Outcome of expandable endoprosthesis: A single centre retrospective review

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Abstract
Purpose: Expandable endoprosthesis allows limb salvage in children with an option to leading a better life. However, the revision rate and implant-related complications impose as a limitation in the skeletal immature. This study investigates the functional outcomes and complications related to expandable endoprosthesis in our centre. Materials and Methods: Twenty surviving patients with expandable endoprosthesis from 2006 till 2015 were scored using Musculoskeletal Tumour Society (MSTS) outcomes instrument and reviewed retrospectively for range of motion of respected joints, limb length discrepancy, number of surgeries performed, complications and oncological outcomes. Patients with less than 2 years of follow-up were excluded from this study. Results: Forty-five percentage patients reached skeletal maturity with initial growing endoprosthesis and 25% of patients were revised to adult modular prosthesis. One hundred fifty-seven surgeries were performed over the 9-year period. The average MSTS score was 90.83%. The mortality rate was 10% within 5 years due to advanced disease. Infection and implant failure rate was 15% each. The event-free survival was 50% and overall survival rate was 90%. Conclusion: There is no single best option for reconstruction in skeletally immature. This study demonstrates a favourable functional and survival outcome of paediatric patients with expandable endoprosthesis. The excellent MSTS functional scores reflect that patients were satisfied and adjusted well to activities of daily living following surgery despite the complications.

Keywords
bone tumour, expandable endoprosthesis, functional outcome, limb salvage, survival outcome

Date received: 9 September 2018; Received revised 8 April 2019; accepted: 24 April 2019

Introduction
Amputation is no longer the mainstay of treatment in musculoskeletal oncology of the extremities. With advances in orthopaedics, chemotherapy, implant designs, imaging and surgical expertise, it is now possible to carry out limb salvage surgery (LSS) without compromising the surgical margins and function. Various studies have established the superiority of LSS compared to amputation. The resected tumour bone now can be replaced with a metal prosthesis with an articulating joint to allow movement and function. The return to function is almost immediate and it is not influenced by the subsequent adjuvant treatment. Various studies with large series report 10 years implant survival to be around 80%. LSS in children is challenging due to the dynamic nature of their bone. The common problems faced in the skeletally immature are the narrow medullary canal, which limit the stem size and choice of implants, and the continuous bone remodelling, that is, growth both in width and length,
which eventually leads to loosening of the prosthesis and multiple revision surgeries. This group of patients experiences limb length discrepancy (LLD) due to resection of the involved growth plate and disruption of the adjacent growth plate. An expandable endoprosthesis enables periodic lengthening to match the growth of the unaffected limb. We describe a single centre experience of using expandable endoprosthesis for skeletally immature with primary bone tumour for limb salvage.

Materials and methods

Study design and inclusion criteria

A retrospective review of 20 skeletally immature patients treated by LSS with expandable endoprosthesis for primary bone tumour during a 9-year period (2006–2015) at a single tertiary care referral centre. Each patient has a minimum of 2-year follow-up.

Objective

The primary objective of this study was to determine the functional and survival outcome. The secondary objectives were to identify the common complications and implant failure rates.

Implant, surgical procedure and follow-ups

The prostheses were custom-made by Eagle Osteon Technologies, Chennai, India. The implants were made from titanium alloy. The maximum amount of lengthening achievable was determined by the length of the custom-made prosthesis, which in turn was determined by the length of bone resected. The manufacturing process generally took between 4 and 6 weeks. An example of the schematic diagram and the final product is shown in Figure 1.

The following outlines the steps taken from the time of patient’s presentation up to insertion and the lengthening of these endoprosthesis.

