

Growing Without Pain: The Noninvasive Expandable Prosthesis is Boon for Children with Bone Cancer, as well as Their Surgeons!

Abstract

Background: Orthopedic oncology has evolved over the past few decades to favor limb salvage over amputations. The noninvasive expandable prosthesis can be lengthened with an externally applied magnetic field eliminating the pain, stiffness, as well as the risk of infection. We present the largest series in Indian experience with this implant over the last 8 years while analyzing its benefit to the surgeons and the patients, but are we able to justify the cost effectiveness? Materials and Methods: Eighteen implants were used in 16 patients with nonmetastatic primary bone sarcoma from May 2006 to June 2015. All implants were manufactured by Stanmore implants worldwide based in London, UK. Lengthening was done in the outpatient department during the followup visits using an external electromagnetic coil. The function was assessed using the musculoskeletal tumor society (MSTS) score. Results: The patients had a mean age of 10.25 years at the time of surgery. The mean followup was 49.56 months. Twelve patients are alive at a followup after surgery. The prostheses were lengthened by a mean of 31.64 mm and average lengthening per session was 4.18 mm. The mean MSTS score was 28.83. Two revisions for jammed mechanism and two patients had a successful two-stage revision for delayed infection. Conclusion: The noninvasive expandable prosthesis is an ideal implant for children undergoing limb salvage surgery for bone sarcoma who are expected to have more than 3 cm of limb length discrepancy at maturity. The initial high cost compared to a minimally invasive expandable implant can be recovered as there is no additional cost of lengthening. The small amounts of lengthening at more frequent intervals is more physiological as compared with the minimally invasive type where more lengthening is done to minimize the number of procedures. While the functional and oncological outcomes are comparable, this implant allows limb lengths to be maintained without pain, functional compromise or risk of infection.

Keywords: Bone tumors, expandable prosthesis, limb length discrepancy, limb salvage, noninvasive lengthening

Introduction

Orthopedic oncology has evolved over the past few decades to favor limb salvage over amputations for patients with sarcomas due to increased knowledge about the disease and advances in imaging modalities, surgical techniques, adjuvant, and chemotherapy. 1-3 Limb-salvage operations have shown a local recurrence rate of between 5% and 10%, comparable with that achieved by amputation. 4

Cure rates for bone sarcomas are reaching 70% to 80% with limb salvage surgery being performed as a routine.⁵ However, encasement of major neurovascular structures by the tumor, local tissue contamination following pathological fractures and local

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recurrence after the salvage operations may warrant an amputation.⁶

Endoprosthetic reconstruction for limb salvage operations in skeletally immature patients has been a challenge with the fixedlength endoprostheses leading to limblength inequalities at skeletal maturity.7 Extendable endoprosthetic replacements have been developed over the years and now are an established and safe alternative^{1,3,5,8} allowing limb lengths to be maintained in skeletally immature patients over their period of growth. The gold standard minimally invasive expandable mega prosthesis requires a surgical procedure with a small incision to turn a screw to achieve a lengthening. These prostheses, are good functionally and psychologically, although each lengthening procedure is an operation and is accompanied by pain as

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Manit K Gundavda, Manish G Agarwal

Department of Orthopedics, P.D. Hinduja National Hospital and Medical Research Centre, Mumbai, Maharashtra, India

Address for correspondence:
Dr. Manit K Gundavda,
B/204, Hilton, Shastri Nagar,
Andheri West,
Mumbai - 400 053,
Maharashtra, India.
E-mail: manit.gundavda@gmail.
com

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well as need for intensive rehabilitation to achieve good function. The risk of stiffness, neurovascular damage, and peri-prosthetic infection is a matter of concern; and in some cases even leading to an amputation.⁹

The externally applied magnetic field to lengthen the noninvasive expandable prosthesis eliminates the pain, stiffness, as well as the risk of infection. The objective of this paper is to present our experience with this implant over the past 8 years while analyzing its benefit and cost effectiveness.

Materials and Methods

Children undergoing limb salvage surgery for bone sarcoma and expected to have a limb-length discrepancy of >3 cm at skeletal maturity were offered the noninvasive expandable endoprosthesis. Those willing to bear the cost of the implant and consented to be a part of the study were included in the study.

Eighteen implants were used in 16 patients with a nonmetastatic primary bone sarcoma (13 osteosarcoma, 1 Ewing's sarcoma, 2 revisions of the standard prosthesis to expandable) were reconstructed with an implant having the noninvasive expansion mechanism (15 distal femoral prosthesis and 3 joint saving intercalary implants) between May 2006 to June 2015. All implants were manufactured by Stanmore implants worldwide based in London, UK [Table 1].

