

An extendable modular endoprosthetic system for bone tumour management in the leg

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ABSTRACT

A modular endoprosthetic system has been developed at the Groningen University Hospital and the University of Twente. The system can bridge a defect resulting from the resection of a malignant bone tumour which has developed around the knee joint of a child. Since the other healthy leg continues to grow, the system includes an element whose length can be adjusted non-invasively by using an external magnetic field. In addition to this lengthening element, there are one hip and two knee components, connectors of various lengths, and fixation elements. The paper describes the elements of the modular endoprosthetic system. Tables are created by means of which the elemental composition of such an endoprosthesis can be determined for each individual patient.

Keywords: Endoprosthesis, tumour, modular system, limb salvage

INTRODUCTION

In young children, a malignant tumour may develop in the femur, usually at the distal metaphysis, and up to about ten years ago amputation of the leg was the only treatment. Nowadays it is often possible to save the leg, especially in cases where a good reaction is observed after chemotherapy. Resection of the affected region can be followed by reconstruction with the aid of an endoprosthesis¹⁻⁵. This method has the drawback that, in time, a difference in leg length will occur, since the distal femoral and the proximal tibial epiphysis are also removed. For this reason a new endoprosthetic system has been developed at the Groningen University Hospital and the University of Twente to bridge the bony defect. This system is special in that it contains an element whose length can be adjusted non-invasively, so that the growth of the other healthy leg can be matched.

There are three basic features regarding the composition of an existing endoprosthetic system.

1. There is a restricted number of sizes and types of ready-made, standard prosthesis.
2. There is one standard concept. For each patient a custom-made prosthesis is produced by adapting the sizes of the concept prosthesis.
3. The system consists of several ready-made modules, each with a restricted number of sizes and types.

A surgeon who uses a ready-made, standard prosthesis has a limited choice of types and must, to some

extent, increase the necessary bone resection to suit the nearest available size of replacement. Improving this would mean a considerable investment for a large stock of endoprostheses⁶.

The advantage of implanting a custom-made prosthesis is the adaption of the replacement to the patient instead of the reverse. However, manufacture of custom-made prostheses used to take some time, generally two to eight weeks; however, this situation may be improved by utilizing computer-aided design and manufacturing techniques and by using pre-fabricated modules to be assembled by the manufacturer.

A logical further improvement is to assemble a modular endoprosthesis before the operation. Since an endoprosthesis consists of various modules, many different endoprostheses can be assembled in spite of the limited number of component modules^{7,8}. An extra advantage is that a modular endoprosthesis allows for the replacement of one component by another in case of failure or merely to adapt the endoprosthesis type to altered needs of the patient. Existing fixations to bone can remain unimpaired and surgical trauma is minimized.

The endoprosthetic system which we have developed is of the modular type and contains the following elements (Figure 1):

- lengthening elements of various lengths
- two knee components
- a hip component with various heads and necks
- connectors of various lengths
- bone-prosthesis connections (fixation elements).

With these components, an endoprosthesis for each patient can be assembled, its composition depending

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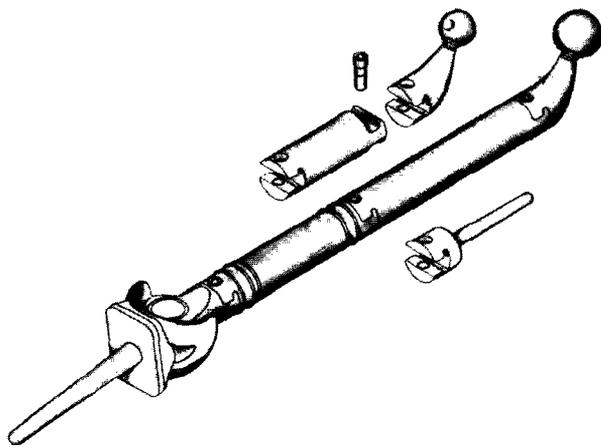


Figure 1 Modular endoprosthesis system

on the length of the resection and on the identity of the resected bone itself (femur or tibia). All components will be described briefly.

To link the different modules, a universal connection was constructed and tested *in vitro*⁹ with a single torsional loading of 200 Nm in both directions, a torsional fatigue loading of 28 Nm during 10^6 cycles at a frequency of 10 Hz, a single four-point bending load of 320 Nm in four perpendicular directions, and bending fatigue loading during 10^6 cycles between 23 and 72 Nm at a frequency of 10 Hz. No permanent deformation was observed after the tests. Non-destructive testing did not reveal any cracks.

