Benefit of an anatomical prosthesis designed specifically for cephalotuberosity fractures. Presentation of technical solutions to improve humerus consolidation and radiological and clinical analyses of the results.

Benefit of an anatomical prosthesis designed specifically for cephalotuberosity fractures.

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Introduction: In the treatment of complex cephalotuberosity fractures, hemiarthroplasty has an important role together with osteosynthesis and reversed prosthesis.
We sought to evaluate a new implant designed specifically for the treatment of cephalotuberosity fractures (Humelock®, FX Solutions).
Firstly we put together a working group in order to analyse the causes of failures in different types, and to propose technical solutions to enable the implant to be adjusted in height, and to improve the position and setting of the tuberosities. Once the anatomical study data had been validated, we then tried to test the hypothesis that these results were applicable and could be repeated using this implant in current clinical practice.

Equipment and method: An anatomical study was carried out on 11 cadavers so as to confirm the placement of the stem at a height, and the screw fastening of the stem. Next a multi-centred prospective non-randomized clinical study enabled us to analyse clinical and x-ray results for the implant in 30 subjects, this being 31 shoulders. Three groups were established in order to compare the different options offered by the implant.

Results: The anatomical and clinical data allowed us to confirm Murachowsky's data. All but one (undersized) of the stems, were fastened with screws in a perfectly stable way. In the hemiarthroplasty version, healing of the tuberosities in a good position was very clearly improved by the use of the Offset Modular System (OMS®) and specialized loop sutures, both being technical points found to be useful and effective by all clinicians.

Discussion: This prosthesis now forms an integral part of implants specifically for cephalotuberosity fractures. Two options allow for the top of the patient's humerus to be preserved if the vascularisation criteria permit, or to perform a hemiarthroplasty which would present a good outcome for fixing the tuberosities in a good position, for optimal shoulder function.

Introduction

Treatment of complex cephalotuberosity fractures in subjects under 70 years remains problematic. In fact, when the use of reversed prosthesis is contra-indicated, osteosynthesis may not always be a workable solution; either because of unfavourable cephalic vascularisation criteria*, or due to the complex shape of the fracture where a comminuted fracture does not allow a mechanically reliable traditional implant.

In 1970, Sir Charles Neer presented a series* of fractures treated with an anatomical prosthesis, with a rate of tuberosity fixation around the prosthesis of 95%. Since then, all teams, using increasingly sophisticated implants, have struggled to attain this level.

This study will present the technical solutions which we chose to simply optimize the height adjustment of the implant. We will also show the options chosen to stabilize the tuberosities, and the solutions introduced with the implant to improve their consolidation in an anatomical position.

Depending on the type of fracture, this original implant allows a choice of either a hybrid version such as "Bilboquet" according to the original concept designed by Doursounian* in 1990 and validated since then by numerous teams**, or a specific hemiathroplasty for fractures, with or without a tuberosity positioning support system (Offset Modular System®) as required by the case in hand.

We will be presenting a serie of clinical and x-ray results for the options chosen, with their respective rates of tuberosity consolidation in order to evaluate the benefit of innovative development in this very demanding area of surgery.

Equipment and Method

A preliminary anatomical study was made on 11 cadavers as well as a prospective multi-centred clinical study of the 31 cases.

The aims of the anatomical cadaver study were several: to control the mechanical reliability of the diaphyseal fixation, its safety with regard to neurovascular elements, and to check Murachowsky's data on the distance of the upper side of the pectoralis major - top of the humeral head.

The option chosen for pinning the height of the stem has been to fix directly onto the actual stem, in order to save time on what we considered to be the essential part, namely the synthesis of the tuberosities. The upper side of the clavicular fascicle of the pectoralis major is located and a test screw is placed to position the humeral head 5.5 centimetres from the pectoral marker. The primary fixing is carried out by means of a pin on the distal part of the stem, so as to be able to produce a primary tuberosity reduction on the test site, and to monitor the result with an x-ray image intensifier in neutral, internal and external rotation positions.

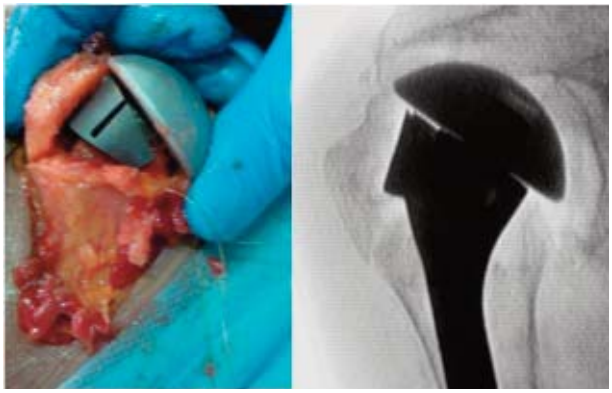
The prospective clinical study, carried out between 2009 and 2011, allowed us to clinically evaluate 30 patients, this being 31 cases, by measuring the range of articulation, scoring them as Constant and/or quick Dash, and by X-ray exam with an analysis of the position and consolidation of tuberosities around the implant, and whether or not loop sutures or OMS were used. All subjects had been treated with a fracture-specific stem, with diaphyseal fixation.