The extent of the tumor of involved leg was undertaken using radiographs [Figure 1a] and Magnetic resonance imaging (MRI) [Figure 2b] while disease staging was performed by whole-body ⁹⁹Tc scanning or positron emission tomography scanning and computed tomography (CT) of the chest to detect metastases. There were 15 osteosarcomas, and one Ewing's sarcoma all of which were



Figure 1: A case of distal femur osteogenic sarcoma implanted with a noninvasive expandable endoprosthesis. (a) Preoperative radiograph and level of resection marked. (b) Section of resected tumour. (c) Postoperative scannogram with limb length discrepancy. (d) Scannogram at latest followup with expanded prosthesis and equal limb lengths

diagnosed by percutaneous needle biopsy¹⁰ and all patients received neoadjuvant chemotherapy based on international protocols. Enneking staging of musculoskeletal neoplasms was used and all lesion were classified as Stage-IIB lesions.¹¹ The lesions were resected *en bloc* with a wide margin of bone of about 3–5 cm for joint involving resections; whereas 2–3 cm of bony margin was maintained for intercalary to the defined limits of the tumor.

The prosthesis was custom-designed using a preoperative CT and MRI of the affected limb to determine the length and diameter of the intramedullary stem after taking into consideration the level of the intended bony resection. Since it is a custom implant; production time is approximately 3–4 weeks and delivery time of 1–2 weeks adds up to 4–6 weeks for the implant to be delivered from date of placing the order with the company. The choice of length options (Currently, the three length options; 50, 70, and 90 mm growth sections are available [Figure 3c]) was determined by the length of resection, predicted future growth and anticipated leg-length discrepancy. Longer resection length offered the option to choose a longer expandable growth section for the joint.

Postoperative physiotherapy was started from the next day and patient mobilized as soon as comfortable and pain-free. All patients resumed chemotherapy following suture removal and wound check at 2 weeks. Followup was every 3 months for the first 3 years, every 6 months for the next 2 years and subsequently annually. Limb lengths were recorded at each followup and lengthening was performed at an out-patient clinic in case of limb length discrepancy. Local radiographs obtained after lengthening [Figure 2d] was compared to the immediate previous radiographs to confirm lengthening. The total lengthening performed while allowing knee range of motion and no compromise to the neurovascular status was meticulously recorded for each patient. Patients were functionally evaluated at their latest followup visit using the Musculoskeletal Tumor Society (MSTS) scoring system.¹² The frequency of lengthening sessions was subjective to the patient's ability to visit the out-patient clinic to keep up with the growth of the contralateral limb [Figure 1d]. It was in the cases of delayed intervals between lengthenings where jamming of gears or requirement of booster was noted to overcome the soft tissue tension.

Prosthesis and lengthening

We used prostheses by [©]Stanmore Implants Ltd. namely the Juvenile Tumour System "JTS" noninvasive extendable prosthesis in 13 of our patients [Figure 1] while custom intercalary lower limb joint sparing noninvasive extendable implants were used in three patients [Figure 2] designed specifically to treat midshaft intercalary resections in the femur or tibia, which offers custom designed patient specific prostheses with a variety of fixation methods, hydroxylapatite collars, and surface treatments of either silver or titanium nitride.

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5 mm 0-100 30 90 mm expansion allowed Minimally invasive lengthening Loosening of implant 2 cm 0-120 30 At 2 years postimplantation, booster required. Soft tissue release of peri-prosthesic membrane 5 mm 0-120 30 membrane	6 Male 9 Left Distal OGS JTS distal 12 femur femur	9 Left Distal OGS JTS distal femur	Left Distal OGS JTS distal femur femur	Distal OGS JTS distal femur femur	OGS JTS distal femur	JTS distal femur	stal	12		50	2.5 cm			Total lengthening completed. Fully expanded prosthesis	57
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5 mm 0-120 30	Revised to JTS 10 distal femur	SI	SI	SI	SI	SI	SI	10		04	2 cm	0-120	30	At 2 years postimplantation, booster required. Soft tissue release of peri-prosthesic membrane	40
	9 Male 9 Right Distal OGS JTS distal 10 femur	9 Right Distal OGS JTS distal femur	Right Distal OGS JTS distal femur	OGS JTS distal femur	OGS JTS distal femur	JTS distal femur	stal	10		50	5 mm	0-120	30		50