The universal connection was also tested *in vivo*¹⁰ in combination with a lengthening element. Three animal experiments with two prototypes were performed. The prototypes were implanted in the tibia of goats for 1.5, 2 and 4 months. After each period, the two parts of the universal connection were found to be firmly attached to each other. No wear marks were visible, and disassembly was easy.

The modular endoprosthesis system can be used after resection of the proximal tibia, the distal, proximal or entire femur. In order to decide the components from which an endoprosthesis should be assembled in each situation, a number of starting points were defined. Guidelines for the composition of an endoprosthesis were then determined.

COMPONENTS

Lengthening element

The lengthening element is adjusted non-invasively to follow the growth of the other normal leg. This is achieved by using an external rotating magnetic field which causes rotation of a small permanent magnet in the prosthesis. The magnet drives a motion screw via a gearbox. This screw forces two telescopic tubes apart. The polygonal shape of the inner tube prevents rotary movement between the tubes. To shield the lengthening element from moisture a bellows made of silicone rubber was glued to the lengthening element. The final prototype of this lengthening element (Figure 2) was tested *in vitro*¹¹ as well as *in vivo*¹⁰.

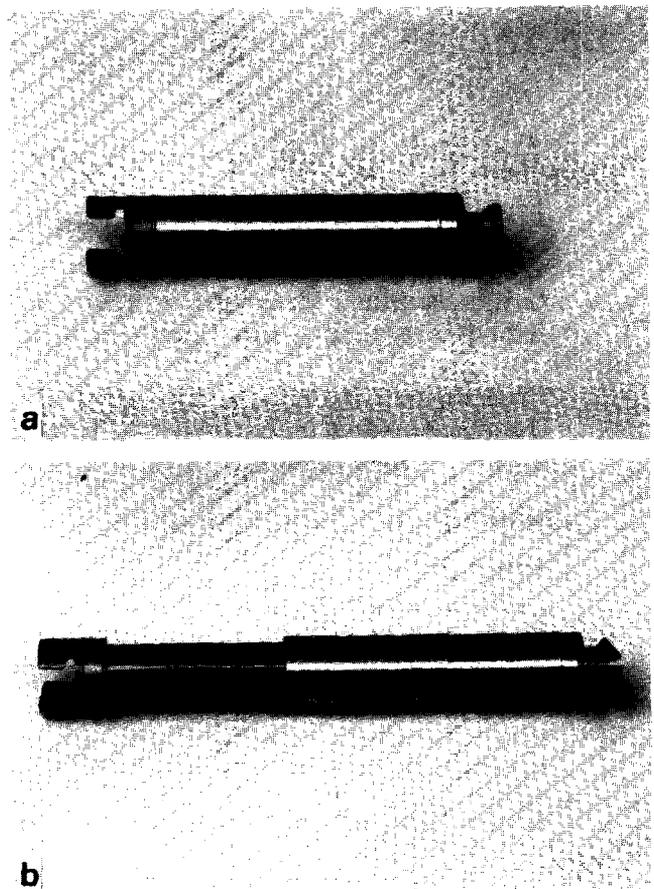


Figure 2 Lengthening element without bellows a, before and b, after full extension

To check the effectiveness of the power supply, the lengthening element was loaded with 450 N, 30 mm eccentric acting, and lengthened by a magnetic field of 0.02 T. Extension appeared to be possible even after five days of inactivity. Since during use in patients forces of 200 N at most are expected, this test proved the satisfactory functioning of the lengthening element. The outer and the inner tube were tested for strength in the same way as the universal connection; no permanent deformation was observed. In order to check whether the bellows and glue bonding were watertight and if the reduced pressure (caused by an increasing volume during elongation of the lengthening element) was equalized by gas diffusion, a prototype was immersed in aerated Ringer's solution and lengthened in steps of 5 mm while measuring the pressure in the model. The bellows and glue bonding proved to be watertight: after four days no moisture had infiltrated the prosthesis. The lowering of the pressure caused by 5 mm lengthening had decreased by 90% in 19 hours.

To check the complete lengthening element with bellows and universal connection, three prototypes were implanted in the tibia of goats. The total extension of 28 mm was reached after seven weekly extensions of 4 mm. All extensions resulted in 4 mm elongations, in spite of an ectopic bone bridge between the two bone segments which had bridged the prosthesis completely. The bellows was intact and had protected the prosthesis from moisture.

