

PROSTHETIC SHOULDER REPLACEMENT FOR FRACTURE:

RESULTS OF THE MULTICENTRE STUDY

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INTRODUCTION:

Most surgeons would agree that shoulder replacement for fracture is probably the most technically demanding form of arthroplasty.

Most surgeons would also agree that patients who receive a shoulder prosthesis for fracture, often elderly and seen as emergencies, are the most difficult to trace and review in the framework of a clinical study.

The difficulty in following-up these "unfaithful" patients is explained by the fact that the functional result is often modest if not poor, and that these patients are not motivated to be followed-up by a surgical team that they often could not choose at the outset.

We must pay homage to the teams who made enormous efforts to trace and review these poorly motivated patients.

I – MATERIALS AND METHODS

All the cases of shoulder replacement for fracture of the proximal humerus performed between September 1991 and December 2000 were included.

A form specially adapted to fractures was created and sent to all the surgical teams. The forms were then collected until the 1st of February 2001 and were entered onto a database (Excel, Microsoft, USA). The results were analysed with the help of the statistical department of the University Hospital of Nice. (Dr STACCINI).

Three models of prosthesis were used during this period: Aequalis-Standard, Aequalis-Open and Aequalis-Fracture. **Tableau I** summarises the different series according to the implant use and the number of patients reviewed, as well as the patients revised after a shoulder replacement for fracture.

Table I: The different series / implants studied

Series / Implants	Years	N° of operations	N° of patients reviewed	Follow-up (min-max)	Review rate
Standard-Aequalis	1991-97	491	300	4 years (2-10)	61%
Open-Aequalis	1997-99	68	53	19 months	78%
Fracture-Aequalis	1999-2000	68	31	9 months	51%
Revision Surgery	1991-99	51	47	2 years	92%
Total		678	431		63,5%

In total out of 678 patients who received a shoulder prosthesis for fracture, 431 patients were reviewed clinically and radiologically. This corresponds to a review rate of 63,5%, which is

commendable, considering the difficulties of tracing and reviewing these patients. Of the 491 patients who received a Standard-Aequalis prosthesis, 31 patients had died et 160 patients lost to follow-up. In total, 300 patients who received a Standard-Aequalis for a fracture could be reviewed and X-rayed with a minimum of 2 years of follow-up (the average follow-up was 4 years, between 2 and 10 years), which corresponds to a follow-up rate of 61%. Nevertheless there were 406 patients for who complete pre-and per-operative records were available. These patients formed the basis of the epidemiological study. The two more recent implants, having a shorter follow-up, were studied separately and were not included in the epidemiological study. On the other hand, among 51 patients re-operated on following a prostheses implanted for fracture, 47 were reviewed with radiography to evaluate the result. There were 29 prostheses from the Aequalis series and 18 prostheses operated in other centers.

II – EPIDEMIOLOGY (N=406):

The epidemiological study was performed on 406 patients who received an Aequalis-standard prosthesis for whom we had complete pre-and per-operative records.

ξ Patients:

- The majority of patients were female: 75% (306 cases).
- The average age was 68 years (between 26 and 94 years), the women were older than the men (71 years versus 60 years)
- 80% of the patients were retired and only 4% were occupational injuries
- 6,5% were diabetic and 4% alcohol dependent.
- The proximal humeral fractures were caused by simple *trauma*. In 82% of the cases it followed a simple fall and in 10% of cases a motor vehicle accident.
- 11% of fractures were associated with another fracture of the upper limb and 6% were associated with a fracture of the lower limb, this supports the prevalence of osteoporosis in these elderly patients.
- 5% had associated neurological lesions (21 cases).