Preoperative. Patients presenting with a primary bone tumour first underwent magnetic resonance imaging (MRI) of the involved limb to determine the feasibility of LSS. The local extent of the tumour and the involvement of the neurovascular structures were assessed. Subsequently, staging studies were performed to determine the systemic extent of the disease, which consisted of computed tomography (CT) thorax and bone scan. The final diagnosis was confirmed via a tissue biopsy. Neoadjuvant chemotherapy was initiated immediately after confirmation of the diagnosis. Our Centre uses Children’s Cancer Group (CCG-7921) chemotherapy protocol for osteosarcoma and European EURO-E.W.I.N.G. 99 chemotherapy protocol for Ewing’s sarcoma. During neoadjuvant chemotherapy period, the custom-made growing endoprosthesis was ordered based on measured lower limbs films and MRI scan.

Surgical procedure. All surgeries were performed by a single surgeon and assisted by the team members. Wide resection was carried out in all cases. The biopsy tract was excised en bloc with the tumour and sent for histopathology examination. For the initial series of cases (2006 up to 2014), the prostheses were cemented. However, after 2014, these
prostheses were inserted without cement and modifications such as spikes at the end of the tibial plates, wider and longer stems we used to achieve better stability of the implant. These changes were made to facilitate revision of the prosthesis in the future. Complex reconstruction such as free tissue transfers or the use of nerve/vessel grafts was not indicated in any of our cases. However, a gastrocnemius rotational flap was regularly used for cases of proximal tibia resections for soft tissue coverage of the implant and reconstruction of the extensor mechanism. The initial design of the prosthesis incorporated a hinge rotating knee mechanism but these were changed to simple hinge prosthesis to reduce the thickness of the tibial component. This allowed us to preserve the proximal tibial growth plate without altering the level of the knee joint. Longevity of the implant is not a major concern as these implants are temporary and will eventually be converted to adult modular prosthesis upon attaining skeletal maturity.

The proximal humerus resections were carried via deltopectoral approach. The shoulder joint capsule was reconstructed with polypropylene mesh, and the remnant of rotator cuff muscles was sutured to the reconstructed capsule.

Post-operative management. Intravenous antibiotic was given for a minimum of 5 days. Skin staples were removed 14 days after the surgery.

Check radiographs were carried out on postoperative day 1. Physiotherapy was started after wound inspection. Majority of our patients were discharged between days 5–7 post-operatively once they had started ambulating full weight bearing with a knee brace for better stability. Patients with proximal humerus resections were discharged earlier with arm sling for 6 weeks.

Adjuvant chemotherapy according to the respective protocol was resumed 2–3 weeks after surgery, once the surgical wound had healed completely. After the completion of treatment, patients were followed up at three monthly intervals for the first 2 years, then at six monthly intervals for the next 3 years and once a year for up to 10 years.

Lengthening. The prosthesis design used is the Lewis-type expandable adjustable prosthesis (LEAP). It requires a minimally invasive surgical procedure for lengthening under the guidance of an image intensifier. The lengthening is performed using an Allen key (Figure 1). It is carried out once there is more than 1 cm of LLD. The LLD was determined via both clinical and radiological (long leg measured radiographs) examinations during follow-ups.

At each sitting, the limb is lengthened by 1.0 cm for proximal tibia, 1.5 cm for distal femur and 0.5 cm for humerus. This controlled lengthening is to prevent over stretching of adjacent neurovascular structures and joint contractures due to the differential muscle stretching ability. This procedure is usually followed by regular physiotherapy and continuous passive motion (via the continuous passive movement (CPM) machine) in the ward. In cases where there is over lengthening or poor compliance which leads to fixed flexion deformity of the knee, manipulation under anaesthesia or posterior capsular release (PCR) was required before further lengthening could be performed.

Survival and statistical analysis. Survival outcomes were determined by event-free survival (EFS) and overall survival (OS). Statistical analysis was carried out using SPSS version 20. A p-value of <0.05 was considered statistically significant.

For this study, the EFS is defined as the length of time after primary treatment for cancer that the patient remains disease or complication free. An event is the onset of recurrence of disease (locally or systemically). OS is defined as the length of time from the date of diagnosis to the point of reference time for those who are still alive (with or without disease). Functional outcome was evaluated based on Musculoskeletal Tumour Society (MSTS) scoring system.

