasty or
Angular Stable Plate?

This study is currently recruiting participants.

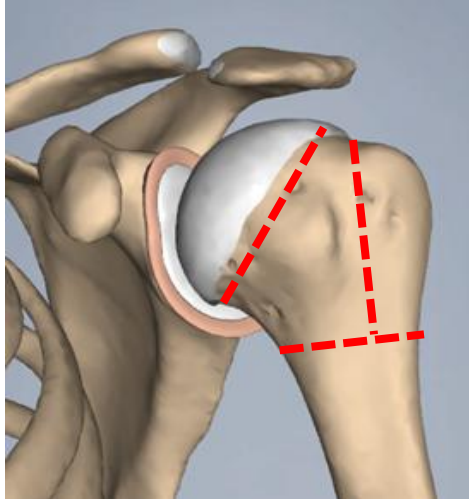
Verified by Tore Fjalestad, Oslo University Hospital, January 2013

| | |
|----------------|--|
| Sponsor: | Oslo University Hospital |
| Collaborators: | Sykehuset Telemark Sykehuset Asker og Baerum Sykehuset Ostfold Helse Førde Sykehuset i Vestfold HF |



Fractures of the Proximal Humerus

Fracture types



Fracture and Dislocation Classification Compendium - 2007

*Orthopaedic Trauma Association
Classification, Database and Outcomes Committee*



Fractures of the Proximal Humerus

AO / OTA classification 1990 / 2007

Type A

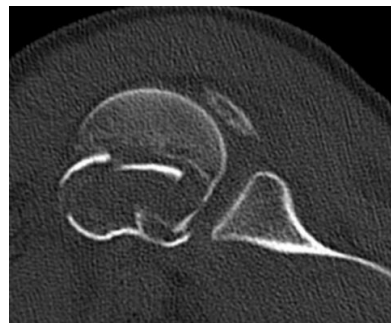
Extra articular
2 part

Type B

Extra articular
3 or more parts

Type C

Intra articular



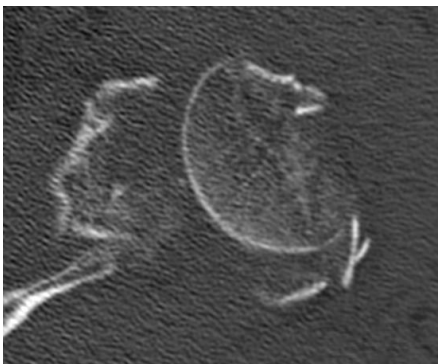
| | | | | |
|-------------------------------------|--|---|---|-------------|
| Unifocal extra-articular | 11-A1 tuberosity | 11-A2 impacted metaphyseal | 11-A3 non-impacted metaphyseal | |
| Bifocal extra-articular | 11-B1 with metaphyseal impaction | 11-B2 without metaphyseal impaction | 11-B3 with glenohumeral dislocation | 20 % |
| Bifocal | 11-C1 with slight displacement | 11-C2 impacted with marked displacement | 11-C3 dislocated | |

Fractures of the proximal humerus

Control Group



Patient nr. 2



60 patients

Open reduction and Philos +
tread cerclages to secure the tubercles

Fracture of the Proximal Humerus

SURGICAL OPTIONS

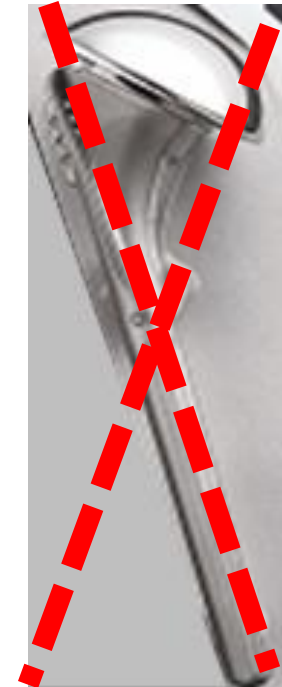
Do Reverse Prothesis give a better functional outcome than ORIF ?



