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Original article

Assessment of a press-fit proximal femoral modular reconstruction implant (PFMR®) at 14.5 years. A 48-case series with a disturbing rate of implant fracture

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ABSTRACT

Introduction: The PFMR® proximal femoral modular reconstruction implant (Protek, Sulzer Orthopedics, Switzerland) is a straight modular stem in sanded titanium with press-fit anchorage, intended to achieve spontaneous bone reconstruction following Wagner's principle. The aim of the present study was to analyze long-term clinical and radiological outcome.

Material and method: A single-center retrospective study included 48 PFMR stems implanted in 47 patients between 1998 and 2002. Results in this series were previously reported at 7 years' follow-up. Clinical assessment used PMA and Harris scores. Radiologic assessment focused on stem stability and osseointegration, and bone stock following Le Béguec.

Results: Twenty-three patients were seen at a mean 14.5 years' follow-up (13 deceased, 11 lost to follow-up), including 1 with bilateral implants, i.e., 24 stems. PMA and Harris scores, stem stability and osseointegration and bone stock were stable with respect to the 7-year findings. Radiology found 7 stem fractures in the Morse taper, i.e., in 29% of implants. Two of these cases required femoral implant replacement; 5 were asymptomatic.

Discussion and conclusion: Long-term outcome for PFMR stems was clinically and radiologically satisfactory for the 16 patients free of mechanical complications. The Morse taper fracture rate was high, and higher than reported elsewhere. The usual risk factors for implant fracture were not found in the present series. The modular design of the press-fit revision implant is its weak point; monoblock implants should be used in patients with good life-expectancy.

Level of evidence: IV (retrospective study).

1. Introduction

The complexity of total hip replacement (THR) revision is mainly due to the fact that femoral loosening is accompanied by an often severe proximal bone defect, hindering primary fixation within the previous implant bed.

The Proximal Femoral Modular Reconstruction implant (PFMR®: Protek, Sulzer Orthopedics, Switzerland), designed by Le Béguec [1], allows stable and lasting fixation thanks to intramedullary press-fit anchorage of the Wagner stem [2] with spontaneous bone regeneration thanks to the sanded titanium surface treatment. The modular design allows limb length to be restored, and the stem to be positioned in version so as to enhance hip stability.

Modularity, however, also incurs complications.

Modular implant fracture in hip replacement is an established but fairly rare phenomenon, with incidence of 0.23–0.27% [3]. The main reported causes are corrosion, fretting, stress shielding, pitting corrosion, and fatigue fracture [4–7].

The PFMR® stem is a major revision implant for complex cases, but its modular design incurs a risk of weakness that may lead to fracture. The aim of the present study was to assess long-term stem survival and onset of mechanical complications and to determine failure modalities and risk factors. The study hypothesis was that the modularity of the PFMR® implant incurs an inevitable risk of fracture at the junction.

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2. Material and methods

2.1. Implant

The Proximal Femoral Modular Reconstruction (PFMR®) system (Protek, Sulzer Orthopedics, Switzerland) was designed in 1994 and marketed until 2009. It comprised a set of femoral stems in a histocompatible alloy, Protasul-100®, containing titanium, aluminum and niobium (Ti 6A17Nb), with surface treatment by high-pressure corundum sanding. This surface treatment is known to be an osteophilic substrate, promoting spontaneous regeneration and osseointegration. Each implant comprises 2 components (Fig. 1): a proximal metaphyseal component and a distal component, assembled by a Morse taper. Instrumentation is also modular, enabling 2-stage implantation of the components, so as to allow trials at each stage.

2.2. Proximal components

Proximal components come in 2 designs: fluted or cylindrical. Both comprise 4 parts of different heights, increasing by 10-mm steps from P1 (55 mm) to P3 (85 mm). The neck-shaft angle is 135° and cervical offset 44 mm in all parts. The lateral part of the proximal component is wide in the sagittal plane, and grooved and ribbed. It has a conical orifice for assembly with the distal component.

2.3. Distal components

The distal components come in 3 lengths: 140, 200 and 260 mm. Diameters increase by 2-mm steps from 14 to 22 mm for the 140 mm length, 14 to 24 mm for the 200 mm length, and 16 to 24 mm for the 260 mm length, i.e., 16 parts in all.

