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When numbers don't satisfy science: multicenter studies and digital protocols

Fabrizio Rivera[1], Luca Comba[2], Loris Perticarini[3], Francesco Benazzo[3]

[1] Orthopedics and Trauma Department, SS Annunziata Hospital, ASL CN1, Savigliano (CN), Italy; [2] Orthopeadics and Traumatology Department, Faculty of Medicine and Surgery, CTO Hospital, University of Turin, Turin, Italy; [3] Robotic Prosthetic Surgery Section, Unit of Sport Traumatology, UO Orthopedics and Traumatology, Brescia, Italy

Summary

Megaprostheses were introduced in oncological orthopedic surgery for reconstruction after bone tumor resections with good results; more recently, megaprostheses have been receiving an increasing role even in non-neoplastic hip and knee conditions like periprosthetic and very comminuted osteoporotic fractures and in treatment for resistant non-union of femur fractures. Nevertheless, literature about the use of megaprosthesis, especially in non-oncological musculoskeletal conditions, is still lacking high evidence level studies showing long-term outcomes. The purpose of this paper is carry out a review of the current megaprosthesis literature and present a multicenter study on a new prosthetic implant ("SMS multicentric study"), collecting the data on the use of a single implant (Smart Modularity System/SMS) in 11 orthopedic centers in order to obtain clinical and radiographic results.

Key words: megaprosthesis, fracture, multicentric study

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Correspondence
Fabrizio Rivera
Orthopedics and Trauma Department, SS Annunziata Hospital, ASL CN1, via Ospedali 5, 12038 Savigliano (CN), Italy. E-mail: rivgio@libero.it

Conflict of interest
The authors have no conflict of interest to declare.

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Introduction

Megaprosthesis are commonly defined as particular bone and joint prosthesis, which can bridge and compensate for large bone defects with important loss of bone stock. Their modularity and multi-component designs made these implants available for variable resections, helping the surgeon in different challenging situations like reconstruction in bone tumor management as well as non-neoplastic hip and knee conditions like periprosthetic and very comminuted osteoporotic fractures and as treatment for resistant non-union of femur fractures [1]; therefore, megaprosthesis can be considered as a limb salvage option in very carefully selected patients when other surgical strategies are not feasible.

The increase in the incidence of femoral fracture is expected to have important consequences for the healthcare system, since femoral fractures in the elderly are associated with multiple comorbidities and are becoming a great challenge to deal with, as reported in many studies [2-4].

The number of joint replacements like total knee arthroplasties performed continues to rise annually and it would be expected that complications including periprosthetic fractures and wide loss of bone stock will become increasingly common conditions to deal with [5].

Megaprosthesis was introduced in oncological orthopedic surgery with good results, but literature about the use of megaprosthesis in non-oncological musculo-

skeletal conditions is still lacking high evidence level studies showing long-term outcomes [6].
The purpose of this paper is to carry out a review of the megaprosthesis literature and present a multicenter study on a new implant (*SMS multicentric study).*

SMS multicentric study

The *SMS multicentric study* aims to collect the data on the use of a single implant in 11 orthopedic centers to obtain clinical and radiographic results.

Smart modularity system

The SMS (smart modularity system) was created by referring as starting points to the large clinical experience given by Waldemar Link MP and Endomodel revision systems [7,8].
The smart selection of specific implants from these two systems led to the creation of useful configurations which characterize prosthetic reconstructions for both the proximal and distal femur (Fig. 1A,B).
Furthermore, a very straightforward, immediate and easy-to-use instrument set emerges from a deep rationalization of already existing instruments, with the integration of only a few useful components.
The system refers to the treatment of bone metastasis and periprosthetic or high energy fractures in older patients as the main clinical indications.
Throughout the assembly of different components, the system allows the surgeon to choose a reconstruction which ensures optimal mechanical stability and desired performances.
Concerning proximal femur reconstruction, the system allows the usage of a metallic core, made by the combination of different cemented stems and proximal bodies, and of modular UHMWPE augments to replace the patient's bone loss, in addition to a titanium support ring to guarantee a good bony interface on the resection line. The reconstruction length can be intraoperatively decided and ranges from 80 mm to 200 mm, with 10 mm steps. Concerning distal femur reconstruction, the system allows the usage of different sizes of femur and tibia components, connected to cemented stems of various lengths and to modular titanium augments which can replace the patient's bone loss of metaphyseal and diaphyseal portions of the femur. The reconstruction length can be intraoperatively decided and ranges from 50 mm to 200 mm.