Philos angular stable implant



Reverse Total Shoulder Arthroplasty

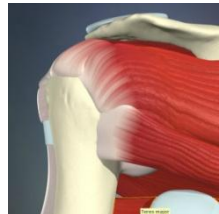


Hemiprosthesis

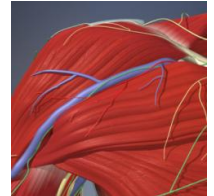
Fracture of the Proximal Humerus

Pro et contra RTSA

- ✓ In total 20.000 RTSA during 20 years
- ✓ Indications: Cuff arthropathy, Revision of anatomical prosthesis
- ✓ "Better outcome than hemiarthroplasty"
- ✓ Age limit 70 years? But PHF different from Cuff arthropathy



| The elderly patient with an acute PHF | | |
|---------------------------------------|-------------------------------|--|
| Prosthesis | Hemiprosthesis | RTSA |
| Depends on | Rotator cuff | Deltoid muscle |
| Healing of tubercles | Critical | Optimal results |
| Problem | Not proven better than Philos | Deltoid "fatigue" Scapular notching |
| Revisjon / CS <30 | | Expected at 9-10 yrs |
| Funksjon | 40-50% poor | More predictable |
| Evidence | Level 1- 4 | Level 3-4 |



Fractures of the proximal humerus

Level III evidence RTSA

Study details

Garrigues G. E., Johnston P. S., Pepe M. D., Tucker B. S., Ramsey M. L., Austin L. S.

Hemiarthroplasty versus reverse total shoulder arthroplasty for acute proximal humerus fractures in elderly patients

Orthopedics, 2012;(35):e703-8

[This study in Medline](#)

| | | |
|---|---|----------------------------------|
| Study Type: Therapy | Study Design: Cohort study | Class of Evidence: III |
| Purpose: To investigate whether reverse total shoulder arthroplasty provides improved functional outcomes compared with hemiarthroplasty for fractures in elderly patients. | | |
| P Patients | Acute proximal humerus fractures (N = 23, elderly) | |
| I Intervention | Reverse total shoulder arthroplasty (n = 11) | |
| C Control | Hemiarthroplasty (n = 12) | |
| O Outcome | American Shoulder and Elbow Society score, University of Pennsylvania shoulder score, and Single Assessment Numerical Evaluation score, forward flexion | |

Results:

- Reverse total shoulder arthroplasty outperformed hemiarthroplasty with regard to all outcomes measures assessed

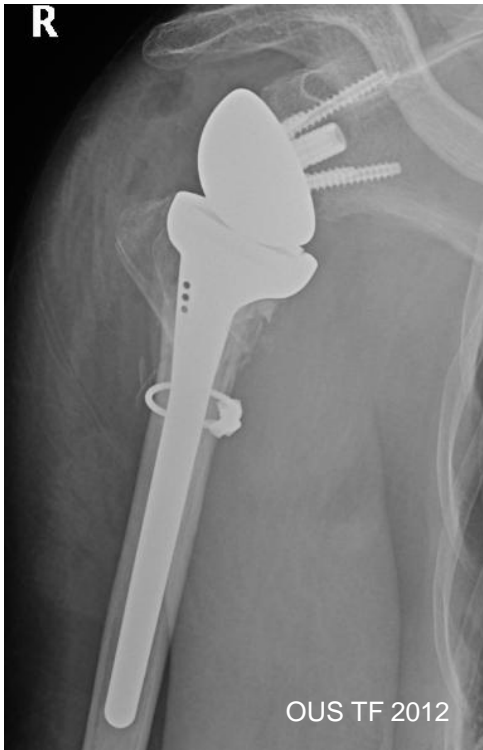
AUTHOR'S CONCLUSION:

Reverse total shoulder arthroplasty is a reliable option for acute proximal humerus fractures that are not amenable to closed treatment or reconstruction in elderly patients. Improved functional outcomes when compared with hemiarthroplasty must be balanced against the increased cost and limited life expectancy of patients with this injury.