	Followup (months)	45	09	58	84	72	84	2	
	Outcome/ complication	Impant length- ened at 50% boost	FFD: Release of quadriceps, iliotibial band, quardicepsplasty and MUGA infection: Nail AB-cement spacer in exchange of implant	Gastrocnemius flap cover for soft tissue	Intermittent- ly jamming of gears. Not affected length- ening	Difficulty in lengthening at last attempt: Stuttering and jamming of gears. Reversal was smooth	Local wound complication immediate post-operative AB-cement spacer in exchange for implant	Lengthening performed immediate postoperative to test the expandable gear mechanism	
	MSTS	30		24	30	30		26	
	Range of movement	0-120	06-0	0-75	0-120	0-120		0-100	
	LLD after final length ening	2 mm		4 mm	No LLD	2 cm		No LLD	
	Amount of lengthening (mm)	31		50	46	46		7	
	Number of lengthening	∞		12	6	10		-	
	Implant	JTS distal femur	JTS distal femur	Re-implanta- tion JTS distal femur	Joint sparing expandable custom intercalary prosthesis	Joint sparing expandable custom intercalary prosthesis	Joint sparing expandable custom intercalary prosthesis	Spacer removal, re-im- plantation of expandable prosthesis	
	Pathology/ reason for insertion	OGS	SDO		SDO	SDO	Ewing's		
	Site	Distal femur	Distal femur		Fe- mur di- aphy- seal	Fe- mur di- aphy- seal	Proximal tibia di- aphy-seal		
	Side	Left	Left		Right	Right	Right		
	Age at implantation (years)	11	6		10	∞	2		
d	Gender	Male	Female		Female	Male	Female		
Table 1: Contd	Case Implant	10	Ξ		12	13	41		
Table	Case	∞	0		10	=	12		

Case	Case Implant Gender	Gender	Age at implantation (vears)	Side	Site	Pathology/ reason for insertion	Implant	Number of An lengthening len	Amount of lengthening (mm)	LLD after final length ening	Range of movement	MSTS score	MSTS Outcome/ score complication	Followup (months)
13	15	Male	10	Right	Distal	OGS	JTS distal			D			Mortality:	2
)	femur		femur						Pulmonary	
													metastasis and	
													bone metastasis	
													before he could	
													be lengthened	
4	16	Female	11	Left	Distal	OGS	JTS distal						Mortality:	
					femur		femur						Developed	
													leukaemia as a	
													complication of	
													chemotherapy	
15	17	Male	7	Right	Right Distal	OGS	JTS distal						Mortality:	9
					femur		femur						Pulmonary me-	
													tastasis before	
													he could be	
													lengthened	
16	18	Male	∞		Distal	OGS	JTS distal						Mortality:	
					femur		femur						Pulmonary me-	
													tastasis before	
													he could be	
													lengthened	

Noninvasive expandable endo-prosthesis (Stanmore implants worldwide based in London, UK). UGS=Usteogenic sarcoma, J1S=Juvenile tun AB=Antibiotic, LLD=Limb length discrepancy, MSTS=Musculoskeletal tumor society, MUGA=Manipulation under General Anaesthesia



Figure 2: A case of diaphyseal osteogenic sarcoma of femur undergone intercalary resection with joint sparing noninvasive expandable prosthetic reconstruction. (a) Preoperative radiograph with limb length discrepancy. (b) Preoperative magnetic resonance imaging showing joint sparing disease. (c) Postoperative radiograph showing intercalary noninvasive expandable custom prosthesis. (d) Radiograph at last followup showing lengthened implant

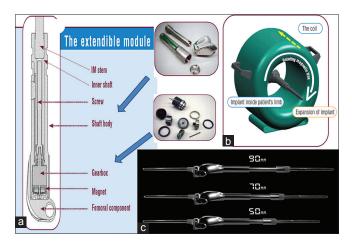


Figure 3: Prosthesis and Lengthening apparatus. (a) Cross-section of distal femoral component of the noninvasive expandable prosthesis. (b) External drive unit. (c) Three length options; 50, 70 and 90 mm growth potential



Figure 4: Out-patient lengthening performed by placing the implant within the external drive unit

The custom designed implants are fabricated from titanium alloy (Ti 6Al 4V) and cobalt chromium molybdenum alloy. Remaining gearbox parts and power screw are made of stainless steel, while the magnetic disc is made from rare earth magnetic (NdFeB) material [Figure 3a]. Liquid paraffin is used to lubricate the gearbox mechanism.¹³

