

Long-term follow-up of children treated with the Repiphysis expandable prosthesis for lower extremity bone sarcoma

Karim Masrouha^a, Miguel Abboud^b, Raya Saab^b, Samar A. Muwakkit^b, Nabil Khoury^c, Rachid Haidar^d and Said Saghie^d

Expandable endoprostheses provide a limb salvage option for skeletally immature patients with bone sarcoma of the lower extremities. Initial reports of the Repiphysis prosthesis were encouraging; however, medium-term follow-up revealed high complication rates. We report on the long-term follow-up of a cohort of patients treated with the Repiphysis prosthesis. Eleven patients were included in the study. Data collected included sex, age at surgery, duration of follow-up, site of disease, histologic diagnosis, number of lengthening sessions, amount lengthened, postoperative complications, endoprosthetic failure, mode of endoprosthetic failure, duration from index surgery to failure and to revision, type of revision surgery and final limb-length discrepancy. The average duration of follow-up from the time of surgery was 180 months (range, 144–215 months). Fifteen Repiphysis implants were used in 11 patients. All implants failed with an average time from surgery to failure of 36 months (range, 3–72 months). Twenty-four complications were observed: one wound dehiscence, two deep infections, 18 mechanical failures, implant collapse with destruction of proximal tibia epiphysis in two and one periprosthetic proximal femur fracture with dislodgement of the stem.

Introduction

Bone sarcomas are the most common primary bone tumors in children. Prior to the 1970s, amputation was the mainstay of treatment, yet mortality was high due to metastatic disease. With advances in neoadjuvant chemotherapy and surgical techniques, limb salvage surgery (LSS) became a viable option; particularly that it carries similar rates of local recurrence and survival as compared to amputation [1]. LSS has thus become the standard of local control in limb sarcomas and the list of contraindications has decreased over time with some surgeons expanding the horizons to include vascular bypass and nerve grafting to save the affected limb.

Since these tumors most commonly arise in areas of rapid growth such as the distal femur, proximal tibia, and proximal humerus, skeletally immature patients may develop a significant limb-length discrepancy (LLD) following resection. This obstacle was overcome with the advent of expandable prostheses. Lewis published one of the first reports on the use of expandable

Despite being an option for limb salvage, the Repiphysis prosthesis has a high rate of mechanical failure and need for revision, similar to other expandable implants. The authors, therefore, recommend full disclosure of the potential short- and long-term complications and need for revision, as well as alternative treatment options if their use is considered. Level of evidence: IV (Therapeutic).

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^aDivisions of Pediatric Orthopedic Surgery and Orthopedic Oncology, Department of Orthopedic Surgery, NYU Langone Health, New York, New York, USA, ^bDepartment of Pediatrics and Adolescent Medicine, American University of Beirut Medical Center, Children's Cancer Institute, ^cDepartment of Diagnostic Radiology and ^dDivision of Orthopedic surgery, Department of Surgery, American University of Beirut Medical Center, Beirut, Lebanon

Correspondence to Said Saghie, MD, Division of Orthopedic Surgery, Department of Surgery, American University of Beirut Medical Center, P.O. Box 11-0236, Riad El-Solh, Beirut 1107 2020, Lebanon
Tel: + 961 (1) 350000 (ext 5444); fax: +961 (1) 363291;
e-mail: ss15@aub.edu.lb

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endoprostheses to help minimize LLD [2,3]. These designs required multiple open surgical procedures for lengthening [2–5]. Later generations allowed for lengthening using magnetic waves, thus precluding the need for repeated surgery. The Repiphysis prosthesis was the first commercially available expandable endoprosthesis which had a lengthening mechanism that did not require surgery. The device, originally manufactured as the Phenix prosthesis (Phenix Medical, Paris, France), was reintroduced by Wright Medical Technology (Arlington, Tennessee, USA) and received FDA approval in 2002. The Repiphysis Limb Salvage System was later acquired by MicroPort Orthopedics Inc. (Arlington, Tennessee, USA), which is the current manufacturer of the implant.