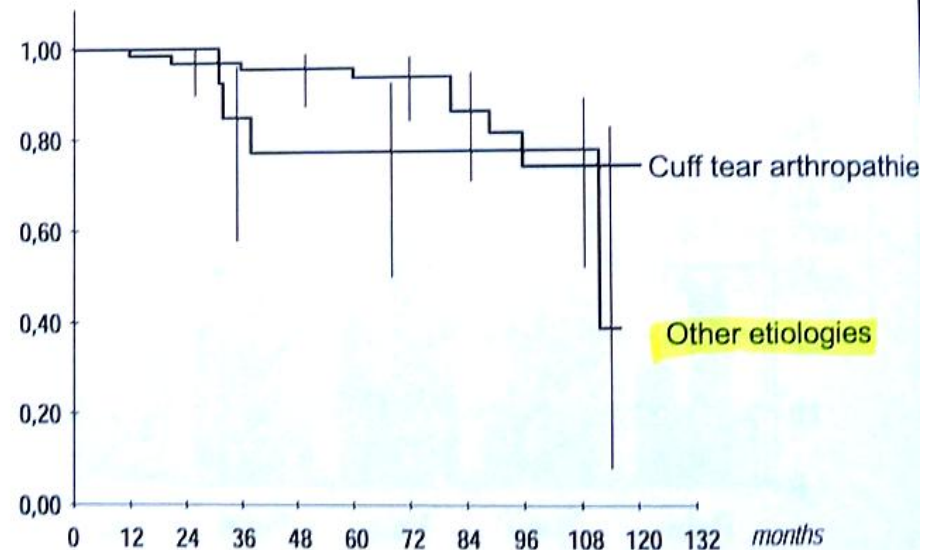
Fractures of the proximal humerus

Survival RTSA



Long term results Reverse TSA

Survivorship (Kaplan-Meier) - Failure = Revision or C.S. < 30



8th Biennial AAOS/ASES Shoulder and Elbow: Current Techniques and Controversies



Results and Complications of Reverse TSA
Iannotti JP, Madden M, Cleveland Clinic
ASES may 2012

OUTCOMES

Primary outcome

Constant score

"Blinded" physiotherapists
Problems Sensitivity, Validity, ...

Secondary outcomes

Oxford Shoulder score

Shoulder specific self assessment

15D score

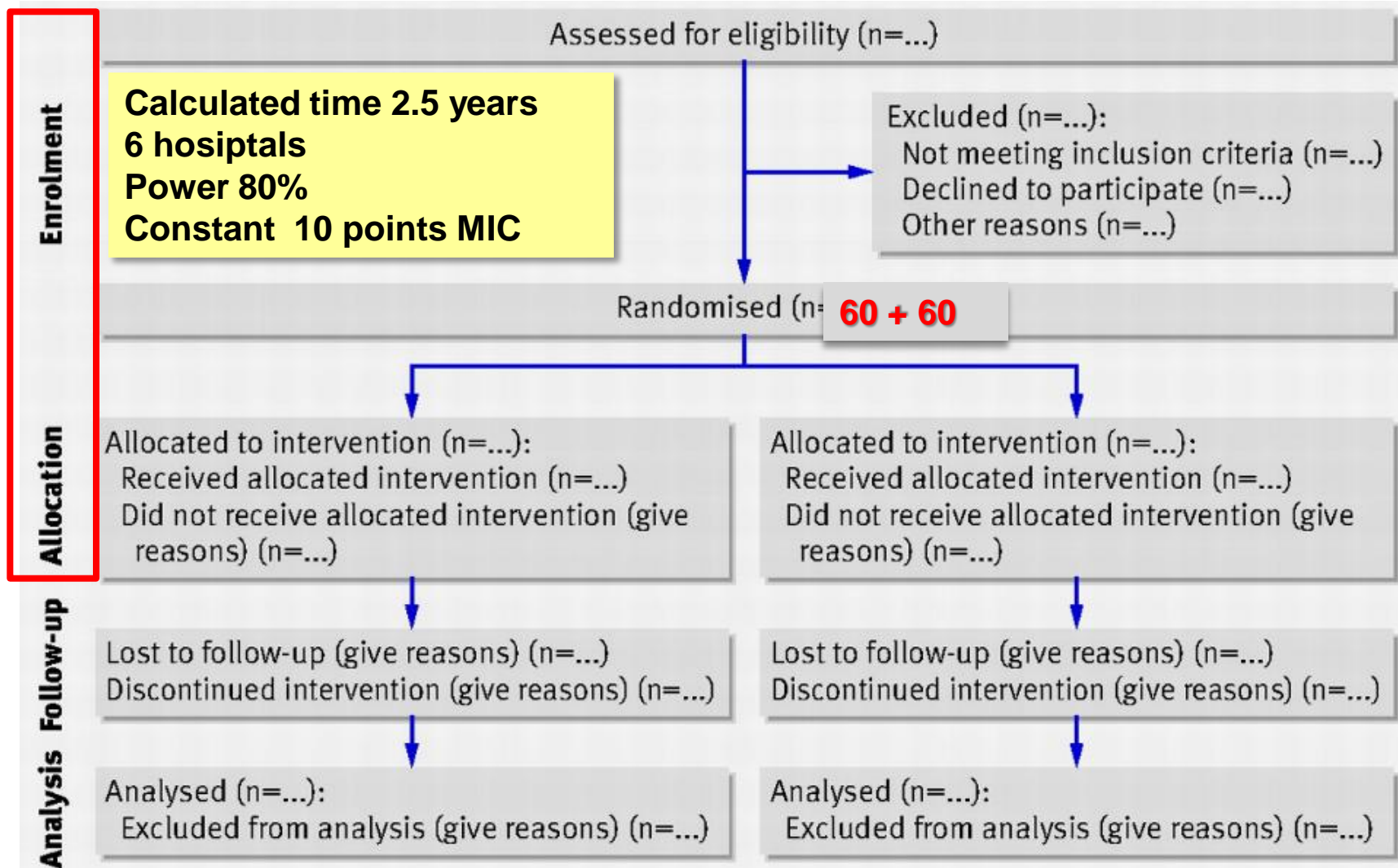
Quality of Life - generic
→ Calculation of QALY's