ξ Indications for surgery/ Fracture classification:

The fractures were classified according to the classification of Neer and the AO classification. We have divided the fractures into 5 groups

- Two- and three-part fractures
 - **Four-part fractures**
 - Two-and three-part fractures with dislocation
 - **Four-part fractures with dislocation**
 - Intra-articular fractures of the humeral head(“head-splitting”)
- | |
|-------------------------|
| 80 % (Neer) / 77 % (AO) |
|-------------------------|

Apart the “head-splitting” fractures which do not exist in the AO classification, the other 4 groups were found in equivalent proportions in the two classifications. Therefore we can say that although no perfect classification exists, both Neer’s classification and the AO classification allows reasonably accurate categorisation of proximal humeral fractures

We found that 80% were 4-part fractures with or without dislocation according to Neer’s classification, and 77% with the AO classification.

ξ Surgery:

- *the operative delay* averaged à 8 days (from 0 et 45 days)
- *the delto-pectoral approach* was used in 98% of cases
- *the fracture jig* was not used in 54% of cases
- *bone grafting* was only performed in 54% of cases
- *an acromioplasty* was performed in only 2% of cases and the *coraco-acromial ligament* was resected in 4%
- *a rotator cuff repair* was performed in 8,5%
- *a biceps tenodesis* was performed in 24% (this is probably an underestimation du to the fact that many tenodeses are semi-obligatory during the tuberosity fixation.)

ξ Post-operative:

- Immediate post-operative radiography: 49 % of tuberosity reductions were considered average or poor de by the surgeons themselves.
- *60% of patients were immobilised post-operatively*, most often in internal rotation (63,5%)
- *rehabilitation* was performed in a specialised centre in 64% of cases.
- *83% of patients underwent immediate passive mobilisation (Neer's "early passive motion")*.
- 5% of complications occurred immediately post-operatively with 8 neurological injuries (temporary in 6 cases) and 5 infections.

In summary, the epidemiology of this series is consistent with that found in the literature: the patients were elderly (71 years) women (75%) and osteoporotic (17% had associated bony lesions) who had a fall (82%), and who sustained a four-part fracture, with or without dislocation, in 8 out of 10 cases. In one half of the cases, the surgeon felt that, according to the post-operative X-ray, the reduction of the tuberosities onto the prosthesis was not satisfactory.

III - RESULTS OF THE STANDARD-AEQUALIS PROSTHESIS (N =300) :

The results of the Standard-Aequalis prosthesis were derived from 300 cases with between 2 to 10 years of follow-up (average = 4 years).

ξ Objective results according to the corrected Constant score:

Excellent (< 100):	19%	}	39%
Good (85 to 100):	20 %		
Average (65 to 85):	26 %	}	61%
Poor (< 65) :	35%		

ξ **Constant score at the last review :**

Pain (15 points) :	12
Activity (20 points) :	13
Mobility (40 points) :	22
Power (25 points) :	7
Absolute Constant =	54
Adjusted Constant =	73,5%

ξ **Articular Mobility :**

Active forward elevation :	103°
Passive forward elevation :	120°
Rotation external active (RE1) :	21°
Active internal rotation:	39°
External rotation in abduction (RE2):	39°

Functional results are consistent with the literature: at the last review, 19% of shoulders remained painful or very painful, and the average active forward elevation reached barely above the horizontal (103°)

ξ **Radiological results:**

35% initial malposition of the tuberosities
24% tuberosity migration

53% of the tuberosities were ununited or malunited

Radiological analysis allows the quantification of mistakes observed with the fixation and healing of the tuberosities: the tuberosities, initially malpositionned in one out of three (35%), migrate in a quarter of the cases (24%) and at the last radiographic review, they were ununited or malunited in half of the cases (53%) !

ξ **Subjective results:**

Very satisfied:	35.5%	}	80.5%
Satisfied:	45%		
Disappointed:	13%	}	19.5%
Dissatisfied:	6.5%		

We note the presence of a difference between the objective results (only 40% of good or excellent results) and the subjective results (80% of patients very satisfied or satisfied!). Undoubtedly, this is due to the fact that the functional demands of elderly patients are modest.