We also evaluated a tuberosity reinsertion technique using specific loop sutures in order to obtain a reliable attachment which could be repeated on any type of fracture. In addition we evaluated the mechanical benefit of an optional stem implant, the Offset Modular System® (OMS).

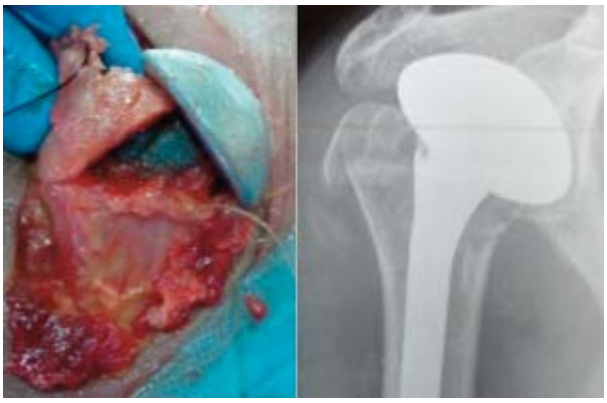
This is actually a focussed option which both facilitates positioning and fixing of tuberosities according to the amount of tuberosity remaining, and equally allows supply of cancellous graft from the humeral head to be in contact with the prosthesis.

Figure 1 : Offset Modular System

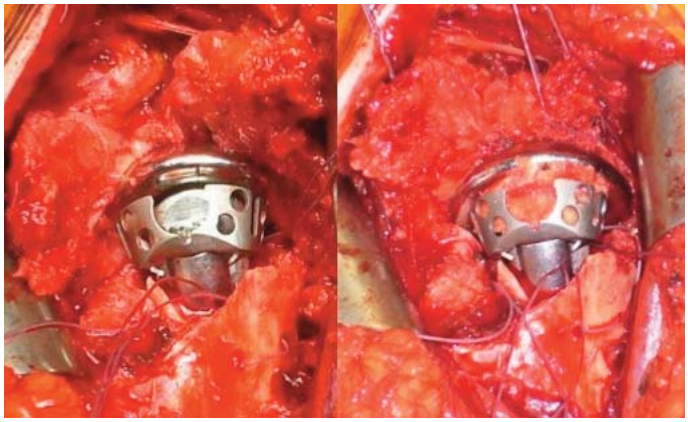
A: Presentation



B: Tuberosity with OMS



C: Tuberosity without OMS



D: OMS with graft

E: Anatomical consolidation of tuberosities

Three groups of patients were identified.
Group 1 consisted of patients initially presenting with a CT2 cephalotuberosity fracture according to Duparc classification* (4 fragments, valgus impacted humeral head) with favourable cephalic perfusion criteria, permitting preservation of the humeral head. These patients were given an anchor for the stem on the humeral head, with an anchoring plate, in line with the Bilboquet procedure described by Doursounian in 1990*.

Figure 2: Humelock with anchoring plate

Group 2 consisted of patients presenting with a CT3 or CT4 fracture according to Duparc classification, for whom we carried out a hemiarthroplasty, without OMS or use of loop sutures.

Group 3 consisted of the same type of patients as group 2 (CT3, CT4) but for whom the hemiarthroplasty was combined with OMS and loop sutures for positioning and anchoring the tuberosities.

Results:

The anatomical and clinical study allowed us to find a measurement top of the humeral head / pectoralis major of 5.5 cm +/- 5mm according to data in published literature, confirming the height adjustment tool perfected for this implant. The ancilliary of the double distal fixation allowed all the stems to be fixed securely except 1/32 cases, because of a manifest under-sizing of the stem compared with the diaphysis of the patient.
The anatomical study allowed us to show the mechanical benefit of the OMS in facilitating tuberosity positioning. (figure 2). This study has lead us to further refine the cage walls, to enable biological exchange around the prosthesis (figure 3).

The global series comprises 30 patients (31 shoulders) with an average age of 71 years (33-90) 7 of whom are men. According to Duparc classification, there are 8 CT2 fractures, 12 CT3 fractures and 11 CT4 fractures. The average follow-up is 17.6 months. 12patients had a follow-up over 2 years. The functional results of the global trials are shown in table 1. In this series there was 1 immediate post-traumatic plexus damage, due to the occurrence of a complex regional pain syndrome, which explains the worst result of the series. No infection or dislocation was observed afterwards. In one case, the tuberosities did not consolidate and in two others they disappeared over time although they were previously in the correct position. (secondary avascular necrosis).

