Faulty design increases the risk of neck fracture in a hip prosthesis

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ABSTRACT – From October 1993 to May 1994, we performed 35 total hip arthroplasties (20 women) using a Charnley type modular 28 head manufactured by Medical Tec Brazil. 9 fractures through the neck of the stem prostheses occurred, all but 1 in men, after mean 4 (0.3–6) years. All fractures were due to an inadequate confluent radius causing abnormal transmission forces through the neck. The higher the load (men, heavy body weight), the greater the risk of fracture. The metallographic, chemical and microhardness analyses showed no abnormalities. We ascribe these fractures to faulty design of the stem prosthesis.

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Fracture of the neck of a hip prosthesis is rarely reported in the medical literature, especially when the femoral component is forged in a single piece and not welded (Carlsson et al 1977, Burstein and Wright 1985, Aspenberg et al. 1987, Rand and Chao 1987, Farfalli et al. 1993).

From October 1993, we used a cemented Charnley femoral stem type (Medial Tec Brazil) in primary or revision total hip arthroplasties, with cemented or cementless cups. We stopped using this type 8 months later, when the first implant fracture occurred.

We analyzed the risk factors for prosthetic neck fracture in patients operated on with this stem design.

Patients and methods

From October 1993 until May 1994, 35 hip arthroplasties were done using the modular Charnley stem type made by Medical Tec. 20 females and 15 males, with an average age of 70 (46–68) years, were operated on. 19 hips were operated on the right and 16 on the left side.

The average weight and height of these patients were 70 (45–94) kg and 1.66 (1.45–1.90) cm. The preoperative diagnoses were arthrosis (22), cervical hip fracture (5), hip dysplasia (1), rheumatoid arthritis (1) and revisions of loosened arthroplasties (6).

The operations were carried out by a team of 4 surgeons, using a posterolateral approach, without trochanteric osteotomy and using cement delivered by syringe and proximal pressurization preceded by placement of a plug.

We evaluated the patients at the time of their follow-up and/or by phone interview. Of the 35 patients, 1 could not be located and 1 died of unrelated cause leaving 33 hips (cases) to be studied. Their daily physical activities were classified as follows: grade I–aerobic activity, playing tennis; grade II–walking 1 mile a day, playing golf; and grade III–walking indoors. After a mean follow-up of 4 years, 9 patients had fractured the prosthetic neck (Figure 1). The average time from arthroplasty to implant fracture was 53 (4–68) months.

The influence of sex, age, height, weight, side, etiology and activity on the risk of fracture was determined with uni- or multivariate analyses, using chi (square) and Cox regression analysis. Survival analysis was done with Kaplan-Meier's method.

All prostheses removed because of a fracture were examined at the National Institute of Indus-

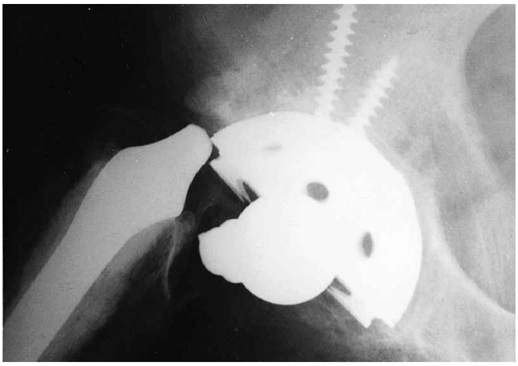

Figure 1. Fractured neck of femoral component.

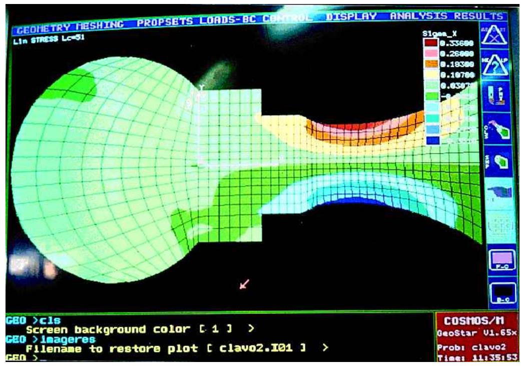

Figure 2. The distribution of tension in the head and neck of a femoral component.

trial Technology by direct observation, conventional microscopy and electron microscopy. These methods permit a complete examination of the fracture, metallographic and chemical analyses, microhardness study and calculation of the tensile concentration factor. In the metallographic analysis, samples were taken from several areas, including the fracture site and unfractured areas. These were placed in resin casts and prepared with established methods including roughing, polishing and attack for scanning by electron microscopy, using attack reagent number 25 of ASTEM R-407-70.

