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Increased loosening of cemented straight stem prostheses made from titanium alloys. An analysis and comparison with prostheses made of cobalt-chromium-nickel alloy

Accepted: 22 October 2000 / Published online: 12 April 2001
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Abstract We studied the rate of aseptic loosening of three different types of femoral stems in primary total hip replacement. After a median follow-up of 10.2 years 4/147 CoCrNi (SS77) straight stems (type M.E. Müller) were revised. After a median follow-up of 7.7 years 32/239 Ti-6Al-7Nb (SS77) were revised and after a median follow-up of 5.2 years 52/203 SLS Titanium alloy stems were revised. Whereas the first two stems are of identical design (smooth-blasted, anterior and posterior collar), the SLS stem design is different. Surgical procedure and cementing technique have remained unchanged. There is a significantly higher risk of failure for smaller titanium stem sizes and in males and patients who are physically active. This indicates that the greater elasticity of the Titanium alloy is one of the factors responsible for loosening.

Résumé Nous avons étudié le taux de descellement de trois différents types de tiges fémorales utilisées lors d'une arthroplastie primaire totale de la hanche. Après un suivi moyen de 10,2 années, 4 tiges droites de type CoCrNi (SS77) (type M.E. Müller) sur 147 ont été révisées. 32 tiges en alliage Ti-6Al-7Nb sur 239 ont été révisées après un suivi moyen de 7,7 années, alors que 52 tiges de type SLS Titane sur 203 ont été révisées après un suivi moyen de 5,2 années. Les deux premières tiges présentent le même type de design. Les tiges SLS sont quant à elles d'un autre type. La procédure chirurgicale et la technique de cimentation sont restées inchangées. Le risque d'échec est significativement plus grand pour les plus petites tiges en titane, chez les hommes ainsi que

chez les patients physiquement actifs. Ceci montre que la plus grande élasticité de l'alliage en titane est un des facteurs responsable de descellement.

Introduction

In 1977 M.E. Müller introduced the straight stem prosthesis (SS 77) made of a CoCrNi alloy with firstly a standard (SSS) version and then later a 'lateralising' (SSL) version. From 1984 the SS 77 prosthesis was manufactured from titanium alloys, mainly Ti-6Al-7Nb. In 1989 the self-locking straight stem (SLS) made of Ti-6Al-7Nb was introduced. All straight stems are double-tapered [8]. Whereas the SS 77 is smooth blasted and has an anterior and posterior collar to inhibit subsidence in the cement mantle, the SLS variant is thicker, rough blasted proximally, and has no collar. We stopped using cemented straight stems made of titanium alloys in our hospital in 1993 even before statistical analysis showed a significant difference in risk of failure.

Materials and methods

We analysed 589 consecutively implanted primary hip prostheses. With bilateral arthroplasty we considered only the first implant during the observation period (1984–1993) in order to ensure the independence of our observations. One-hundred and forty-seven stems made of CoCrNi (101 SSS, 46 SSL) were inserted between 1984 and 1987, and 239 straight stems made of titanium alloy (63 SSS, 176 SSL) were inserted between 1987 and 1990. Two-hundred and three SLS stems made of titanium alloy were inserted between 1990 and 1993. The aetiology of the hip disorder and indications for surgery were similar (Table 1). The operative technique was not modified throughout the period 1984–1993 [8]. It always included pre-operative planning, a transgluteal approach, the use of a bone plug and Sulfix 6 cement with antegrade filling. In 6.3% of the two titanium groups either Palacos or a 'trial' cement was used.

Until the end of 1999 follow-up was routinely performed at 4 months, 1, 2, 5, 10 and 15 years and then only if the patient developed symptoms. Subjective information, clinical and radiological findings (AP view of pelvis centred on the symphysis, and a

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Table 1 Data for the three periods of implantation (*n.d.* no data)