Results

Demography

Over 200 limb salvage surgeries with endoprostheses were performed during the study period. Of these, a total of 28 patients were less than 18 years of age. Six patients of the 28 patients (21.42%) had adult modular endoprostheses because they were nearing skeletal maturity. The remaining 22 patients (78.57%) had expandable endoprostheses. Two patients were excluded, as their follow-up was less than 2 years during the time of review. Resultant 20 patients were recruited.

Male to female ratio was 4:1 (male/female: 16/4). The mean age at presentation was 12.8 years (range: 5–17 years). The youngest male was 5 years old and oldest 17 years old, the youngest female was 12 years old and oldest 16 years old at time of surgery.

Clinical presentation

Only one patient had Ewing’s sarcoma and 21 patients had osteosarcoma. The distal femur (n = 11) and proximal tibia (n = 6) were the most common sites of primary malignant bone tumours. There were two cases (10%) of total femur and one proximal humerus replacements. For the lower limb prosthesis, there were 12 cases (60%) of cemented hinge rotating prosthesis, and the rest were simple hinge prosthesis inserted without cement.

Limb lengthening

A total of 56 lengthening procedures were carried. The average resection length for the lower limb prosthesis was 20 cm (range: 15–24 cm). By nature of the growth potential, the younger patients required more lengthening procedures. The mean LLD in 19 patients that underwent lower limb replacements at the end of the study period was 30.2
mm. The largest LLD was a case of distal femoral resection that had a discrepancy of 74 mm. This was because his treatment was complicated by implant infection and proximal stem cut out. In three of the cases, the operated limb was still longer (maximum LLD: 24.6 mm) compared to the unaffected limb as the prosthesis inserted longer at the primary surgery. Thus, only 16 patients underwent lengthening procedures, amounting an average of 3.3 lengthening procedures per patient.

There was only one case of proximal humerus lengthening, in which the total lengthening done was 4 cm, but the actual increase in length of the arm was only 2 cm. This was due to the proximal migration of the prosthesis and distal migration of the stem leading to violation of the elbow joint (Figure 2). Further lengthening was not carried out for this patient.

Follow-up

The mean duration of follow-up was 79.55 months (range: 33–110 months). Seventeen (85%) of 20 patients were followed up for more than 5 years duration. Two (10%) of the 20 patients developed metachronous bone metastasis during the follow-up period and had to undergo wide resection with modular endoprosthetic. Two patients (10%) with osteosarcoma of the distal femur diagnosed at an early age of 9 and 10 years had achieved maximum lengthening of the implant and underwent revision to another expandable endoprosthetic.

Local recurrence. One patient (5%) had local recurrence and unfortunately developed it twice. The first recurrence was treated with wide resection and split skin grafting. The second recurrence at the same site required a repeated wide excision and gastrocnemious rotational flap. In both incidences, LLS was successful. This patient remains disease free at the time of this review.

Distant bone metastasis. We encountered two patients (10%) with distant bone metastasis. Both patients received a second line chemotherapy followed by LSS. The first patient was a case of osteosarcoma of the femur and had a total femur growing endoprosthesis replacement. He subsequently developed a bone metastasis to the proximal humerus 18 months after completion of primary treatment. He underwent a proximal humerus resection and endoprosthesis replacement. Unfortunately, he developed a local recurrence over the same proximal humerus site a year later and had to undergo a forequarter amputation. He eventually succumbed to extensive systemic metastasis.

The second patient presented with a humerus metastasis 24 months after completion of primary treatment and had a total humerus replacement done. He remains disease free at the time of this review.

Lung metastasis. Eight patients had lung metastasis (40%) at presentation. Four patients had stable metastasis (nodules smaller than 5 mm on serial CT scan of the lungs). The other four patients required metastectomy due to progression of the lung metastasis (three unilateral and one bilateral). Two of the patients in this metastectomy group eventually developed recurrent lung metastasis and succumbed to the disease. The remaining two patients did not develop new lung metastasis during treatment or follow-up.