Initial reports described positive short-term results [6–9], but there were increasing concerns regarding high complication rates and poor functional outcomes at longer follow-up [10–13]. In particular, it was noted and later confirmed in a systematic review, that the

Table 1 Demographics and patient outcomes

Patient number	Sex	Age at surgery (years)	Duration of follow-up (months)	Site of disease	Amount lengthened (cm)	Duration to endoprosthetic failure (months)	Mode of endoprosthetic failure	Duration from surgery to revision (months)	Type of revision surgery	Final LLD (cm)
1	F	8	215	Femur	4.0	42	2B, 3A, 6A	53	Repiphysis	
1		12			5.0	21	3A	22	Total femur	1
2	F	12	207	Tibia	2.0	40	3A	46	MP	0
3	F	11	207	Tibia	3.0	36	3A	176	MP	2
4	F	10	198	Tibia	0	3	4A	3	Repiphysis ^a	
4		13			4.0	65	3A	-	-	2.5
5	M	7	189	Femur	4.5	30	2B, 6A	51	Repiphysis	
5		11			4.5	21	2A, 3B	-	-	13
6	M	11	173	Femur	6.5	18	3A	26	Repiphysis	
6		14			5.0	25	3A	29	MP	2
7	M	13	172	Tibia	0	3	4A	54	Knee fusion	0
8	F	13	166	Tibia	4.0	72	3A	144	MP	2
9	M	9	152	Tibia	4.0	36	2B, 3A	63	MP	5
10	M	9	152	Tibia	4.0	65	2B	70	MP	0
11	F	7	144	Femur	4.5	70	2B, 3A	84	MP	2

F, female; LLD, limb length discrepancy; M, male; MP, modular prosthesis.

^aRe-implanted prosthesis.

noninvasive implants had lower revision-free survival than implants which required open procedures for lengthening [14,15]. We have previously reported on our short- and medium-term experience using this implant [13]. The aim of the present study is to report on the long-term radiographic and clinical outcomes of these patients.

Methods

This is a cohort of skeletally immature patients with bone sarcoma of the lower extremity who underwent wide resection and endoprosthetic replacement using the Repiphysis Limb Salvage System at a tertiary multidisciplinary children's cancer center between 2002 and 2008. Demographic, clinical and radiographic data were retrieved from our institution's prospectively collected database after obtaining institutional review board approval. Data collected included sex, age at surgery, duration of follow-up, site of disease, histologic diagnosis, number of lengthening sessions, amount lengthened, postoperative complications, endoprosthetic failure, mode of endoprosthetic failure [16], duration from index surgery to failure and to revision surgery, type of revision surgery, and final LLD.

There were 17 patients treated with primary resection and endoprosthetic reconstruction with the Repiphysis system during the time period indicated. Details regarding chemotherapy, surgical technique, postoperative rehabilitation and lengthening procedures were previously reported [13]. Six patients died of their disease during follow-up and were not included in the present study. The 11 surviving patients had complete follow-up data and were included in the analysis.

Results

Clinical follow-up

Of the 11 patients included in the study, six were women and five were male. The average age at the primary

resection surgery was 10.3 years (range, 6.8–13.7 years). The diagnosis was osteosarcoma in 10 patients and Ewing sarcoma in one. The tumour was located in the distal femur in four patients and the proximal tibia in the remaining seven (Table 1).

The average duration of follow-up from the time of surgery was 180 months (range, 144–215 months). Three patients had a second Repiphysis inserted for additional lengthening. One prosthesis that was removed for a deep-seated early infection was later reinserted and lengthened successfully. Therefore, a total of 15 Repiphysis implants were used. All of these implants failed with an average survival time from surgery to failure of 36 months (range, 3–72 months) and to revision of 46 months (range, 3–176 months). Several patients had a significant delay between the diagnosis of implant failure and revision surgery. In particular, patients 3 and 7 were delayed due to financial reasons and patient 8 was delayed due to parental preference to postpone the surgery.