IV - COMPLICATIONS :

ξ **Per-operative complications: 3% (12 cases).** (n=406)

Among the per-operative complications there were 4 fractures, 3 injuries to the axillary artery and 2 neurological injuries.

ξ **Immediate post-operative complications: 5 % (21 cas)** (n=406)

These were neurological complications (1.9%) and infections (1.2%).

In all, 2 neurological complications were permanent (0,5%) and 6 were temporary complications.

ξ **Complications related to the tuberosities (n = 300):**

The late complications were dominated by malposition and migration of the tuberosities which leads to malunion and nonunion in half of the cases (**Table II and Figures 1,2,3**)

Table II: Radiological results of tuberosities with the Standard-Aequalis prosthesis

Standard-Aequalis Prosthesis	GREATER TUBEROSITY	LESSER TUBEROSITY	BOTH TUBEROSITIES
Initial Malposition	90 (30 %)	49 (16 %)	104 (35 %)
Migration	78 (26 %)	26 (9 %)	73 (24%)
Malunion + Nonunion	147 (49 %)	68 (23 %)	160 (53 %)

These tuberosity-related complications appear clinically as stiffness (8.3%), pseudo-paralytic shoulder (11%), reflex sympathetic dystrophy (5.3%), and dislocation (1.6%).

Figure 1 : Tuberosity Positioning, Migration and Healing

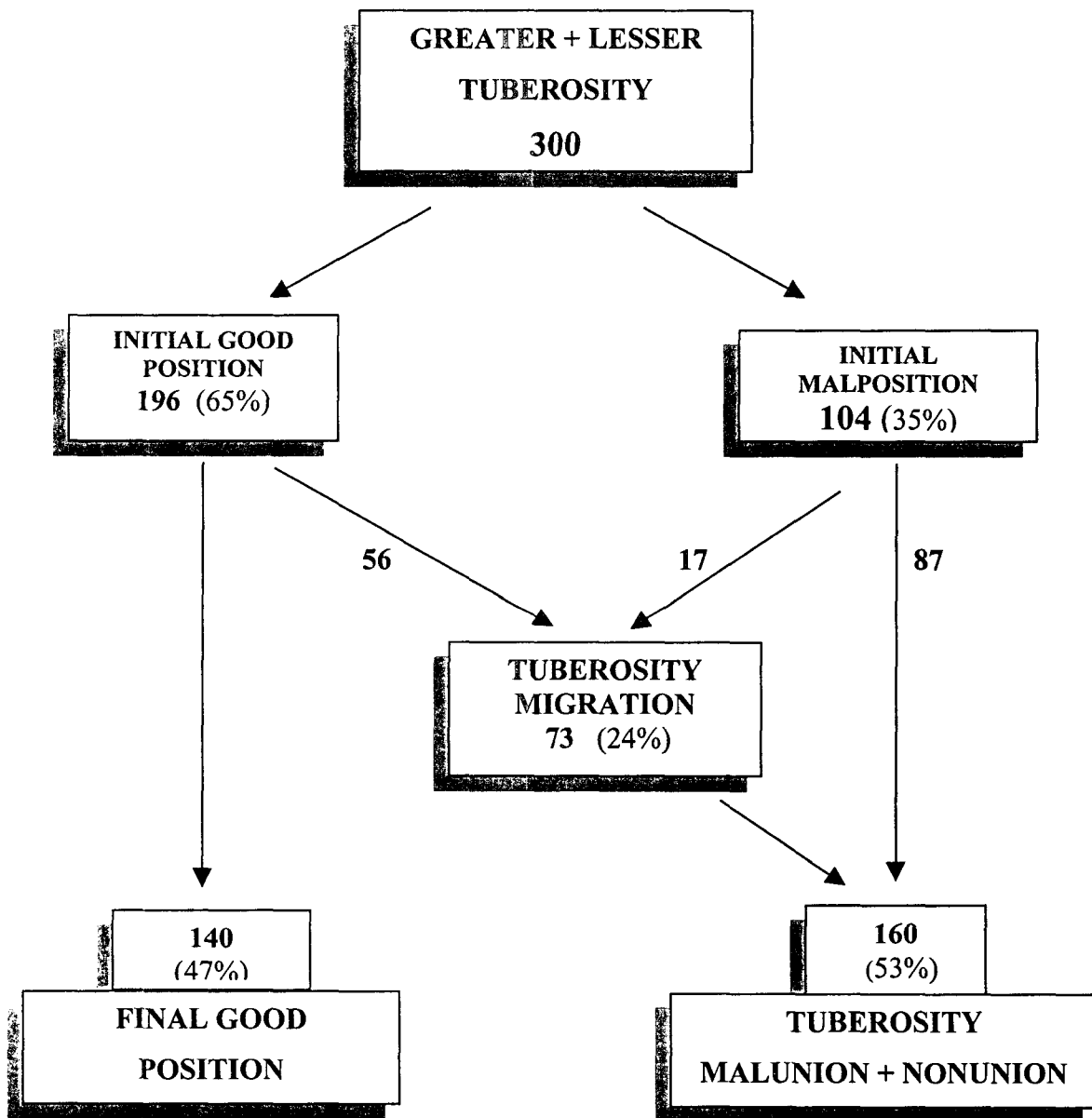


FIGURE 2 : Greater Tuberosity Positioning, Migration and Healing

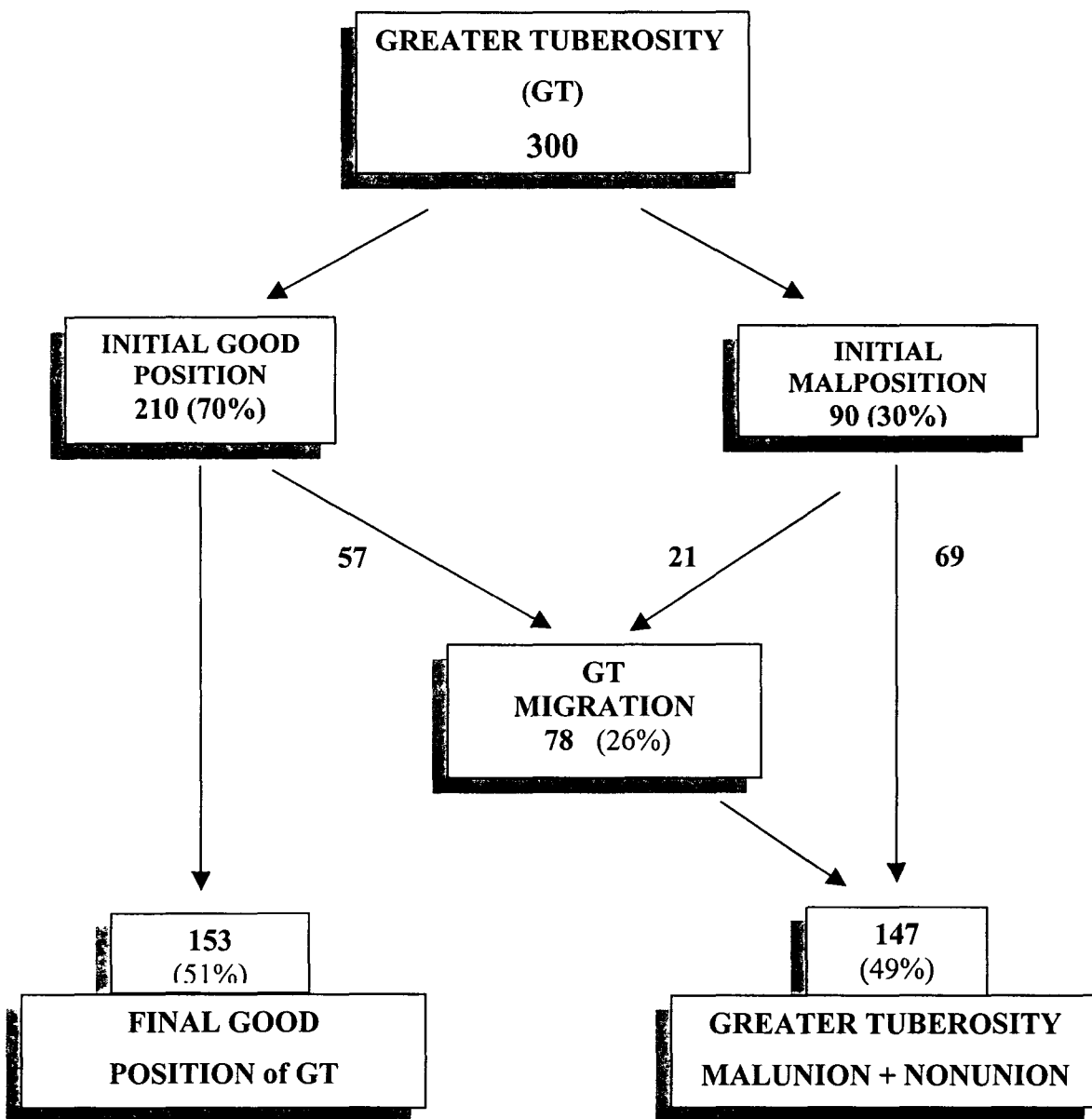
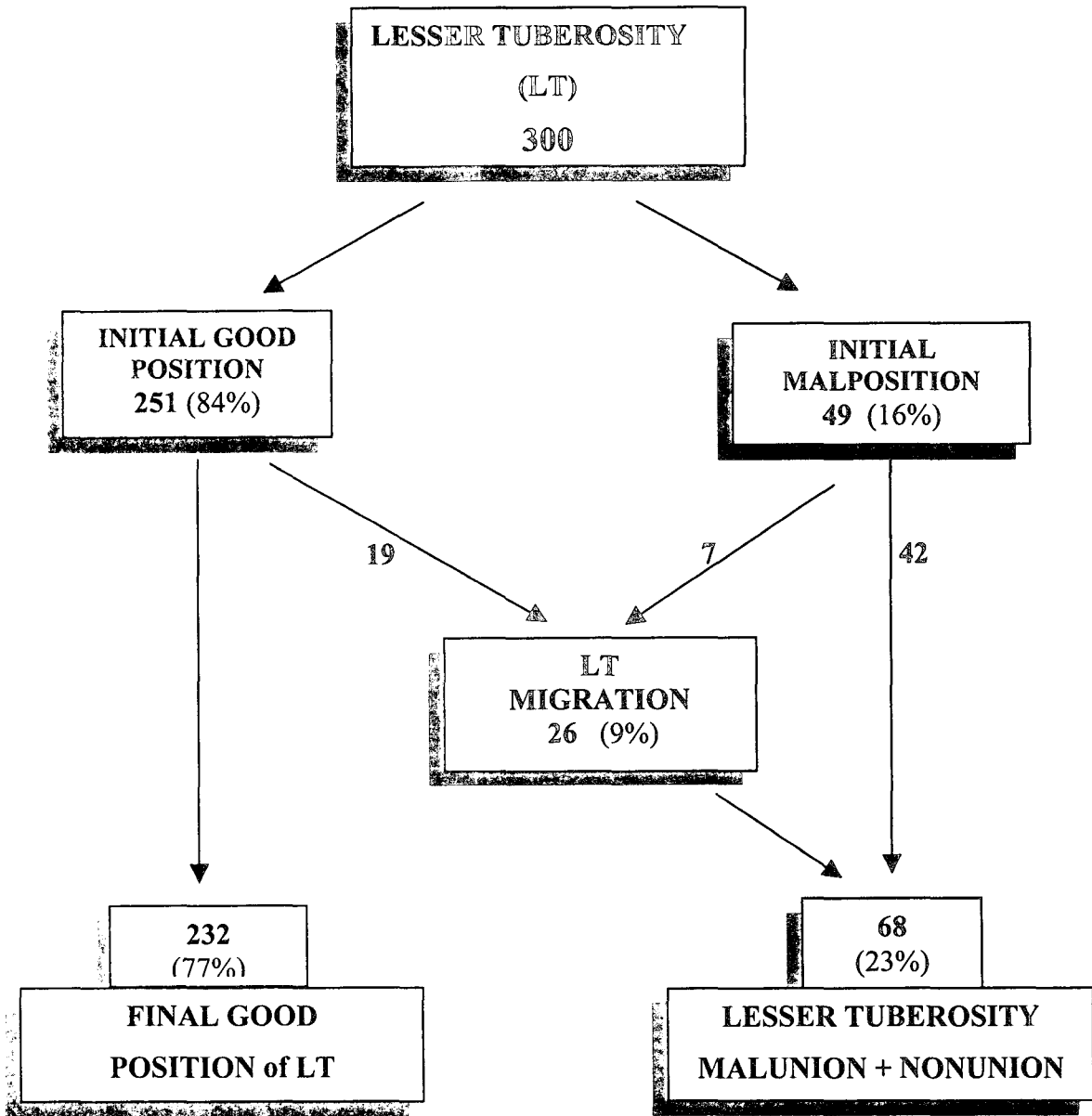