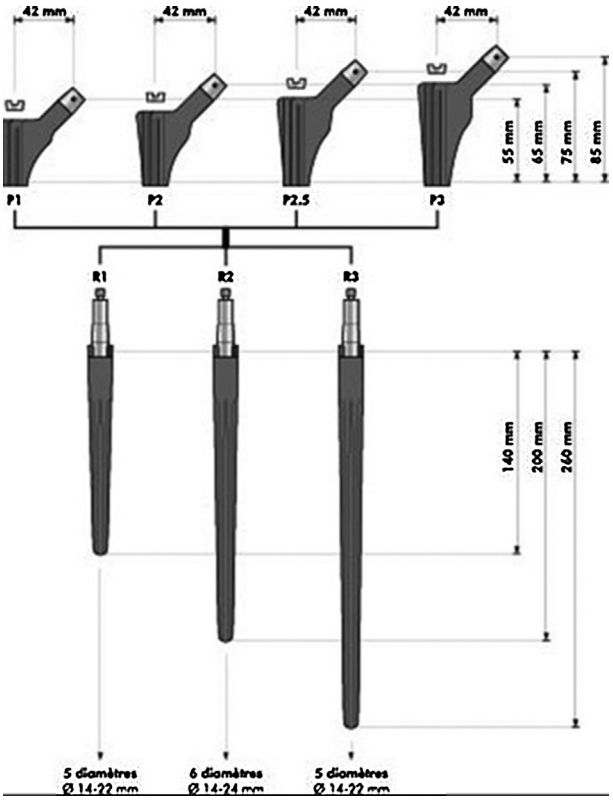


Fig. 1. Dimensions and combinations. The full PFMR system comprises 4 proximal and 16 distal parts. Modularity allows 64 stems of different dimensions to be constructed.

Distal components consist of straight stems with 8 longitudinal ribs. Components of 18-mm diameter or more have an anteroposterior flat section which increases in size with the diameter (elasticity reserve). The implants are tapered, with a 2° slope; the conical part is distal, with height varying according to implant length: 100 mm for 140 mm stems, and 120 mm for 200 and 260 mm stems.

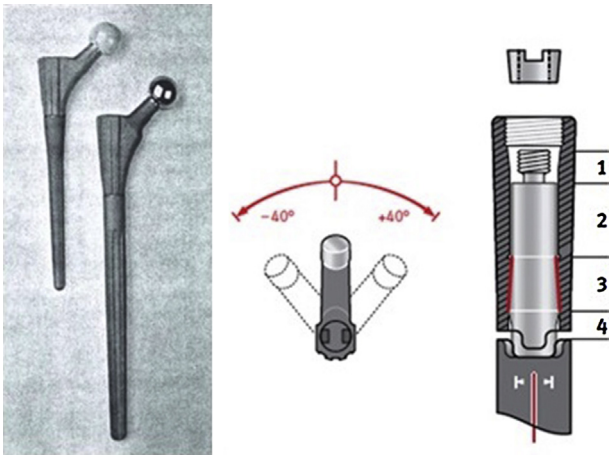
2.4. Assembly system

The two metal components are connected by a Morse taper (Figs. 2 and 3). The male taper is assembled on the distal component by fretting, during manufacture in the factory. The proximal part consists of 4 areas: a threaded zone for the security nut, a cylindrical zone for centering the two components for assembly, a finely grooved conical zone to ensure mechanical fit between the two components, and a narrower zone concentrating stress in flexion. Anteversion can be adjusted from +40° to −40° ahead of assembly.

After assembly, there remains a gap of about 1 mm between the two components, concentrating stress in flexion and allowing micromovements without producing metal debris.

2.5. Patients

The single-center continuous retrospective study included 48 stems implanted between 1998 and 2002 in 24 female and 23 male patients (1 bilateral implantation in a male patient): 30 right (62.5%) and 18 left (37.5%). The series comprised 44 implant revisions (92%) and 4 primary implantations (8%) (3 adaptive femoroplasties and 1 major sequela of childhood osteoarthritis (Table 1).



Figs. 2 and 3. Assembled PFMR stems. Adjusting metaphyseal anteversion, and Morse taper system.

Table 1
Demographic data (n = 48 patients).

	Mean or number	Minimum	Maximum
Age (years)	73	43	86
Weight (kg)	74	40	100
Height (cm)	164	146	187
BMI (kg/m^2)	27.4	18	40
Gender			
M	24		
F	24		
Side			
Right	30		
Left	18		

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