	08/84–06/87	07/87–11/90	11/90–11/93
Stem type	CoCrNi	Ti SS 77	Ti SLS
Median follow-up (years)	10.2	7.7	5.2
Person-years	1407.0	1767.1	1060.5
Number of patients	147	239	203
Deaths before revision	72	73	39
Aseptic loosening stem	4	32	52
Other revisions	3	2	1
Stem size			
7.5	10%	17%	22%
10.0	37%	44%	46%
12.5	54%	39%	32%
Gender: male	59%	51%	63%
Diagnosis of arthritis	66%	72%	68%
Side of implant: left	41%	43%	45%
Implant on opposite side	19%	13%	8%
Physical stress: yes	<i>n.d.</i>	16%	20%
Age (years)	68.7 (9.80) ^a	69.3 (9.50) ^a	69.5 (9.70) ^a
Body weight (kg)	73.5 (12.91) ^a	73.0 (12.60) ^a	74.3 (12.89) ^a
Body height (cm)	167.0 (8.04) ^a	166.4 (8.24) ^a	166.8 (9.13) ^a
Surgeon			
Chief physician	56%	38%	29%
Senior physician	34%	38%	37%
Resident	10%	24%	33%

^a Means (SD)

“faux profile” view) were recorded. Only 6.8% of the patients were lost to follow-up.

The decision for revision remained unchanged during the whole period of the study and was undertaken mainly because of progressive destruction of the femoral bone stock. Whenever possible it was performed at the time when a relatively simple procedure would ensure a good result.

The aim of our statistical analysis was to identify the potential risk factors responsible for hip prosthesis failure due to aseptic loosening of the stem. Revisions of the stem due to other causes were treated as censored observations. Variables considered were stem type, stem size, offset of stem, type of cement, age, body weight, body height, diagnosis of arthritis, gender, side of implant, implant on opposite side, physical stress and the experience of the surgeon (Table 1). All these parameters were measured at the time of implantation. In addition the possible influence of a subsequent implant on the opposite side was regarded as a time-dependent factor. Our primary interest was focused on the effect of stem type. Due to the relatively high age at replacement and the quality of modern total hip prostheses, many patients die before their hip prosthesis fails. Death can also be regarded as a specific kind of censoring which differs fundamentally from other causes of censoring such as migration or the termination of the study. In addition studies assessing hip prosthesis failure can result in unbalanced groups in relation to mortality. A careful failure time analysis must be accompanied by an analysis of any differences in the mortality risk in the three groups, and we used a competing risk model in order to account for concurrent mortality. The Cox proportional hazard model for cause-specific hazard functions was used to determine the influence of potential risk factors on hip prosthesis failure and death before revision. For model building the co-variate stem type was noted in each analysis when assessing the influence of a second factor. All factors showing an effect on failure or mortality ($P < 0.05$) were considered in the multi-variate analysis. In addition all of these co-variables showing any effect on failure or mortality in the multi-variate analysis were entered into the final Cox model. Crude cumulative incidence curves were used to estimate failure probabilities. Due to the small number (four) CoCrNi prostheses which failed this group was not considered in the multi-variate analysis.

Fig. 1 Revision due to aseptic loosening of stem; by stem type

Results

The CoCrNi group was clearly distinguished from the titanium groups by the very good results with the probability of a revision within the first 5 years after operation being 0% in the CoCrNi group, 5.5% in the titanium SS 77 group (95% confidence interval: [3.2%, 9.3%]), and 14.1% in the titanium SLS group ([10.0%, 19.9%]; Fig. 1).

Multi-variate analysis of the two titanium groups leads to the following results: the co-variables of offset of stem, body weight, body height, diagnosis of osteoarthritis, side of implant, implant on opposite side, the experience of the surgeon and any subsequent replacement of the opposite hip show neither an influence on the risk of prosthetic failure nor on the risk of the patient dying.

Table 2 Cox proportional hazard model, hip prosthesis failure (*CI* confidence interval, *p.s.* physical stress, *RR* relative risk)

Covariate	Aseptic loosening			Mortality		
	RR	95% – CI	<i>P</i> -value*	RR	95% – CI	<i>P</i> -value*
Stem type						
Titanium SS 77	1.00		<0.0001	1.00		0.302
Titanium SLS	3.20	[2.00; 5.13]		1.26	[0.81; 1.95]	
Stem size						
7.5	5.77	[2.90; 11.47]	<0.0001	0.75	[0.43; 1.31]	0.07
10	2.69	[1.45; 5.00]		0.62	[0.41; 0.93]	
≥12.5	1.00			1.00		
Gender						
Female	1.00		<0.0001	1.00		0.0465
Male, no p.s.	3.15	[1.70; 5.80]		1.60	[1.07; 2.39]	
Male, p.s.	5.24	[2.80; 9.80]		0.86	[0.34; 2.17]	
Age						
<65 years	1.00		0.0015	1.00		<0.0001
65–75 years	0.64	[0.38; 1.08]		1.81	[0.90; 3.65]	
75 years	0.26	[0.12; 0.58]		5.38	[2.72; 10.63]	

**P*-value of likelihood ratio test statistic

The type of cement used did not have any influence on the risk of failure.