Knee components

The two knee components used in the modular endoprosthesis system are derived from an existing semi-constrained knee prosthesis, made from a Co-Cr-Mo alloy. In one knee component the tibial stem is replaced by the universal connection. The tibial part of this knee component is 20 mm in length. In the other knee component the femoral stem is replaced by the universal connection. The femoral part of this knee component is 55 mm long. Both components are obtainable in a left or right configuration.

Hip component

The hip component, used in the modular endoprosthesis system, is derived from an existing hip prosthesis and can be provided with various heads and necks of different materials and sizes. Instead of a stem, this hip prosthesis is provided with the universal connection. The hip component is 70 mm long and obtainable in a left or right configuration. For acetabular replacement, any system (even bipolar) with appropriate cup diameters can be used.

Connectors

The connectors are composed of a hollow shaft with two lids, which are provided with the universal connection. They are manufactured in two parts, the shaft with one lid, and the other lid separately. In order to fasten the two parts of the connector, they may be welded together. Both TIG-welding and plasma arc-welding were tried¹². Plasma arc-welding was preferred because of the small size of the heat-affected zone. Two plasma arc-welded test pieces were subjected to the loading tests as described previously. Both the weld and the shaft were tested and neither showed any permanent deformation. A non-destructive test did not show any cracks. A hole was made in one lid to allow free movement of the protective gas used during the welding process. After the welding process was completed, the hole was closed by a UHMW-PE plug.

Bone-prosthesis connection

The endoprosthesis, assembled from the modular endoprosthesis system, is fixed to the remaining part of the femur with a custom-made, press-fit fixation. A stem, on which the contours of the bone are transposed, is placed in the medullary canal and extracortical side plates with unicortical screws provide for the primary rotation stability. The fixation to the remaining part of the tibia is performed by a stem cemented in the medullary canal. At the Groningen University Hospital these fixations have been applied to the fixation of tumour prostheses^{13,14}. After an observation period from two to eight years no failure was observed.

COUPLE CORROSION

Most elements of the modular endoprosthesis system are made of Ti-6Al-4V. When two elements are manufactured from different material, stocks their composition, although restricted to limits according to ASTM-F136, could differ as much as to cause couple corrosion. Coupling Ti-6Al-4V elements to the Co-Cr-Mo knee component or to Co-Cr-Mo heads of the femur component could also cause couple corrosion. Rostoker *et al.*¹⁵ have performed an investigation on couple corrosion. Potential corrosion couples were formed, amongst others, between Ti-6Al-4V and 316L stainless steel, cast Co-Cr-Mo alloy, Ti-6Al-4V itself, a Co-Ni-Cr-Mo alloy and graphite. The couples were tested *in vitro* for 100 days in a 1% saline solution at a temperature of 37°C. It appeared that no combination except 316L with Ti-6Al-4V created a corrosion problem. By comparing the results of other couples with results of long term *in vivo* experiments, it is probable that the *in vitro* experiments of 100 days are comparable with *in vivo* experiments of at least six years. This research would indicate that couple corrosion among elements of the modular endoprosthesis system is very unlikely to occur.

STARTING POINTS FOR THE COMPOSITION OF THE MODULAR SYSTEM

- (1) The endoprosthesis system has to be suitable for children from age ten years with a tumour in the femur, the knee or the proximal tibia.
- (2) At implantation, the prosthesis may be 20 mm longer than the resected bone, without compromising the function of the neurovascular bundle. Also, a permanent difference in leg length of 20 mm at most is permitted. Therefore, the necessary lengthening capacity may be reduced by 40 mm at most. Consequently, for tumours in the proximal femur (maximum further length growth 38 mm, (Figure 3), no lengthening element is necessary.
- (3) In tumours of the distal femur, the knee or the

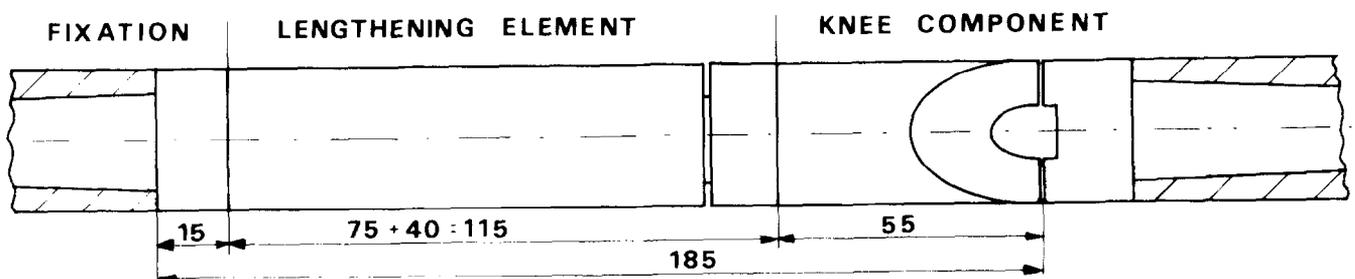


Figure 3 Modular endoprosthesis system to be used after a resection of the distal femur (dimensions in mm)

Table 1 Extra growth (mm) of the femur and tibia of the healthy leg (with regard to the affected leg) as measured on healthy children (min=5 percentile, mean=50 percentile, max=95 percentile).