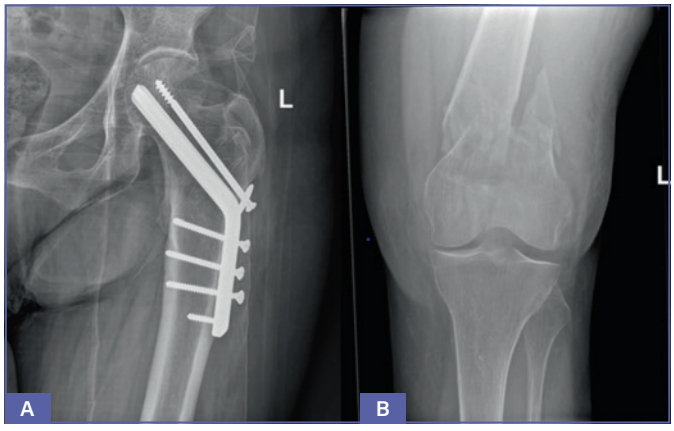

Figure 1. 86-year-old woman with multifragmentary fracture of left distal femur (AO/OTA 33C2).

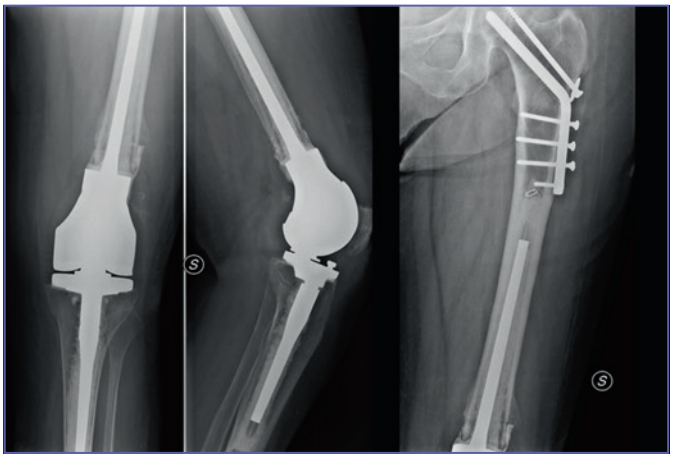

Figure 2. 7 months of follow-up after joint replacement with SMS (Smart Modularity System).

Data collecting

The database includes patients treated with megaprosthesis after prosthetic loosening with important bone loss, periprosthetic fracture, very comminuted periarticular fractures, bone resection after bone infection or primary and secondary tumor. The surgeons have to fill in the data required (*Gruppomulticentricosms.com*), such as the kind of implant (proximal/distal femur, proximal tibia), days of hospitalization, complications and clinical outcome. The clinical scores chosen were *Toronto Extremity Salvage Score* (TESS), *Musculoskeletal Tumor Rating Scale* (MSTS) (hip or knee), *Hip disability and Osteoarthritis Outcome Score* (HOOS), and *Knee injury and Osteoarthritis Outcome Score* (KOOS). TESS has been developed to address the shortcomings of the MSTS in providing a scoring system that emphasizes the possibility to the patients to recovery the daily activity [9].
Radiographic evaluation is done collecting the pre-operative, post-operative, and follow-up (1 month, 3 months, 6 months, 1 year and 2 years afterwards) radiological x-rays, eventual periprosthetic fractures, presence of stem migration with angle variation, radiolucent lines, and implant failure.