Surgeries

A total of 124 surgical procedures were performed for these patients. The average procedure per patient was 6.2 (Table 1).

| Procedure                              | Number of surgeries |
|----------------------------------------|---------------------|
| Lengthening                            | 56                  |
| Chemopert insertion and removal         | 30                  |
| Manipulation under anaesthesia          | 7                   |
| Wound debridement for infected endoprosthesis | 6              |
| Thoracotomy                            | 4                   |
| Posterior capsular release              | 4                   |
| Revision to new growing endoprosthesis  | 4                   |
| Revision to modular prosthesis          | 3                   |
| Local recurrence resection              | 2                   |
| Metachronous bone metastasis operated   | 2                   |
| (endoprosthesis)                       |                     |
| Two-stage revision to modular prosthesis| 2                   |
| Forequarter amputation                  | 1                   |
| Rotationplasty                         | 1                   |
| Above knee amputation                   | 1                   |
| Plating (periprosthetic fracture)       | 1                   |
| Total                                  | 124                 |
Complications

List of complications are given in Table 2.

Implant infection. Three patients (15%) had implant infections and all three developed the infection after lengthening procedures. First patient required four debridement surgeries, which included a two-stage revision and exchange to an adult endoprosthesis. Second patient was a case of distal femur endoprosthesis, which showed a proximal femoral stem septic loosening after lengthening procedure. He underwent three surgical debridement and retention of the endoprosthesis, but the infection persisted. He eventually opted for a Van Ness Rotationplasty. The third patient is described under the periprosthetic fracture as he had both complications.

Periprosthetic fracture. Two patients (10%) developed periprosthetic fracture. The first was over the femur and patient underwent internal fixation with plating. The fracture healed well, but one of the lengthening procedures was complicated with infection. Subsequently, had to undergo a two-stage revision with a new growing endoprosthesis after which lengthening was continued. He unfortunately developed a recurrent infection in the new endoprosthesis, which eventually leads to an above-mentioned knee amputation. The second was peri-prosthetic fracture at the proximal third of the femur and was treated with hybrid mesh cast for 3 months. In both cases, the fractures united well, and the patients were able to ambulate full weight bearing after the fractures united.

Prosthesis cut out. There were two cases (10%) of distal migration of the stem post lengthening procedures. They were cases of proximal humerus (Figure 2) and proximal tibia (Figure 3) endoprosthesis where the stems subsided during lengthening procedure and perforated the adjacent joint. Both patients were observed, as the implants were stable and their daily functions were uncompromised. We did not perform any more expandable endoprostheses for upper limb after the encounter.

Failure of screw-jack system. Two patients (10%) had an early failure of the growing endoprosthesis screw-jack mechanism. The first implant failed to reach the maximum manufacturer specified length and the other had blunting of the turning nut grooves at the first lengthening, thus resulting in failure to lengthen further. Both cases were revised into new expandable endoprosthesis.

Soft tissue failure. Lengthening of growing endoprosthesis often causes stiffness of the adjacent joint due to soft tissue contracture and hamstring tightness. Interventions such as manipulation under anesthesia (MUA) and PCR are sometimes required to improve the range of motions of the affected limb. Seven (35%) of our patients required MUA and four (20%) required PCR.

Functional score

Overall mean MSTS scores for the patients were 90.83%. Lowest score was seen in the patient with humeral stem migration (76.7%), and the highest score obtained was 100% for a case of distal femur expandable prosthesis (Figure 4).

Status of the patients

The status of the patients at the end of the study is shown in Figure 5. Slightly over half of the patients retained the expandable endoprosthesis with 16 patients (80%) completing the lengthening. Upon completion of final lengthening in these cases, there was an LLD of less than 2 cm and the patients had acceptable functions. A quarter of the cases were converted to adult modular endoprosthesis. Ten percentage succumbed to their disease and 10% ended up with amputation or rotationplasty secondary to infection.