The portable external drive unit and 220-volt power source allow lengthening in outpatient clinics. A rotating electromagnetic field at a speed of 3000 RPM passes through the coils and placing the prosthesis at its center [Figure 3b] causes rotation of the magnetic disc within the implant

and achieves implant lengthening at a rate of 0.23 mm/min – approximately 1 mm every 4 min [Figure 4].¹³

Results

Eleven boys and five girls with high-grade primary malignant tumors of the lower limbs were treated with resection of the lesion and replacement with the noninvasive extendable endoprosthesis. Their mean age at implantation was 10.25 years. Twelve out of the 16 patients were successfully lengthened without any reported pain during the lengthening process. In one patient reversing the mechanism and shortening by 2 mm was necessary to regain full extension after final lengthening, all other patients regained their usual level of function immediately after or by the day after lengthening with no neurovascular compromise. The rotating implant gearbox, when energized by the external magnetic field, was heard using a stethoscope placed on a bony prominence: The malleolus, tibial shin, or greater trochanter.

The number of lengthening procedures for each patient varied from one to twelve. The mean time from the implantation to the latest followup was 49.56 months (2–84). The mean lengthening achieved during each procedure was 4.18 mm. Patients were lengthened by a mean of 31.64 mm (2–65 mm), the mean knee flexion angle being 110° (70° to 120°).

The mean MSTS score was 28.83 of 30 (ranging 24–30).

The implant related issues during the study were seen in five patients of which only two required interventions for the failure of lengthening mechanism while 1 fully extended prosthesis at 50 mm was re-implanted with an implant with lengthening potential of 90 mm in to maintain equal limb lengths [Figure 1d]. There was jamming of gears in two patients that resolved without intervention and did not affect lengthening. One patient lengthened at 50% boost while another patient required 100% boost to facilitate lengthening. In one patient, open surgery and release of peri-prosthetic membrane were undertaken for inability to extend in spite of 100% boost and manipulation.

One case developed a flexion deformity with periarticular contracture which was initially manipulated under GA to achieve only a 25° flexion and hence had to undergo open surgery with quadricepsplasty and release of quadriceps and iliotibial band. The same patient later developed periprosthetic infection. In the total of two cases that developed delayed infection, implant was removed and length maintained by an antibiotic cement spacer over a K-Nail until infection was controlled and the implant could be re-implanted [Figure 5]. Before re-implantation prostheses were treated with ethylene oxide sterilization instead of autoclaving to prevent damage to the magnet gear system. Three patients died of disseminated metastatic disease, and one patient died of leukemia from complications to chemotherapy.

In our series, there has been no prosthetic failure or stem fracture and no evidence of loosening in all but one case where femoral intramedullary stem loosening was noted 6 years postimplantation following the full expansion of the implant which was revised successfully to another JTS implant and successfully lengthened thereafter.

Discussion

Limb-salvage procedures for patients with bone tumors is an established treatment, but in children: Skeletal immaturity leading to limb-length inequality at the end of the growth phase has long been a challenge to the orthopedic oncologists. ¹⁴ In the past, modified adult endoprostheses have been developed with modular midsections that were exchangeable for progressively longer sections. ⁹ The advent of the minimally invasive designs excelled over the modified adult prostheses, but lengthening was under anesthesia and required a small surgical incision to expand the prosthesis. This implant continues to remain the gold standard for limb salvage in skeletally immature patients but with the risk of anesthetic complications and infection.

In the mid-80s, Professor John T. Scales of the Centre for Biomedical Engineering (Institute of Orthopaedics), the pioneer of much of the limb salvage implant technology and Mr. Rodney Sneath, a leading orthopedic oncology surgeon, originated the concept of a noninvasive extendible implant.¹³ During the late 80s, the project was begun and the technology platform selected.

The first designs capable of noninvasive expansion were introduced in the 1990s.¹⁵⁻¹⁸ The Phenix prosthesis (Phenix Medical, Paris, France)¹⁵ in 1990, lengthened on the controlled melting of a polyethylene tube with a spring, using an external electromagnetic field.

Unlike with the Repiphysis (a competing implant manufactured by Wright medical technologies), in our series there were no breakages; specifically due to the gear based lengthening mechanism of the implant.

The use of expandable endoprostheses to maintain leg length in the skeletally immature has become the most acceptable method of treatment, we attempted to over-lengthen the prosthetic replacement at insertion by 1–2 cm, avoiding damage to neurovascular structures and to reduce the number of further lengthening procedures by reducing the length discrepancy.

It is recognized that there is an increased risk associated with the lengthening and the mechanical reliability of extendible implants as compared to the adult endoprosthesis.