Economic Evaluation

Radiographic Evaluation

Fractures of the Proximal Humerus

The revised **CONSORT** statement. Altman et al 2010



Fractures of the Proximal Humerus

<http://www.oslo-universitetssykehus.no>

The screenshot shows the homepage of Oslo University Hospital. At the top left is the logo with the text "Oslo universitetssykehus". To the right, there are links for "English", "Kontakt oss", and font size adjusters. Below the logo is a navigation menu with "Aktuelt" (highlighted with a red box), "Pasient", "Fag", "Jobbsøk", "Media", and "Om oss". A search bar with a "Søk" button is also highlighted with a red box. The main content area features a large image of a woman and a baby. To the right are buttons for "Pasientrettigheter", "Helsenorge.no", "Behandling", and "Kvalitet". Below this is a section for "Sykehusoppholdet" and "Sykdom og behandling". The "Sykdom og behandling" section includes an illustration of a family and a list of medical conditions: "Hjerte og blodårer", "Kreft", "Muskel og skjelett", "Nerver og hjerne", "Psykisk helse og avhengighet", "Svangerskap og fødsel", "Transplantasjon", and "Rehabilitering". A link "> Vis alle emner" is present. To the right of this section is a "Delta i forskning" section with a "Forskning" button (highlighted with a red box) and a "Raskere tilbake" link. At the bottom left, there are links for "Avdelinger" and "Aktuelle". At the bottom right, there is a "Siste nytt" section and a "Samhandling" button.



Klinisk studie: Brudd i overarmsbenet: Gir platefiksasjon eller protese best resultat?

Studiens hensikt er å finne ut hvilken av to etablerte behandlingsmetoder som gir best resultat ved komplekse brudd i øvre del av overarmen. Brudd i dette området er hyppige hos personer over 60 år, og utgjør en tredel av alle brudd hos eldre, mens bare hvert femte brudd er av kompleks type, det vil si et brudd som omfatter tre eller flere fragmenter, som alle er slått ut av stilling. Selv om slike brudd er vanlige, finnes det ikke dokumentasjon for hva slags behandling som er best (Cochrane).

Av Tore Fjalestad, overlege Ph.D., Oslo universitetssykehus

De ulike behandlingsmetodene er ikke-operativ, operativ med rekonstruksjon og fiksering av knokkelen eller erstatning av den ødelagte knokkelen med kunstig ledd (protese). I alle tilfelle vil fysioterapibehandling være viktig, og opptreningen tar regelmessig seks måneder eller mer.



