

ASEPTIC LOOSENING OF CEMENTED TOTAL ARTHROPLASTIES OF THE HIP IN RELATION TO POSITIONING OF THE PROSTHESIS

New Utilization of the Tschuprow-Cramer Statistical Test

H. COUDANE, A. FERY, J. SOMMELET, J. LACOSTE, P. LEDUC & A. GAUCHER

Clinique de Traumatologie et d'Orthopédie, Nancy; Services des Explorations Fonctionnelles, Vandoeuvre les Nancy, and Clinique de Rhumatologie, Vandoeuvre les Nancy, France

A statistical study of 1200 McKee-Farrar cemented total prostheses of the hip demonstrated the importance of a horizontal position of the cup and a valgus position of the prosthetic stem, in avoiding aseptic loosening of the prosthetic parts. A new test (the Cramer test) showed that a statistical bond exists between the position of the prosthesis and the occurrence of aseptic loosening.

Key words: arthroplasty; hip joint.

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A retrospective study of a large series of cemented total prostheses of the hip can form the basis of a statistical study of the factors determining aseptic loosening. The study can be based solely on clinical and radiographic parameters as they are related to biomechanical considerations.

The orthopaedic surgeon verifies the hypotheses generated from biomechanical studies, checking that relationships exist between several data.

These relationships are coded as regards quantitative data such as statistical calculations of mean, variance, correlation "r" and test "t". Calculations of qualitative data are less applicable because the distribution laws are not known.

The cases have to be numbered. Proportional percentages must be calculated and the probability (*P*) calculated by the Chi-Square test.

The computerization of the patient data gives an infinite range of possibilities for studying the bond between qualitative data. The Chi-Square test allows the probability of existence of this bond to be checked. It has, however, a basic de-

fect – it does not measure the strength of the bond. It only allows evaluation of the risk of error when it has been established that this bond does exist.

The Tschuprow coefficient (*T*) on the other hand indicates the strength of the bond, taking into consideration:

- the number of degrees of freedom (d.f.),
- the correlation table of Chi-Square,
- the number (*n*) of observations in compliance with the formula.

$$T = \sqrt{\frac{\chi^2}{n \sqrt{d.f.}}}$$

The Tschuprow coefficient has not been used very often until recently because of the requirement of large numbers. The Tschuprow coefficient behaves like the correlation coefficient *r*: it remains greater than 0 and lower than + 1 and complies with a non-linear law (Figure 1) (Kendall & Stuart 1961).

For the correlation tables where the number of

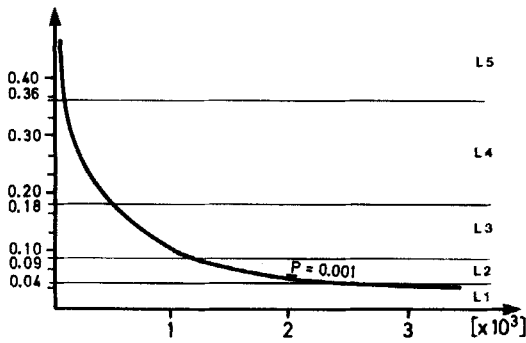


Figure 1. The advantages of the Tschuprow statistical test. Statistical sample – the curve corresponds to $P = 0.001$.

$T < 0.045$ L₁ bond strength “insignificant”
 $0.045 < T < 0.090$ L₂ bond strength “weak”
 $0.090 < T < 0.180$ L₃ bond strength “medium”
 $0.180 < T < 0.360$ L₄ bond strength “strong”
 $T > 0.360$ L₅ bond strength “very strong”

lines r is smaller than the number of the columns c , T is replaced by Cramer coefficient C

$$C = \frac{\chi^2 (r-1)^{1/2}}{n}$$

the limits of which are always 0 and +1. C and T are very close to each other having the same correlation (Morice & Chartier 1954).

PATIENTS AND METHODS

A total of 977 patients' journals were selected retrospectively and registered on cards by means of a numerical code. These patients had been operated upon with total arthroplasty of the hip between 1968 and 1974. The average follow-up period was 40 months (range 12–120 months).

A total of 1200 prostheses had been fitted. The cemented prosthesis, metal-on-metal, McKee-Farrar type or McKee modified Merle D'Aubigné-Postel type, was used. Each card included 80 different parameters (sex distribution, age at operation, preoperative diagnosis, postoperative course, and follow-up events etc.).

Approximately 80,000 pieces of information were memorized and statistically analysed, applying the Chi-Square and Tschuprow tests (T).

A multifactor study of several contingency tables was performed. The strength of the bond between data was determined and at the same time the P values were compared.