Age (yr)	Male	Female	Distal growth femur			Proximal growth tibia			Total growth femur		
			min	mean	max	min	mean	max	min	mean	max
10		8	59	76	93	39	50	61	84	108	132
11		9	46	63	80	30	41	52	65	89	113
12		10	30	49	69	18	31	44	42	70	97
13		11	12	34	56	5	20	36	17	48	78
14		12	0	20	40	0	11	24	0	28	56

proximal tibia, the distal femoral and the proximal tibial and fibular epiphyses are always resected or deactivated.

- (4) The growth of the normal leg compared with the affected leg can be determined with the aid of growth tables¹⁶. These list, by age, the increasing lengths of femur and tibia until the end of the growth period, with their deviations. A 2.5% positive correction is applied to the growth length to adjust the data to present-day average heights¹⁷. After resection of the distal femoral epiphysis, the extra growth of the normal leg amounts to 71% of the growth of the femur; after resection of the proximal tibial epiphysis the extra growth of the normal leg amounts to 57% of the growth of the tibia. The extra growths of femur and tibia are listed in *Table 1*.
- (5) The length of a lengthening element equals the lengthening capacity plus 75 mm, a bone-prosthesis connection is 15 mm long.
- (6) In order to keep the number of lengthening elements and connectors within reasonable limits, it was decided to include three lengthening elements with capacities of 40, 60, and 80 mm and five connectors with lengths of 20, 40, 60, 80 and 100 mm.

With these starting points, guidelines for the composition of an endoprosthesis were produced.

ENDOPROSTHESIS COMPOSITION

Endoprosthesis composition after resection of the distal femur

The endoprosthesis to be implanted after a resection of 165 mm of the distal femur is shown in *Figure 3*. The lengthening capacity of the lengthening element is 40 mm. After implantation of the endoprosthesis

Table 2 Composition of the endoprosthesis system after resection of the distal femur (dimensions in mm)

Resection length	Lengthening capacity of lengthening element	Length of femoral connector
185	40	—
205	60	—
225	80	—
245	80	20
265	80	40
285	80	60

the femur is 20 mm longer, which is acceptable, but it does involve a necessary temporary heightening of the healthy leg by 20 mm. The permissible subsequent growth of the healthy leg has increased to 60 mm. If the resection length exceeds 165 mm, the endoprosthesis can be adjusted by implanting a longer lengthening element (with 20 or 40 mm more lengthening capacity) and, in some cases, an extra connector in the femur. The composition of the endoprosthesis system for all resection lengths can be determined from *Table 2*.

Endoprosthesis composition after resection of the proximal tibia

The endoprosthesis to be implanted after a resection of 130 mm of the proximal tibia is shown in *Figure 4*. The lengthening capacity of the lengthening element is 40 mm. As *Figure 4* shows, the tibia is 20 mm longer after implantation of the endoprosthesis, which is acceptable. This increases the permissible growth of the healthy leg to 60 mm. In case of a resection length in excess of 130 mm, the endoprosthesis may be adjusted by implanting a lengthening element 20 or 40 mm longer and, in some cases, an extra connector in the tibia. The composition of the endoprosthesis for all resection lengths can be determined from *Table 3*.