Pasienter

Egentreningsprogram Plateopererte
Egentreningsprogram
Proteseopererte

Leger

Operasjonsteknisk - Gruppe 1:
Reverse protese
Operasjonsteknisk - Gruppe 2:
Osteosyntese Philos
Pasient samtykkeskjema
Studieprotokollen

Innlogging randomisering

Fysioterapeuter

Livskvalitet 15D
Testmetode Constant test
Testmetode Oxford skuldertest
Treningsregime Gruppe 1: Revers
protese
Økonomiskjema

Fractures of the Proximal Humerus

The web side DELPHI

Pasienter

Egentreningsprogram Plateopererte
Egentreningsprogram
Proteseopererte

Leger

Inklusjonskriterium
Operasjonsteknisk - Gruppe 1:
Reverse protese
Operasjonsteknisk - Gruppe 2:
Osteosyntese Philos
Pasient samtykkeskjema
Studieprotokollen
Undervisning for leger

Innlogging randomisering

Fysioterapeuter

Livskvalitet 15D
Testmetode Constant test
Testmetode Oxford skuldertest
Treningsregime Gruppe 1: Revers
protese
Treningsregime Gruppe 2:
Philosplate
Økonomiskjema

Retningslinjer

Retningslinjer for RCT-studier

Godkjenninger

Godkjenning ClinicalTrials.gov
Godkjenning REK Sør-Øst

Andre studier

ProFHER studien i England
AO Traumatoline. Oppdaterte artikler
om proximale humerus brudd
rangert etter evidensnivå
Litteratur review via AO- gruppen
Cochrane database: Proximal
Humeral Fractures 2010
Hele artikkelen
Interventions for treating proximal
humeral fractures in adults



Fractures of the proximal humerus

www. AO TRAUMALINE

AO Traumaline™

Filter studies

Search criteria:

426 titles found for **Recent clinical studies on proximal humerus fractures**

Search

Show all

| CoE | Authors | Year | Title |
|--------|---|------|---|
| I-II | Fjalestad T., Hole M. O., Hovden I. A., Blucher J., Stromsoe K. | 2012 | Surgical treatment with an angular stable plate for complex displaced proximal humeral fractures in elderly patients: a randomized controlled trial |
| I-II | Konrad G., Audige L., Lambert S., Hertel R., Sudkamp N. P. | 2012 | Similar outcomes for nail versus plate fixation of three-part proximal humeral fractures |
| II-III | Good D. W., Lui D. F., Leonard M., Morris S., McElwain J. P. | 2012 | Skype: a tool for functional assessment in orthopaedic research |
| III | Garrigues G. E., Johnston P. S., Pepe M. D., Tucker B. S., Ramsey M. L., Austin L. S. | 2012 | Hemiarthroplasty versus reverse total shoulder arthroplasty for acute proximal humerus fractures in elderly patients |
| IV | Aksu N., Karaca S., Kara A. N., Isiklar Z. U. | 2012 | Minimally invasive plate osteosynthesis (MIPO) in diaphyseal humerus and proximal humerus fractures |
| IV | Clement N. D., Aitken S., Duckworth A. D., McQueen M. M., Court-Brown C. M. | 2012 | Multiple fractures in the elderly |

Fractures of the proximal humerus

Online randomization by NTNU webCRF

 NTNU Norges teknisk-naturvitenskapelige universitet

Det medisinske fakultet > Institutt for kreftforskning og molekylær medisin

Komplekse proksimale humersubrudd, en randomisert studie

Tore Fjalestad, Oslo Universitetssykehus, Ullevål (100)

Log out →

Initial Page

Change password

Information

Stratifisering av pasienten / Stratification

Alle spørsmålene nedenfor må besvares. / All questions are mandatory.

1. * Senter

- Østfold, Fredrikstad, Ø1
- Vestfold, Tønsberg, V2
- Førde, F3
- Telemark, Skien, T4
- Bærum, B5
- Ullevål, U6
- x7
- x8

Randomiser / Randomize

Tilbakestill skjema / Reset

Fullfør senere / Stratify and Randomize later

If System Error, Print Screen and send image to Berit.Bjelkasen@ntnu.no | Last updated: 12.09.2012

Fractures of the proximal humerus

The right direction



TF 2012

Fractures of the proximal humerus

A possibly answer within 7 years



TF 2012