In the present series, we focused on the problem of aseptic loosening. Loosening was in all cases confirmed by re-operation with removal of the prosthesis. We have studied the bond between the occurrence of aseptic loosening and the inclination of the acetabular cup, the position of the femoral component of the prosthesis, the presence or absence of cement under the prosthesis stem and the support of the femoral component on the calcar femorale.

RESULTS

A. The bond between the occurrence of aseptic loosening and the acetabular cup inclination on the immediate postoperative roentgenogram

The distribution of the cup inclinations is shown in Table 1. The statistical analysis showed:

- Chi-Square = 25.89 with 5 d.f. (degrees of freedom).
- Probability = 9.4×10^{-5} .
- The hypothesis of a bond is accepted.
- $T = 0.127$ (strength of the bond “medium”).
- Cramer (C) = 0.19 (“strong”).

In order to clarify these results, further analysis was undertaken of the acetabular cups with an inclination angle to the horizontal of 44° or less. The results of this analysis were:

- Chi-Square = 3.86 with 2 d.f.
- Probability = 0.15.
- The hypothesis of a bond is rejected.
- $T = 0.07$ and $C = 0.0083$ (“weak” bond).

Table 1. The acetabular cup inclination related to the occurrence of aseptic loosening (random selection)

Acetabular cup inclination	No loosening	Loosening	Total
$< 35^\circ$	61	6	67
$35^\circ - 45^\circ$	95	2	97
$40^\circ - 45^\circ$	222	15	237
$45^\circ - 50^\circ$	166	11	177
$50^\circ - 55^\circ$	82	8	90
$> 55^\circ$	32	11	43
	658	53	711

As regards the acetabular cups with an inclination angle of 45° or more the statistical analysis resulted in:

- Chi-Square: 19.29 with 3 d.f.
- Probability = 2.4×10^{-4} .
- The hypothesis of a bond is accepted.
- T = 0.143 (strength "medium").
- C = 0.19 ("strong").

The consequences of these analyses are that the acetabular cup should be inclined less than 44° to the horizontal in order to avoid aseptic loosening.

B. The bond between aseptic loosening and the "Valgisation Coefficient" of the femoral part of the prosthesis

The "Valgisation Coefficient" is defined as the ratio $\frac{a}{b}$ measured on the postoperative X-ray (AP-view), as demonstrated in Figure 2. The coefficient varies from 0 to 1 depending on the position of the stem in relation to the lateral cor-

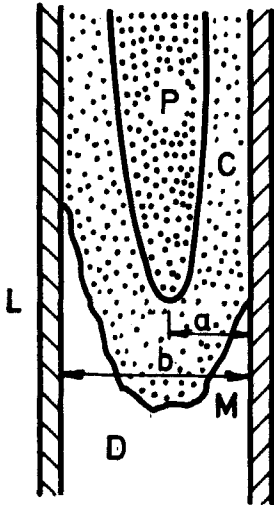


Figure 2. Calculation of the "Valgisation Coefficient" $\frac{a}{b}$
 P = femoral part of the prosthesis.
 C = cement
 L = lateral cortex of the femur
 M = medial cortex of the femur
 D = femoral diaphysis
 a = distance between the tip of the stem and the inner medial cortex of the femur.
 b = diameter of the femoral shaft at the level of the tip of the stem.

Table 2. The "Valgisation Coefficient" of the prosthetic stem in relation to aseptic loosening (random selection)

"Valgisation Coefficient"	Distribution		Total
	No loosening	Loosening	
0.1	23	1	24
0.1 -0.15	8	0	8
0.15-0.20	19	0	19
0.20-0.25	5	1	6
0.25-0.30	5	0	5
0.30-0.35	4	0	4
0.35-0.40	5	0	5
0.40-0.45	2	0	2
0.45-0.50	14	3	17
0.50-0.55	5	1	6
0.55-0.60	7	0	7
0.60-0.65	6	0	6
0.65-0.70	4	1	5
0.70-0.75	7	0	7
0.75-0.80	7	3	10
0.80-0.85	2	3	5
0.85-0.90	1	1	2
0.90	1	0	1
	125	14	139

tex of the femoral shaft. If it is in contact with the lateral cortex the prosthetic stem is in the varus position. A study was undertaken on a random sampling of 139 prostheses. The distribution of the findings is shown in Table 2:

- Chi-Square = 31.96 with 17 d.f.
- Probability = 0.015.
- The hypothesis of a contingency bond is accepted.
- T = 0.236 ("very strong" bond).
- C = 0.48.