FIGURE 3 : Lesser Tuberosity Positioning, Migration and Healing



V - PROGNOSTICS FACTORS (N =300):

ξ Factors with no effect on the prognosis :

- *Age* does not seem to affect the result: nonetheless, there is a tendency to observe worse results in active forward elevation in patients over 75.
- *Sex* has no influence on the result. The result is not worse in women.
- *Operative delay* does not influence the result. The results are the same for those operated within the first 10 days or between the 10th and the 20th day.
- *The type of fracture* does not influence the result. It seems that the result is slightly worse for three-and four-part fracture-dislocations.
- *Tenodesis of the long head of the biceps* seems not to influence the result. This must be interpreted with care due to the number of cases where the long head of the biceps is tenodesed during suture fixation of the tuberosities.
- *Rotator cuff repair* has no influence on the result either.
- *Pre-operative medical conditions and diabetes in particular* did not seem to affect results.

ξ Factors with influence on the prognosis:

- *Malposition and/or migration, and malunion or nonunion of the tuberosities* are the worst prognostic factors ($p < 0.0001$)
- *Restoration of the height and retroversion* could be studied in 60 cases with scaled radiographs and CT scans. Height ($p < 0.03$) and retroversion ($p = 0.03$) appear to be important prognostic factors to be taken into account.
- *The use of the Fracture Jig* is evidently an important prognostic factor both for the Constant score ($p < 0.02$) and active elevation ($p = 0.04$).
- *Rehabilitation in a specialised centre* is a positive prognostic factor.
- *Immobilisation* also has a positive influence on the result ($p = 0.004$): Immobilised patients are two times less likely to suffer tuberosity migration than those mobilised immediately (14% versus 27%).
- *The type of immobilisation* does not influence the result. It does not seem to make a difference if the shoulder is immobilised in neutral rotation or internal rotation; this must be interpreted with caution due to the small number of cases immobilised in neutral rotation. On the other hand, immobilisation in abduction is less favourable than immobilisation at the side ($p = 0,001$). Immobilisation in abduction after a prosthesis for fracture worsens anterior instability already predisposed to by deltoid weakness. Anterior subluxation, by overstressing the fixation of the greater tuberosity, can lead to its migration.