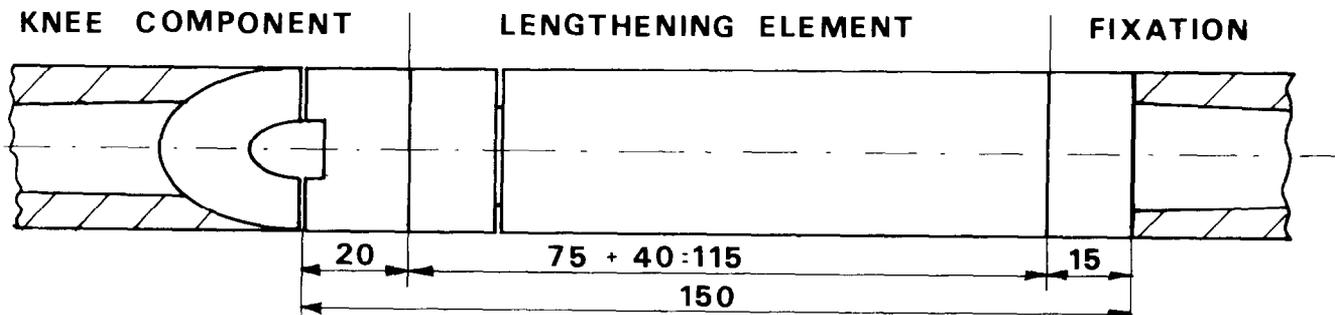


Figure 4 Modular endoprosthesis system to be used after resection of the proximal tibia (dimensions in mm)

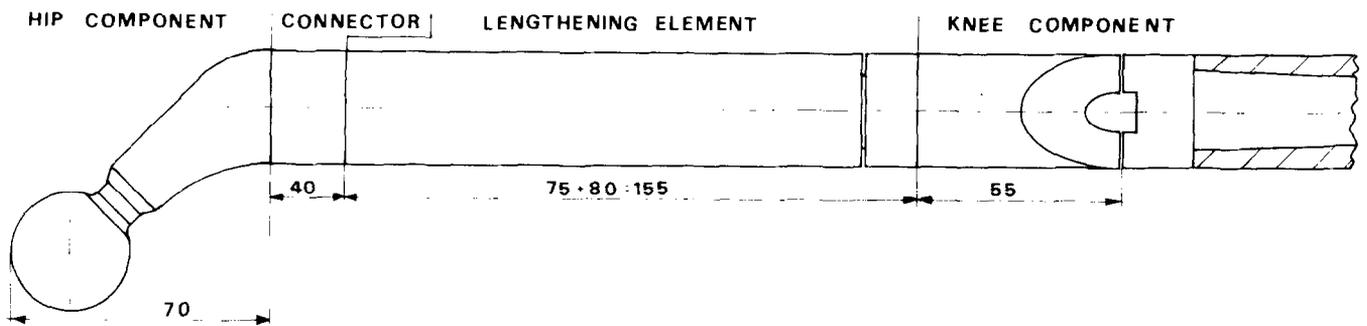


Figure 5 Modular endoprosthesis system to be used after resection of the entire femur (dimensions in mm)

Table 3 Composition of the endoprosthesis system after resection of the proximal tibia (dimensions in mm)

Resection length	Lengthening capacity of lengthening element	Length of tibial connector
130	40	—
150	60	—
170	80	—
190	80	20
210	80	40
230	80	60

Table 4 Composition of the endoprosthesis system after resection of the entire femur

Element	Dimension (mm)	Femoral length
Heightening of healthy leg	20	300-480
	10	300-480
	0	300-480
Femoral connector	20	300-480
	40	300-480
	60	300-480
	80	300-480
	100	300-480
	100	300-480
Lengthening element	40	300-480
	60	300-480
	80	300-480

Endoprosthesis composition after resection of the entire femur

The composition of the endoprosthesis implanted after resection of a femur 300 mm long is presented in Figure 5. The capacity of the lengthening element is 80 mm. After implantation of the endoprosthesis the femur is 20 mm longer, which is acceptable, but it does involve a necessary temporary heightening of the healthy leg by 20 mm. The allowable growth of the healthy leg is then increased to 100 mm. In the case of a longer femur between 300 and 320 mm, implantation of a larger connector is not yet possible. The resected length in excess of 185 mm must therefore be compensated by decreasing the heightening of the healthy leg, which reduces the growth of the healthy leg that can subsequently be permitted. Table 4 presents the composition of the endoprosthesis system for all femur lengths. With the hip component, the system is also suitable for use after resection of the proximal femur (in combination with a bone-prosthesis connection and, if necessary, a connector). In this case, no lengthening element is required.

CONCLUSIONS

The modular endoprosthesis system consists of bone-prosthesis connections, two semiconstrained knee components (in both left and right configurations), lengthening elements (with capacities of 40, 60 and 80 mm respectively), connectors (20, 40, 60, 80 and 100 mm in length), and a hip component with various heads and necks (in left and right configurations) all allowing a correctly sized endoprosthesis to be assembled for boys from age ten and girls from age eight in whom a part of the tibia or femur has been resected as a treatment for a malignant bone tumour. The modular endoprosthesis system described here will be clinically evaluated at the Groningen University Hospital.

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