Two patients did not undergo lengthening due to early infection. Excluding these two, there were an average of three lengthening sessions (range, 2–6) per patient with a mean of 4.2 cm (range, 2.0–6.5 cm) gained per prosthesis. Contralateral epiphysiodesis was performed in two patients to balance the LLD. Nine patients had an LLD of 2.5 cm or less, whereas two patients had an LLD of greater than 2.5 cm at final follow-up (these were 5 and 13 cm, in patients 5 and 9, respectively). One patient was just under seven years of age at the time of surgery for a distal femur osteosarcoma. His prosthesis was lengthened 4.5 cm but the ipsilateral proximal tibial physis was damaged due to collapse of the prosthesis, which impacted tibial growth. This was revised and the second prosthesis could not be lengthened more than 4.5 cm with loosening of the femoral stem and perforation through the cortex. This patient also had a failure of the expansion mechanism. At final follow-up, he had a 13.0 cm LLD

Fig. 1



(a,b) Loosening of the femoral and the tibia stems; note the collapse of the proximal tibia growth plate and the lengthening of 4.5 cm. (c) Scanogram after revision with another Repiphysis prosthesis and additional lengthening. (d) Follow-up after 2 years with loose stems, proximal migration of the femoral stem, fracture of the expansion mechanism and 13 cm LLD despite epiphysiodesis performed on the contralateral limb.

combined from the femur and tibia (Fig. 1). The second underwent resection of a proximal tibia osteosarcoma at nine years of age. He achieved equal leg length with 4.5 cm of lengthening. However, a combination of failure of the expansion mechanism, loosening of the stem and dislocation of the prosthesis leads to a 5.0 cm LLD that could not be corrected with a modular prosthesis.

Complications

Of the 15 Repiphysis prostheses used (in 11 patients), 24 complications were observed: one wound dehiscence, two deep infections, 18 mechanical failures (failure of the expansion mechanism in ten, loosening in six, fracture of the femur stem in one, prosthesis dislocation in one), implant collapse with the destruction of proximal tibia epiphysis in two and one periprosthetic proximal femur fracture with dislodgement of the stem (Table 1). The three patients who underwent revision with a second Repiphysis prosthesis are included twice in the table. Failures were classified according to Henderson *et al.* [16].

In total, twelve prostheses were revised; eight for failure of the expansion mechanism (three had concomitant loosening and three had reached the maximum growth potential), one femoral stem fracture, one deep infection and two for aseptic loosening. Three of the twelve revisions involved using a new Repiphysis device, and one had re-implantation of the same device (the patient with a deep infection).

One patient with a deep infection had unsuccessful attempts to salvage the prosthesis and ended up with a knee fusion several years later. Two patients with a failed prosthesis are awaiting revision surgery.

Revision for failure of the expansion mechanism

Of ten prostheses that sustained a failure of the expansion mechanism, nine were revised. Patient 1 had a jammed expansion mechanism after 4.0 cm of lengthening followed by breakage of the spring and loss of 1.5 cm of length. Patient 2 and 3 had a failure of the expansion mechanism at 40 and 36 months, respectively. This was

after they completed lengthening. The prostheses were revised 6 months and 12 years later, respectively. Patient 5 had a revision of his first prosthesis; his second prosthesis was complicated by loosening, fracture of the proximal femur and breakage of the expansion mechanism as well. Patient 6 had a failure of expansion mechanism at 26 months during his first lengthening (6.5 cm) and at 25 months during his second. A revision within 6 months allowed him not to lose more than 1.0 cm in each time. Patient 8 had a failure of the expansion mechanism 6 years after implantation. Six years later she underwent her prosthesis. At the time of revision, she had lost 2.5 cm out of 4.0 cm gained. Patient 9 sustained a fracture of expansion mechanism three years after their surgery. He was lost to follow-up for two years before the prosthesis, which was completely dislodged, was revised (Fig. 2). At the time of revision, he had lost 3.0 cm out of 4.0 cm gained. Patient 11 had a breakage of the expansion mechanism 6 years later but she revised her prosthesis within a year so she lost only 1.0 cm out of 4.5 cm gained. The average shortening after expansion mechanism breakage was approximately 1.6 cm (range, 1.0–3.0 cm).