In summary, three prognostic factors must be kept in mind:

- 1) Any complication with the tuberosities (initial malposition, migration, malunion, nonunion) is associated with a poor functional result.
- 2) Any malposition of the prosthesis is associated with tuberosity complications, and with a poor functional result
- 3) Patients who are not immobilised are two times more likely to suffer tuberosity migration than those mobilised immediately.

These three prognostic factors are under the surgeon's control!... This means that, if we can obtain an accurate positioning of both the prosthesis and the tuberosities, and if we immobilise the shoulder until healing of the tuberosities is obtained (i.e., abandon the concept of "early passive motion" for fractures), we can expect a good functional result. Immobilisation in neutral rotation seems to be the best compromise, placing a minimum of stresses on the greater tuberosity fixation.

VI - RESULTS OF THE AEQUALIS-OPEN AND AEQUALIS-FRACTURE PROSTHESES:

ξ **Functional Results** : Excluding the length of follow-up, the results of the two series are exactly comparable to the results of the Standard-Aequalis (**Table III**). The results of the Aequalis-Fracture prosthesis are tangibly better though the follow-up is shorter.

Table III: Functional results with the Aequalis-Open and Aequalis-Fracture Prostheses

	Aequalis-Open Prosthesis	Aequalis-Fracture Prosthesis
Number of cases reviewed	52	31
Follow-up	19 months	6 months
Pain	12	12
Activity	14	14
Range of motion	23	26
Power	5	6
Absolute Constant	54	58
Corrected Constant	71%	78%
Active Forward Elevation	105°	114°
Active External Rotation (ER1)	18°	25°

ξ **Anatomical results** : When we compare, the new implants with the Standard-Aequalis prosthesis, the anatomical results are, on the other hand, very different (**Table IV**).

Table IV: Tuberosity Malposition/Migration according to implant

	Aequalis-Standard Prosthesis	Aequalis-Open Prosthesis	Aequalis-Fracture Prosthesis
Number of cases reviewed	300	52	31
Initial malposition of the greater tuberosity	30%	24%	22%
Migration of the greater tuberosity	26%	13%	10%
Nonunion /Malunion of the greater tuberosity	49%	36%	25%

- The frequency of initial malposition of the greater tuberosity with the Standard-Aequalis prosthesis (30%) is explained by the design of this prosthesis which has an excess of

metal at its proximal part and an anterior fin which hinders the anatomical placement of the greater tuberosity. For the **Aequalis-Open prosthesis**, the initial malpositions (24%) can be explained by the persistence of the fin which, though windowed, remained in the way. For the **Aequalis-Fracture prosthesis**, the initial malpositions (22%) were partially due to the design of the prosthesis (which was very medialised), but more specifically to technical errors: lack of lateral bone graft, poor fixation technique.

- **The frequency of migration of the greater tuberosity** decreases from above 26% for the Standard-Aequalis prosthesis, to 13% for the Aequalis-Open prosthesis and 10% for the Aequalis-Fracture prosthesis.

- **The frequency of malunion and nonunion** equally decreases with time with 49% for the Standard-Aequalis prosthesis, 36% for the Aequalis-Open prosthesis and 25% for the Aequalis-Fracture prosthesis.

The explanations for persistent tuberosity migration, malunion and nonunion with the last prosthetic models are: (1) lack of bone graft; (2) breakage of sutures because of the rough surface of the prosthesis at the neck level

In summary, three points must be emphasized:

- 1) The Aequalis-Fracture prosthesis, which has been specifically designed for fractures, gives two times less tuberosity migration (10% versus 26%) and two times less tuberosity nonunion or malunion (25% versus 49%) than the standard model. This allows us to confirm that bony healing is obtained more consistently with the later prosthetic models.
- 2) Initial malposition (22%) and migration (10%) of the greater tuberosity were still a concern with the Aequalis-Fracture prosthesis. This has led us (1) to slightly modify the design of the Aequalis-Fracture, which is a little less medialised and has a polished neck to avoid breakage of sutures, and (2) to teach surgeons how to use the cancellous bone of the cephalic fragment to graft on the lateral part of the prosthesis and how to fix the tuberosities with the standardised technique that we have described
- 3) .The functional results with the Aequalis-Fracture prosthesis are not yet as good as expected. One explanations can be given: the follow-up is short (6 months) and it takes a little longer to regain motion when patients have been immobilised.