Survival

Seventeen of 20 patients completed a minimum period of 5 years follow-up. The calculated 5-year EFS was 50%, and the OS was 90% at 5 years. This was attributed by two mortalities. Implant failure rate (infection, fracture and stem migration) was 35%.

Discussion

The main stay of treatment for primary malignant bone tumour had been amputation but with advances in orthopaedic surgery and chemotherapy, survival rates have improved. This together with innovations in bioengineering made LSS possible. The concept of LSS was introduced in the 1970s and has been established as the modern practice in the management of primary bone tumours affecting extremities.6–8 LSS with the use of fixed length prosthesis

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**Table 2. Summary of complications.**

| Type of failure                  | Occurrence, n = 20 (%) |
|---------------------------------|------------------------|
| **Mechanical**                  |                        |
| Soft tissue failure             |                        |
| Restricted range of motion      | 35                     |
| Wound healing problems          | 10                     |
| Insufficient soft tissue coverage| 5                      |
| Rupture of extensor muscles     | 5                      |
| Structural failure              |                        |
| Screw jamming or breakage       | 10                     |
| Periprosthetic fracture         | 10                     |
| Prosthesis cut out              | 10                     |
| **Non-mechanical**              |                        |
| Infection                       | 15                     |
| Lung metastasis                 | 40                     |

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in skeletally immature patients often leads to LLD. Therefore, expandable endoprosthesis was introduced. The Birmingham Bone Tumour Service introduced the first expandable endoprosthesis for paediatric bone tumours in 1975 by Professor John T Scales. It enables the replacement of the tumour bone with a metal prosthesis as well as retaining mobility of the resected joint and most importantly allows lengthening of the affected limb.4

The LEAP prosthesis requires a minimally invasive surgical procedure, carried out in the operating theatre with image control with the use of an Allen key, inserted via a puncture wound under aseptic technique. It has been widely used with documented promising results.9 Currently, non-invasive expandable prosthesis is available, where lengthening is done in a non-invasive manner via external magnetic coil.10 These, however, are expensive. Our centre still uses LEAP as it is a quarter the cost of non-invasive expandable endoprosthesis.

Lengthening procedures are performed to match the growth of contralateral limb. Younger patients generally required more lengthening and sometimes change of prosthesis once the prosthesis has reached its maximum growth to match their growth. The average LLD at the end of the study period was 30.2 mm. Thus, depending on the age, a patient would need to undergo an average of 3.3 lengthening procedures. Which is acceptable provided no complications occur. The OS in our study was 90% at 5 years that is more than the 60–70% reported in literature.11

Goorin et al. reported that recurrence of disease or metastasis is uncommon. His EFS was 65% for patients with immediate surgery and 61% for those who received neoadjuvant chemotherapy.12 Our EFS was 50% after completion of treatment. Local recurrence was seen in 5% of our patients and 10% had distant bone metastasis. We noted lung to be the commonest site for metastasis with 40% of patients having lung metastasis at presentation. In our centre, we perform lung metastectomy for selected cases (solitary nodules, peripherally located, not responding to chemotherapy) for better survival. However, 50% of our patients with lung metastasis did not require surgery because the lung metastasis had either resolved with neoadjuvant chemotherapy or reduced in size to less than 5 mm. Nodules sized 5 mm and less are generally observed and not removed as they can be difficult to locate during surgery; therefore, we monitor them regularly with CT scans (3 monthly at first and if they remain stable, 6 monthly then yearly). Goorin et al.12 reported a poor prognosis in patients with lung metastasis, but this was not seen in our series as we performed metastectomy for 50% of our cases.
Harris et al. also reported that patients with distant metastasis have a poorer outcome compared to lung metastasis. In our series, 10% of our patients had second bone metastasis and were successfully treated with second line chemotherapy and LSS. Finally, only one of them (50%) eventually succumbed to the disease.