Revision for loosening

Two patterns of loosening have been noted: (1) cemented stem loosening from the resection side (two prostheses); (2) displacement of the smooth stem from the other side of the joint (two prostheses). The tibial component was involved in all four of these prostheses. In two prostheses, there was a loosening of both components. Loosening was associated with other complications in all but one patient. These included the failure of the expansion mechanism in four prostheses, dislocation in one prosthesis, periprosthetic fracture in one and growth plate collapse in two patients.

Revision for infection

Deep infection (type 4 failure) occurred in two patients (patients 4 and 7). The first was diagnosed 4 months after implantation. It was treated with extraction of the prosthesis, insertion of a cement spacer and intravenous (IV) antibiotics for 3 months. Re-implantation of the same prosthesis was performed 6 months later. The same prosthesis was used to limit cost. This patient achieved 45 mm of lengthening following the re-implantation procedure. The second patient had an acute infection. An attempted salvage of the prosthesis with irrigation and debridement, free flaps and IV antibiotics was performed. However, he had a persistent deep infection and loss of soft tissue coverage and he refused further treatment for four years after which he returned for a knee fusion using the Ilizarov technique with medial displacement of the ipsilateral fibula.

Discussion

Over the past several decades, multiple expandable implant systems have been designed for reconstruction

Fig. 2



(a) Early loosening of the tibia stem during ongoing lengthening. (b) Loosening of the tibia stem with fracture of the expansion mechanism three years later. (c) The patient was lost to follow-up for 2 years. He presented with a dislocated prosthesis and total loss of the acquired expansion.

after wide resection of bone sarcoma in the growing child. Initial implants required multiple invasive surgeries for lengthening with short-term results demonstrating revision rates of 23% at a mean follow-up of 2 years [17]. However, in the 1990s new prostheses were developed that allowed for noninvasive lengthening through the application of an external electromagnetic field [7,9,18]. Although there were no complications attributed to lengthening procedures themselves, Wilkins and Souberian reported two mechanical complications in one patient [9]. Following that, short- and medium-term studies showed an unacceptable complication rate. Based on a recent systematic review of expandable endoprostheses, the overall complication and revision rate at more than 10 years follow-up was 89%; however, this was a heterogeneous group and there have been no long-term studies on the Repiphysis prosthesis [15]. The current study reports on the long-term results, at a minimum 12-year follow-up, of 11 pediatric patients treated with

15 Repiphysis prostheses, all of which failed, requiring revision surgery.

The complication rate of the initial cohort was 56% (15 complications in 27 prostheses); two type I, four type II, five type III, three type IV and one type V. The infection rate was comparable to previously published studies involving both Repiphysis and traditional invasively expandable endoprostheses, which have been reported as high as 18% [9,10,13,19–21]. Tibial physal growth disturbance (type 6A failure) has also been described in up to 65% of patients who underwent distal femoral resection [16,22]. Of the four patients in our series who underwent distal femoral resection, two developed a tibial physal growth disturbance.

In 2003, a multicenter study by Neel *et al.* reported the results of 60 expansions in 18 Repiphysis prostheses implanted in 15 patients [7]. The mean follow-up was 21.5 (12.0–33.0) months. There were no complications associated with the lengthening procedures themselves. They had a mean of 3.7 cm of lengthening and MSTTS scores averaging 90 %, but there was a 44% complication rate including six prosthetic fractures and two aseptic loosening [7]. Longer-term studies using the Repiphysis prosthesis, including our own initial cohort, show similar complication rates, with mean MSTTS scores ranging from 67 to 90% and patients gaining a mean of 2.5–3.9 cm of lengthening [10,13,14]. Complication rates were similarly high in the more invasive designs, though the mechanisms were slightly different. Schinhan *et al.* reported on 71 patients treated with invasive expandable endoprostheses, 69 of which were the Kotz Modular Femur Tibia Reconstruction System (KMFTRS) [23]. At a minimum follow-up of 27.2 months, they reported 184 complications, mainly soft tissue failure, structural failure, aseptic loosening and infection, with only 13 patients not suffering from complications [23]. Schiller *et al.* reported on 20 patients who had the KMFTRS prosthesis and found that 35% required revision at a mean of 6.3 years follow-up [24].