A semi-quantitative chemical study of the samples, using an electronics microcatheter for electron microscopic scanning SEM 505, was done. A Vickers microhardness test was performed according to IRAM-IAS U-500-110.

The theoretical factors of concentration of tensions (KT) were calculated on the confluence radius. By considering the characteristic of the fracture, we found that the demands on the neck region were greater during flexion. The theoretical value of kt was therefore calculated, using measurements from a new intact piece by projecting the sections of a larger diameter to a smaller one and the confluence radius at the neck of the prosthesis. The stress concentration factor of R.T. Peterson (1974) graphs were then used.

The overall tension was calculated with a finite model (Figure 2).

Results

We found 9 fractures of the prosthetic neck—8 in men and 1 in a woman. The fracture occurred after an average 53 (4–68) months and it had not been preceded by trauma. We observed no radiographic sign of stem loosening and confirmed that the stems were firmly fixed at revision surgery. The neck fractures were more frequent in men and the patients tended to be younger and weigh more (Table 1).

The overall survival of the prosthesis at 4 years—e.g., the risk of not sustaining a fracture of the neck—was as high as 72% and as low as 50% (Figures 3 and 4) in men.

The multivariate analysis showed that the main independent risk factors for fracture of the femoral component were younger age and heavier weight (Table 2). The model for age-weight explained 39% of the fractures, with a sensitivity of 67% and a specificity of 88% giving a reliability of 95%.

In all the samples the fracture surface had three very different areas from lateral to medial: a smooth surface with beach or clam, shell marks, another with more accentuated beach marks, and a third area with a rough granular appearance.

No differences were seen between samples taken from the fracture sites and unfractured areas. The metallographic examination suggested that the material had no microstructural or metallurgical abnormality.

In all cases, a rupture took place in the area of the confluent radius and then a fatigue crack spread toward the interior of the axis first slowly, then faster until the final rupture.

Table 1. Patient variables analysed

	Fracture	No frac.	Total	P-value
Patients	9	24	33	
Gender				0.007
men	8	8	16	
women	1	16	17	
Activity				0.7
1	1	1	2	
2	2	10	13	
3	5	13	18	
Age, years [a]	62 (9.6)	73 (8.4)		0.004
Weight, kg [a]	79 (7.9)	68 (11.2)		0.006
Height, cm [a]	175 (7.8)	164 (0.2)		0.008
Follow-up, mo [a]	23 (15)	164 (2.2)		0.0001

[a] mean (SD)

Table 2. Multivariate and Cox regression analysis of risks

Variable	Relative risk (95% CI)	P-value
Age	0.83 (0.74–0.94)	0.002
Weight	1.2 (1.0–1.3)	0.004
Activity	0.2 (0.03–1.0)	0.06
Sex	9.2 (0.50–1.7)	0.1
Height	0.99 (0.91–1.0)	0.9
Arthrosis	2.7 (0.32–22)	0.4
Primary	0.85 (0.05–14)	0.9
Right	0.93 (0.24–3.6)	0.9

The implant study showed that all the samples had a microstructure consisting of equiaxial grains of Austenita with a size ranging beween 5 and 6 (medium grain) and no visible carbide precipitant. A semiquantitative chemical study of the samples using an electronic microscope showed that the material was steel alloy AISI 316 (Table 3).

The Vickers microhardness test showed no changes in the values (Table 4).

The technical analysis demonstrated that all fractures occurred at a point where the diameter of the prosthetic neck is smallest (10 mm) and then increases to 11.7 mm diameter by a sharp confluent radius. The neck at this level, on its inferior border, has a circular indentation to facilitate extraction.

The stress concentration factor of R.T. Peterson (1974) graphs yielded a tension concentration in flexion which was 2.5 times higher than if the geometry of the prosthetic neck had been uniform.

Finally, we studied the overall tension, calculated by means of a finite model, by observing the flexion and tension forces in the areas subjected to this prosthesis design. We found that the confluence radius between the femoral head and neck is inadequate with fracture risk.

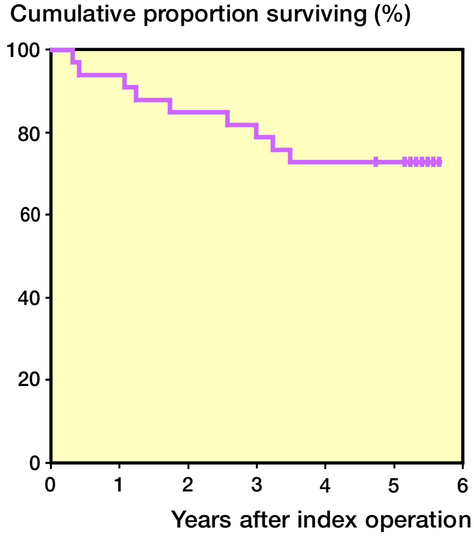

Figure 3. Risk of fracture.