The relative risk (RR) of failure of a titanium SLS stem compared to a titanium SS 77 stem is 3.2 times higher (Table 2). The risk of failure of a titanium stem size of 7.5 is 5.8 times higher and of size 10 more than twice as high when compared to a stem size of 12.5. On the other hand, stem type and stem size do not show any influence on the mortality risk.

Stem revision is significantly more frequent in men with little physical stress at work than in women (RR=3.15). Physical stress or farming work greatly increases the risk of failure (RR=5.24; Table 2). Age has an effect on the risk of stem failure ($P=0.0015$), younger patients tending to have a higher risk of failure. As expected, the risk of mortality is higher in older patients.

On examination of 15 revised stems the manufacturing company found signs of corrosion in five of nine SS 77 stems and in four of six SLS stems.

Discussion

Aseptic loosening and revision

Several publications record complications after the use of cemented titanium stems [4, 6, 7, 9, 15] while only two authors present good results [11, 12] and even one of these describes low femoral loosening with a titanium monobloc stem [11].

Results in relation to the workload and the sex of the patients

In the survival analyses men and younger patients, who were over-represented in our study because of the rural

area, are at a higher risk [10]. But it is obvious that the differences of risk in our titanium groups were significantly higher (Table 2). It can be assumed that the mechanical stress on the prosthesis due to marked physical activity must be higher. Our farmers showed a revision rate of over 50% after 10 years.

Modulus of elasticity – stem size

The modulus of elasticity of titanium is about half that of cobalt-chromium-nickel [1, 13]. According to tests the rigidity of a titanium size 12.5 stem is roughly equivalent to that of a size 7.5 cobalt-chromium-nickel stem. More even distribution of stress on the bone can be expected [7, 11, 15] but the increase of elasticity in titanium stems seems to lead to more micro movements in the stem-cement interface, and the increased incidence of revisions of small stem sizes supports the high influence of elasticity.

Cement

Sulfix cement was used in all three groups. It may be less exposed to mechanical stress and failure in the presence of a ‘stiff’ implant [2]; Simplex P and CMW cement are known to lead to failures when used with titanium stems [6, 15]. Crowningshield et al. established (by finite-element analysis) a correlation between the modulus of elasticity of the stem material and stress in the cement mantle [2]. Reducing the modulus of elasticity of the prosthesis decreases the stress in the femur but increases the stress in the cement.

Surface roughness, surface shape

The 'straight stem system' belongs to the 'shape closed fixation' designs [5]. Immediate and lasting stability is provided in the SS 77 prostheses by smooth blasting and a small collar in an antero-posterior position. Such a stem has greater fixation strength but risks to be more abrasive in the case of micro movement [3]. Once it is 'de-bonded', or loose, it produces more cement damage. When a straight stem is made of a titanium alloy it seems that the risk of 'de-bonding' is highly increased. In addition our investigations showed a markedly higher rate of loosening of the SLS stem which has no collar, no central groove and is more rectangular and has an increased proximal surface roughness (Table 2; Fig. 1). Roughness should lead to a firmer cement fixation [14] but it can also initiate cement cracks that may lead to cement failure [16]. The much more elevated revision rate of the SLS stem proves that these modifications were associated with poor results.

Corrosion

It has been clearly shown that corrosion in cemented titanium stems only follows early loosening and is mostly situated distally [17]. In titanium alloys this corrosion stops when the prosthesis is completely loose.

Follow-up controls of at risk patients

In over one-third of our patients we found signs of early loosening on radiographs before the presence of any pain. Consistent follow-up with radiographs is thus advisable for all patients with cemented titanium stems. Regular follow-up allows the cautious selection of the optimum moment for revision, when the patient is not yet suffering and while the remaining bone stock allows revision with the likelihood of a good functional result. Apart from our routine examination of patients after 1, 2, 5 and 10 years, we introduced additional 'check-ups' after 3.5 and 7.5 years. On the basis of our experience we recommend examinations at least 4, 7 and 10 years after hip replacement.

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