The Juvenile Tumour System (JTS, Stanmore Implants Worldwide, Stanmore, UK) also incorporates a magnetic field for noninvasive expansion after tumour resection in skeletally immature patients. In contrast to the Repiphysis design, the JTS contains a magnetic disc, a gearbox and a power screw embedded within the shaft of the prosthesis. When exposed to an external electromagnetic field the implant expands at a fixed rate. A limitation of the Repiphysis relative to the JTS is that it requires conversion to a nonexpandable adult prosthesis at skeletal maturity while the JTS is designed to be a permanent implant. One of the limitations of the JTS is that the use of MR imaging is contraindicated due to interference with the electromagnetic motor [25]. Given the value of MR imaging for restaging in this patient population, the use of devices that prohibit this

imaging modality must be carefully considered [26,27]. Furthermore, it is not known whether a patient will be able to function with a pediatric size endoprosthesis in the long term. Hwang *et al.* reported on the use of the JTS in a series of 25 patients [18]. They reported a mean of 3.2 cm of lengthening, a mean MSTTS score of 85%, and a complication rate of 38%. Other studies have reported a similar experience, particularly with regards to complication rate and overall survival [19,28,29]. In their series of 42 patients treated with a proximal tibia JTS, Tsagozis *et al.* had a 5-year and 10-year implant survival of 55 and 25%, respectively, suggesting that patients with proximal tibia implants may be at a greater risk for revision [30]. Gilg *et al.* had one of the largest series, which included 51 implants and they reported a 5-year revision-free survival of 61.6% [29], however, a recent report of a heterogeneous group of 299 patients, found that those with the JTS implant (53% of the total cohort) had a greater than 90% rate of implant survival at 10-years follow-up [31].

A recent study reported on their outcomes with both Repiphysis and JTS [21]. They followed up 28 patients who had the Repiphysis prosthesis implanted and 12 patients with the JTS implanted [21]. JTS implant survival was 100% at a mean follow-up of 6.2 years, while the 5-year implant survival of the Repiphysis prosthesis was 21% and all of the remaining implants had been explanted at final follow-up, within less than 10 years [21]. The most common causes for revision included mechanical failure, aseptic loosening and fracture, whereas in the JTS group only the implant was revised for reaching its full lengthening potential [21].

A report on 33 survivors treated with a custom-made expandable implant reported similar results, including a mean lengthening of 4.2 cm and a 5-year prosthesis survival rate of 59.4% [32]. The complications were also similar, including aseptic loosening and infection; however, there were no fractures of the prostheses, just one case of dislocation and another who sustained a periprosthetic fracture. Torner *et al.* reported on the MUTARS Xpand Growing Prosthesis in seven patients (six distal femur and one proximal femur) with a minimum 2-year follow-up [33]. The average lengthening was 3.6 cm. Two patients died of pulmonary metastases with functional prostheses, one patient had a failure of the lengthening mechanism after obtaining MR imaging for trauma, and one patient had a late deep infection. More data is needed on this prosthesis to better understand if its overall complication rate and survival in the medium and long-term differ from the Repiphysis or other expandable prostheses.

This study is subject to all the inherent limitations of a retrospective study design. It is, however, the longest follow-up study on patients treated with this implant and one of the largest initial cohorts. None of the patients

were lost to follow-up and all survivors were followed up for a minimum of 12 years. Additionally, all patients were treated at the same multidisciplinary tertiary cancer center by the same limb salvage team.

In conclusion, although the Repiphysis prosthesis is an option for limb salvage in skeletally immature patients it has significant drawbacks, as with other expandable implant designs, and ultimately requires conversion to an adult prosthesis. Failure of these prostheses may lead to a partial loss of the acquired length. Patients treated with this prosthesis should be monitored closely during and after lengthening. Revision is required as early as possible when fracture of the expansion mechanism occurs. Radiographic signs of loosening or collapse of the tibial plateau are two other indications for revision especially when lengthening is completed.

The authors recommend a full discussion of the potential short- and long-term complications associated with the use of this prosthesis as well as other expandable prostheses, and any alternative appropriate treatment options with patients and their families prior to surgery.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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