Literature review

In the current literature, the largest sample size and longest follow up are found in studies on oncological patients, with heterogenous results. In 2020, Suresh Nathan et al. [10] published the outcome satisfaction in long-term survivors of oncologic limb salvage procedures with an interesting comparison of the results obtained with amputations, arthrodeses and joint replacement salvage surgeries in 162 patients at an average 9.1 ± 3.1 years. In 2015, Capanna et al. [11] retrospectively reviewed 200 patients who underwent large-segment osteoarticular reconstruction after tumor resection, reporting an overall survival (no further surgical procedures of any type after primary surgery), excluding Type 5 failure (tumor recurrence), of 75.9% at 5 years and 66.2% at 10 years. Furthermore, in 2020, Smolle et al. [12] presented their results using metaphyseal segments with articular surfaces for proximal as well as distal femoral replacements reporting high complication rates (45.6% of patients) with infections being most common, especially in the distal femur/proximal tibia, with a cumulative incidence of failure including all complications of 34.3, 40.7, and 67.1% at 3, 5, and 10 years, respectively.

Older patients with periprosthetic fracture and poor bone stock could be managed with prosthetic replacement, allowing immediate weight bearing to avoid the risk of perioperative complication and risk of nonunion. McLean et al. [13] followed 20 patients managed with replacement of the proximal or total femur for salvage of a periprosthetic femoral fracture with bone

Table I. Reported follow-up after megaprosthetic implant in oncologic patients.

Author	Year	Study type	Level	Prosthesis	Sample size (n.)	Clinical score	Follow-up (years)
Pala et al.	Clin Orthop 2015	Retrospective	IV	GMRS	175	MSTS II	8
Ruggieri et al.	The Knee 2012	Retrospective	IV	HRMS	669	MSTS	23
Healey et al.	Clin Orthop 2013	Retrospective	IV	Compress	82	-	10
Goshegher et al.	Clin Orthop 2006	Retrospective	IV	Mutars	250	-	13
Heisel et al.	Int Orthop 2007	Retrospective	IV	Mutars	100	Enneking Score	7
Capanna et al.	Clin Orthop 2015	Retrospective	IV	Megasystem C	358	-	11

Table II. Reported follow-up after megaprosthetic implant in non-oncologic patients.

Author	Year	Study type	Level	Prosthesis	Sample size (n.)	Clinical score	Follow-up (years)
Parvizi et al.	JBJS 2006	Retrospective	IV	MRS	47	HHS	6
Mc Lean et al.	Injury 2012	Prospective	IV	GMRS	20	TESS	12,5
Evans et al.	J Orthop 2016	Retrospective	IV	DFEPR RHK	10	TESS	12
Grammatopoulos et al.	JBJS 2016	Retrospective	IV	Stanmore Modular	80	Oxford hip score	5
Viste et al.	Bone Joint J 2011	Prospective	IV	GMRS	44	HHS	13

loss, reporting no radiological loosening of the prosthetic components for 48 months; they reported six major complications (postoperative dislocation, persistent deep infection, distal femoral fracture distal to the femoral stem in proximal femoral replacement). Ruggieri et al. [14] retrospectively studied the files of 669 patients with musculoskeletal tumors treated with limb salvage and reconstruction to evaluate the long term results of limb salvage surgery and megaprosthetic reconstruction using the fixed-hinge knee KMFTR® and HMRS® prostheses analyzing the design-related modifications and their impact on implant survival, site of reconstruction, functional outcomes, and complications, underlining the importance of the kind of implant used during the reconstruction.

In patients with femoral tumors, periprosthetic fractures with poor bone stock still represent a real challenge for trauma and oncologic orthopedic surgeons; literature in the last years presented megaprosthesis as a viable alternative in cases of femoral fracture with bone stock severely compromised so much that traditional internal fixation or joint replacement would not be enough to provide the stability to allow early mobilization and durable longevity of the implant [1,15].

If we consider the literature about megaprosthetic implant, it can be noticed that papers on oncological cases (Tab. I) generally presented a larger simple size, different prosthetic modular systems, good survivorship, and relatively low complications rate, while those on non-oncological patients (Tab. II) mainly concern periprosthetic fractures, failed ORIF, non-union in osteoporotic bone, infection, and revision surgeries with important loss of bone stock and low number of patients, and results with scores used for standard implants.

In conclusion, the small sample sizes, surgical strategy, different kinds of prosthetic implants, and the indications give a very scarce evidence in clinical practice on the use of megaprostheses. In this scenario, the multicenter cooperative studies proposed could have a fundamental role [16].

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