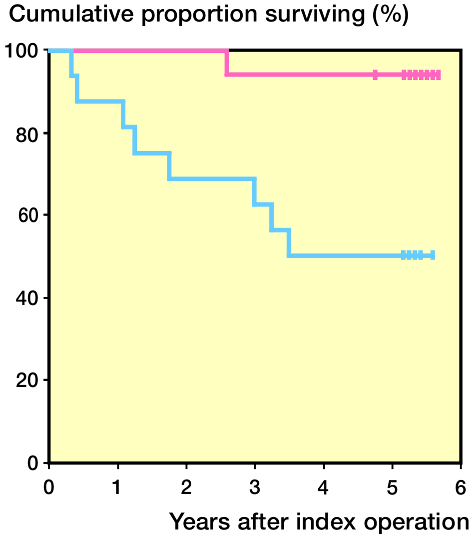

Figure 4. Risk of fracture according to gender.

Table 3. Chemical semiqualitative study of samples

Main samples	Values (%)	IRAM 9401 standard (%)
Silica (Si)	1	1 max
Manganese (Mn)	2.5	2 max
Molybdenum (Mo)	4.5	2–3
Nickel (Ni)	11	10–14
Chromium (Cr)	17	16–18
Iron (Fe)	64	Rest

IRAM = Argentine Institute of Rational Materials.

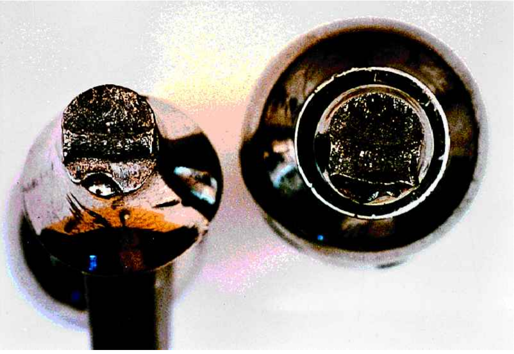

Figure 5. Fracture surface neck of femoral component showing different areas.

Table 4. Vickers microhardness analysis IRAM-IAS U-500 100

Sample location	Kg/mm^2
Zone in the implantant nucleus	220 / 210 / 215
Zone near the fracture surface	250 / 280 / 297

IRAM Argentine Institute of Rational Materials,
IAS Argentinian Siderurgic Institute

Discussion

We found a high rate of fatigue fractures of the neck of the stem prosthesis, some of which occurred early. Only a few reports have been published regarding this complication. Height, weight and age, risk factors for fracture, may be related to high demands due to increased loading.We found no metallographic, chemical or microhardness defects. The cause of fatigue can be related to the prosthesis design, especially the presence of a neck with a sharp confluence radius.

Most fractures are due to defects of the welding of the neck to the prosthesis head. This possibility can be excluded by employing a modular component in which welding is not used, but does not exclude other type of problems, e.g., corrosion (Collier et al. 1992).

Burstein and Wright (1985) and Rand and Chao (1987) reported 2 cases each of cervical fractures in a solid forged, trapezoidal model 28 (t 28) prosthesis. They found no metallurgic defects, but criticized the design of the prosthesis neck. Aspenberg et al. (1987) reported 5 prosthetic fractures through the neck after 5–15 years. They concluded that the fracture could be related to the design or the type of materials used.

In our study, the calculation of the concentration of tension KT yielded values 2.5 times higher in the confluence radius of the prosthetic neck than with tensions of uniform morphology according to our finite model. This fracture began with a crack in the confluence radius due to the presence of high tension at the indentation in the inferior border of the neck. Variable flexion forces during activity caused propagation of the crack and thus exceeded the resistance of the implant.

Several methods can be used to reduce and even eliminate the likelihood of a prosthetic fracture. Surgical technique should be optimized to improve fixation of the implant to the bone. Placement of the prosthesis in a varus position should be avoided to reduce the level of stress on the femoral stem. Attention should be paid to the characteristics of the metal used, avoiding first generation alloys and manufacturing defects in the implant by means of optimal quality control. Modification of prosthetic designs should correct these faults by incorporation of reinforcement in the stress zone, and avoidance of sharp edges and excessive offset. Furthermore, strict quality control, including laboratory and clinical test and appropriate follow-ups, must be established before the products are released into the market.

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