The average procedure per patient was 6.2, which is a lot less compared to 8.7 mentioned in literature. This figure included insertion and removal of cheomoport, excluding it amounts to 4.2 procedures per patient. A higher number of lengthening surgeries translated to a higher complication rate, as such implants required open surgery for lengthening. In our series, three patients (15%) developed infection after the lengthening procedures. The Birmingham group reported a long-term infection rate of 10% in patients with endoprosthesis and another study reported 27%. They also reported an infection rate of 1% per lengthening procedure and only a 20% possibility of cure. The introduction of magnetic non-invasive lengthening endoprosthesis eliminates this risk but comes with a significantly increased cost, which is not economically feasible for the developing countries. Stiffness and contracture following limb cost, which is not economically feasible for the developing countries. A larger cohort of patients would have produced a more reliable outcome but such cases of primary malignant bone tumour requiring expandable endoprosthesis are limited. Our centre holds the largest series of expandable endoprosthesis in our country.

Despite the number of surgeries and complications encountered, functionally patients performed well after limb salvage and endoprosthesis replacement. The average MSTS score in our series was 90.83%. It represents a healthy level of satisfaction among our patients. A similar MSTS functional score was reported by Neel et al., in their series of non-invasive expandable endoprosthesis. It should be noted that their study was on non-invasive expandable endoprostheses. Five-year EFS in our centre was 50%, which is similar to those reported in the literature, that is, 46.7–60.1%. Henderson et al. did a review of 26 cases of expandable endoprostheses and reported an average MSTS score of 87% with residual limb length discrepancy of 0.7 cm but he had 1.42% complication rate with 38% of revision surgeries. Their series contain mixture of invasive and non-invasive expandable prosthesis. Generally, he found that these patients showed high emotional satisfaction. Eckardt et al. in their review of 32 patient have expandable endoprostheses, only 16 had lengthening done as 10 of them passed away due to disease, 3 underwent amputation and another 3 were awaiting lengthenings procedures. The implants used were mixed with 12 of them being the LEAP prosthesis. Fifty percent of his patient who underwent lengthening had complications. Overall, he reports a good to excellent functional scores (MSTS).

The other universal complications of using expandable prosthesis reported in the literature are retardation of growth of the opposite growth plate. Arteau et al. in her review of 23 skeletally immature patient who underwent distal femur Endoprostheses replacement found that 65% of the patient experience tibial growth disturbance with 43% with progressive shortening. In our series, five cases that were converted to adult modular prosthesis, we had to build up the tibia in three cases by 1.5–2 cm to match the joint line on the opposite side.

The use of non-invasive prosthesis is not without complications as the technology is new and the implant design is not tried and tested, unlike the Lead prosthesis. A good example is the Repiphysis Limb Salvage System which has been reported to a high degree of complications, mainly bone loss.

The future of paediatric LSS is heading towards joint sparing surgeries for selected cases where the tumour has not invaded the physis (growth plate). This surgery has been made popular by the Hong Kong group with the aid of navigation surgery and joint sparing implants. On the other hand, the classic rotationplasty is making a comeback and is being used for the very young and for cases unsalvageable implant-related infection. This allows the creation of a mobile knee joint and has a good functional outcome.

As a limitation, this is a retrospective study and depended a lot the records available to us. We were not able to look into non-invasive magnetic expandable prosthesis and compare them to our current series. A comparison between these two would prove useful for further studies and implant selection especially in developing countries. A larger cohort of patients would have produced a more reliable outcome but such cases of primary malignant bone tumour requiring expandable endoprostheses are limited. Our centre holds the largest series of expandable endoprostheses in our country.
Conclusion

LSS using expandable endoprostheses for skeletally immature patients is challenging and imposes several complications but has favourable long-term functional and survival outcomes. Metastectomy should be considered for selective cases as it improves survival. In future lies with non-invasive expandable prosthesis, biological reconstruction or physeal sparing surgeries for skeletally immature.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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