VII - RESULTS OF REVISION SURGERY

Re-operation was performed on average 2 years after primary surgery. Functional results are poor (**Table V**).

Tableau V : Functional Results after Revision

	Pre-op	At Review
Pain / 15 pts	5,2	9,5
Activity / 20 pts	6,8	10,2
Mobility / 40 pts	11,6	17,4
Strength / 25 pts	1,8	3,1
Absolute Constant Score	25,4	40,2

The revision procedures were varied and difficult to classify (Table VI).

Tableau VI : Functional results according to the type of revision/re-operation procedure.

REVISION / RÉOPÉRATION	Nb	Pre-op Constant Score	Post-op Constant Score
Reverse Prosthesis + Tuberosity Excision	6	25	43
Change Prosthesis + Tuberosity osteosynthesis <u>without</u> bone graft	6	17	29
Change Prosthesis + Tuberosity osteosynthesis <u>with</u> bone graft	8	22	50
Resection Arthroplasty (3) ; Arthrodesis (1)	4	14	30
Change Humeral stem for loosening	4	45	50
Conversion of Hemi in Total Arthroplasty	3	19	28
Arthrolysis (open : 7 ; arthroscopic : 3)	10	29	46
Synthesis of diaphyseal Fracture	4	10	42
Debridement for Infection	2	30	45
All Series	47	25	40

In summary, four points must be remembered:

- 1) The primary indication for revision surgery is presented by nonunion or malunion of the tuberosities in more than half of the cases (55% - 26 out of 47 cases).
- 2) When the procedure does not address the tuberosities, there is almost no gain and the score remains worse than the series as a whole (Constant score of 34 points).
- 3) The benefit afforded by the revision of a prosthesis implanted for fracture remains modest, as the score improves from a pre-operative 25 points to 40 points at review. This means that the decision of surgical revision must be taken with care and one must only re-operate only on patients who present with disabling pain. In fact, it is for pain that the intervention provides most benefit.
- 4) Two options are possible in case of revision surgery with prosthesis re-implantation :
 - Reverse prosthesis with excision of the tuberosities (in old patients-over 70 years, and/or advanced fatty degeneration of the cuff muscles-stage 3 or 4)
 - Aequalis-Fracture prosthesis with bone graft (in young patients-under 70 years, and/or without fatty degeneration of the cuff muscles-stage 1 or 2)

CONCLUSIONS:

1. Displaced fractures of the proximal humerus for which a shoulder prosthesis is indicated occur in elderly osteoporotic, female patients, who had a simple fall.
2. Functional results with the Standard-Aequalis prosthesis are still poor, and worse than those obtained in the degenerative and inflammatory conditions.
3. Complications and prognosis are dominated by the malposition and the migration of the tuberosities which lead to their malunion or nonunion. These complications with the tuberosities are under the surgeon's control: accurate positioning of both the prosthesis and the tuberosities in association with post-operative immobilisation of the shoulder until bony healing is obtained, reduce the number of tuberosity complications, and consequently improve the functional results.
4. The use of a prosthesis specially designed for fractures helps reduce, by a factor of two, the frequency of migration of the tuberosities compared with standard prosthesis as well as the frequency of nonunion or malunion.
5. Surgical revision produces variable and often disappointing results, and cannot be recommended apart from in cases of disabling pain and severe functional impairment.

THE KEY POINT IS THE GRATER TUBEROSITY!

THE KEY POINT IS THE SURGEON!