The "Valgisation Coefficients" >0.45 (prosthesis in varus position) and coefficients <0.45 (prosthesis in valgus position) were studied separately. The statistical analysis showed:

- Chi-Square = 13.17 with 1 d.f.
- Probability = 2.8×10^{-4}
- The hypothesis of a contingency bond is accepted
- T = 0.123 (strength "medium").
- C = T.

Table 3. The presence of cement under the prosthesis stem, and the presence of air inclusions, in relation to aseptic loosening (random selection)

	No loosening	Loosening	Total
Presence of cement under the stem	437	30	467
Presence of cement under the stem + air inclusion 5 mm	116	10	126
Presence of cement under the stem + air inclusion 10 mm	5	1	6
Presence of cement under the stem + air inclusion > 11 mm	5	0	5
Absence of cement under the prosthesis stem	89	9	98
	652	50	702

In conclusion, this analysis showed a strong relationship between aseptic loosening and varus positioning of the prosthetic stem.

C. The bond between factors regarding the cement in the femoral diaphysis and the occurrence of aseptic loosening

The following signs are looked for:

1. The presence of cement under the end of the prosthetic stem on the postoperative X-ray.
2. The presence of air inclusion in the cement under the prosthetic stem.

The distribution of the radiographic findings is demonstrated in Table 3. The results of the statistical analysis were:

- Chi-Square = 5.77 with 8 d.f.
- Probability = 0.673.
- The hypothesis of a contingency bond is rejected.
- T = 0.054 ("weak" bond).
- C = 0.064.

This means that the occurrence of air inclusions or lack of a cement plug distal to the prosthetic stem is of no importance in relation to aseptic loosening.

D. The bond between the support of the prosthetic stem on the calcar and aseptic loosening

Support of the femoral part may be direct through contact between the base of the prosthe-

tic stem and the calcar or through interposed cement.

The results of the analysis are shown in Table 4:

- Chi-Square = 2.69 with 4 d.f.
- Probability = 0.611.
- The hypothesis of a bond is rejected.
- T = 0.044 ("weak" bond).
- C = T.

This means that the way the prosthetic stem is supported on the calcar femorale is of no importance in relation to aseptic loosening.

DISCUSSION

The study of a homogeneous series of total hip arthroplasties allowed the computerized analysis of multiple parameters. In the tables, the totals

Table 4. The support of the prosthetic stem on the calcar femorale in relation to aseptic loosening (random selection)

	No loosening	Loosening	Total
Direct support	594	44	638
Support through cement	47	3	50
No support (1)	3	1	4
	644	48	692

(1) Settling of the femoral part in the medullary cavity.

given are different from the number of patients (977) and from the total number of prostheses (1200). This is because we have considered only cases which have been followed up for at least 1 year and true aseptic loosening. Mixed cases with other complications, in particular infectious complications, have thus been excluded. The statistical programming allows studies of samples taken at random and studies of the series as a whole.

The quantitative data were collected from the immediate postoperative X-ray.

Aseptic loosening of the prosthesis is probably one of the most frequently appearing late complications (Coventry et al. 1974, Enneker et al. 1974, Ring 1974). In the present series 6 per cent (72/1200) of the prostheses were thus considered to be loose. Among the 72 loosening, 61 had been re-operated with replacement of the total prosthesis.

The technical criteria for placement of the prosthesis have been described by McKee & Watson-Farrar in 1966. They recommended an inclination of 30° between the cup and the horizontal. The results of our statistical analysis confirmed this technical detail. When the cup angle is more than 45°, the probability of the occurrence of loosening is high and the strength of the contingency bond between the vertical cup and aseptic loosening is "medium". The "Valgisation Coefficient" confirmed the results of biomechanical studies. The probability of the occurrence of loosening in the case of varus positioning of the prosthesis is high and the strength of the contingency bond aseptic loosening - varus positioning is considered as "high" (Coudane 1979, McKee & Chen 1973).

These results create a basis for the long-term follow-up of patients after prosthetic replacement. If pain persists for several years after a cemented total arthroplasty, a study of the roentgenograms may suggest the diagnosis of aseptic loosening, (i) if the "Valgisation Coeffi-

cient" is high (>0.45), corresponding to a varus position of the prosthetic stem, or (ii) if the cup is vertical. There is no need for arthrography or the consideration of the peri-prosthetic line, the significance of which is the subject of controversies (Bard et al. 1976, Coudane 1979).

In the present series, however, anaerobic cultures were not taken routinely at the re-operations. Because of this we can not comment on the occurrence of low-grade deep infection.

In conclusion, this statistical analysis defined the significance of the position of the prosthesis cup and stem in the occurrence of aseptic loosening, a complication which severely affects the long-term results of cemented total prostheses of the metal-on-metal type.

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