Global study	Age	Fractures	Active ABD 6 months	Active AE 6 months	Int Rot active 6 months	Active RE1 6 months	Consolidation tuberosities	Position tuberosities
30 patients 31 shoulders 8 clinicians	71 years [33-90]	8CT2 12CT3 11CT4	96° [40-140]	117° [60-160]	20°	38° [20-55]	28/31 + 2/31 2nd weakening 1/31 pseudart	4/31 malpositioned

Table 1: Global study

We felt it was important to split into three groups in order to justify the technical choices for the placement of the most successful implant. Group 1: CT2 + anchoring plate
Group 2: CT3 or CT4 + hemiarthroplasty, no OMS or loop sutures
Group 3: CT3 or CT4 + hemiarthoplasty with OMS and loop sutures

The details of the 3 groups are shown in table 2.

Group	Age	Fractures	Active ABD 6 months	Active AE 6 months	Int Rot active 6 months	Active RE1 6 months	Consolidation tuberosities	Position tuberosities
Group 1 N=7 Follow-up 20 months	72 years [33-90]	7/7 CT2	92° [50-140]	114° [60-160]	20°	42° [30-50]	7/7+	1/7 malpositioned
Group 2 N=12 Follow-up 21 months	75 years [45-85]	1/12 CT2 5/12 CT3 6/12 CT4	87.5° [50-130]	112.5° [90-140]	20°	43° [40-55]	9/12 + 2/12 : 2nd weakening	5/12 low or malpositioned
Group 3 N=12 Follow-up 8 months	68.6 years [59-80]	7/12 CT3 5/12 CT4	110° [90-140]	126° [110-140]	30° [15-40]	27° [20-45]	all strong	all good position

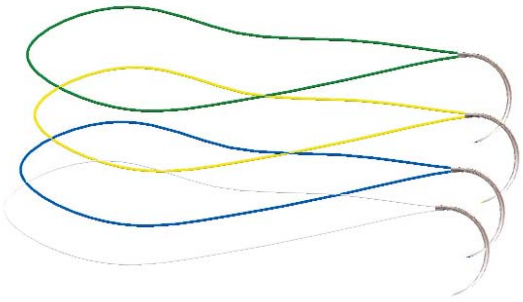
Table 2: The 3 groups of patients

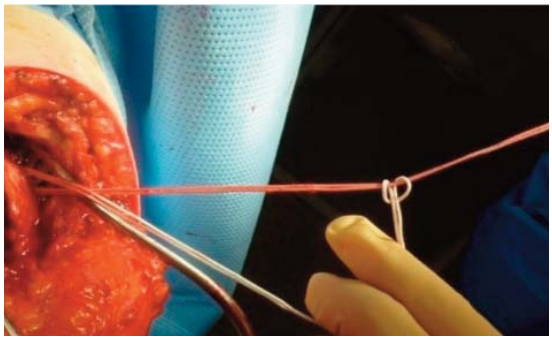
In group 1, (CT2 + preservation of humeral head) a case of necrosis in the humeral head was observed in a patient of 90 years, but on account of correct function and more importantly complete benignancy, the patient was not returned to surgery. Finally a premature return to surgery was observed, due to a secondary mobilization of the cephalic synthesis. (post-operative episode).

In group 2 (prosthesis without OMS or use of loop sutures) we observed 5 mal-positions with low tuberosities.

In group 3 (use of OMS system and loop sutures to complete tuberosity suturing) the results were better.

The tuberosity suturing technique with loop sutures was possible to repeat and found to be efficient by all clinicians.





Discussion:

These results firstly confirm the benefit of using a hybrid implant which allows the humeral head to be preserved where possible, depending on the type of fracture. While in these few cases of preserving the humeral head, one finds excellent published results in terms of consolidation of the tuberosities *, the very low rate of necrosis in the cephalic extremity is doubtless due to the very strict selection of indications for preserving the head. If a question remains over a vascularisation risk, it was preferable to proceed with the hemiarthroplasty option, that is to say, using the same stem, but with a prosthetic head.

These results have also allowed us to compare the use of a traditional hemiarthroplasty with a modern hemiarthroplasty system, whose main objective is to encourage tuberosity consolidation. The series of Sofcot*, made by Boileau*, and more recently, Reuther*, showed results of 40 to 66% for tuberosity mal-position or pseudarthrosis. One cannot question the quality of the osteo-sutures here, for all that, these figures show that the implant has a great significance in the consolidation and good positioning of tuberosities. More recently, Krishnan*, and subsequently Boileau* published a series of trials with results showing rates of 21% and 13% respectively for pseudoarthrosis in tuberosities with a fracture-specific stem, which reassured us in our research into a performance implant to treat cephalotuberosity fractures.

As far as the implant studied in this work is concerned, the objective improvement in rates of consolidation of tuberosities and patient function has strengthened the technical choices which were used for this cementless implant, whether this be for the use of loop sutures for osteo-suturing, or in facilitating consolidation in the anatomical position of tuberosities using the OMS system.

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