The key advantages of the noninvasive lengthening prosthesis used in our patients lies in the fact that first; the prosthesis stays *in situ* indefinitely and does not need to be changed at the end of the growth period as there is no reversal of lengthening by the failure of gear mechanism reported till now. Revision is only likely to be necessary if the patient grows in excess of the maximum possible lengthening of the implant. Second, the lengthening is measured and controlled (rate of 0.23 mm/min) allowing accurate record of limb lengthening each session and expansion of implant remaining for future growth.

Early and regular physiotherapy is important to maintain a good range of movement, prevent peri-prosthetic adherent tissue/scar formation and allow extension of the prosthesis to be achieved with less force on the gearing mechanism. Immediately after lengthening, some decrease in terminal



Figure 5: A case Ewing's sarcoma of tibia with joint sparing limb salvage; developed postoperative infection requiring temporary antibiotic-cement spacer and revision surgery. (a) Preoperative radiograph of tibial Ewing's sarcoma. (b) Intercalary expandable reconstruction prosthesis. (c) Postoperative discharging sinus over operative wound. (d) K-Nail-antibiotic cement spacer. (e) Re-implantation of prosthesis

knee range of motion was noted, which recovered completely with exercise.

The patient resumes all activities of daily living.

Restrictions to contact sports and loading activities, running and jumping are avoided to increase the life of the implant and delay need for revision due to implant failure.

Better stem fixation and reduced loosening rates were an incidental finding and could be attributed to the use of a hydroxyapatite-coated collar¹⁹ on the proximal stem of the femoral component, permitting bone bridging over the implant ingrowth and reducing the chance of aseptic loosening by forming a biological purse string/bonding at the stem prosthesis junction.

Saving the natural knee joint gives the patient greater joint longevity than would be otherwise available with an implant. Patients gain further benefit from natural motion and a far greater range of movement, proprioception and natural sensation as was seen in the 3 cases implanted with the custom intercalary diaphyseal reconstruction expandable prosthesis.

The functional and oncological outcomes, complications such as infection and stiffness are a comparable match to those with the standard nonexpandable implants.

We expect the jamming of expansion mechanism to reduce with evolution and improvement in technology.

Financial cost efficiency

Noninvasive expandable implants are more expensive than minimally invasive lengthening implants. However, in the longer term, they are a cost-effective solution for those patients that will require multiple lengthening procedures. If the patient is nearing skeletal maturity and the expected extension required is <25 mm, a noninvasive mechanism would not be the most cost-effective solution financially, unless there was an increased risk of infection.

The noninvasive expandable implant also has significant health economic benefits. A recent US study identified that it costs US\$ 267 to undertake a noninvasive lengthening procedure compared to approximately US\$ 8,000 if surgery is required.²⁰ In the Indian scenario, the cost of each invasive lengthening procedure would range anywhere from 20,000 to 50,000 INR and assuming each patient with a minimum bony resection; a 50 mm extension of the implant requires a minimum of five sittings to be able to lengthen regularly and comfortably. There are other "hidden" cost-savings too with the noninvasive lengthening: These include in-patient care, surgical and physical rehabilitation which are not necessary for noninvasive lengthening. The risk of infection is ever-present, and there are documented cases of infection that can be directly related to the invasive extension procedure. The cost to revise an infected prosthesis to both the patient and health service provider

is significant. Minimizing surgical intervention minimizes the risk of infection, a solution which is provided by the noninvasive extendable implant; where there is no cost of lengthening as it is an outpatient procedure but the high cost of the implant is a barrier to widespread use (varies from 17 to 20 lakh INR).

Nonfinancial cost efficiency: Quality of life

Limb-salvage in the skeletally immature is predominantly about minimizing the decline in quality of life for the patient. The simplest solution for many patients would be an amputation but, in today's society, this would be unacceptable. Now, after many years of research and development, there is the technology available to maintain equal limb lengths at skeletal maturity. The noninvasive extendable implant eliminates the inconvenience to both, the patient and family if they require multiple hospitalizations for invasive lengthening. This implant allows limb lengths to be maintained without any pain, functional compromise or risk of infection.

Conclusion

The noninvasive expandable prosthesis is an ideal implant for skeletally immature patients undergoing limb salvage surgery for bone sarcoma who are expected to have more than 3 cm of limb length discrepancy at maturity. The initial high cost compared to a minimally invasive expandable implant can be recovered as there is no additional cost of lengthening. Lengthening is painless with no loss of function. The small amounts of lengthening at more frequent intervals are more physiological than with the minimally invasive type where more lengthening is done to minimize the number of procedures. As we present the largest case series in India, this unique prosthesis has shown promising early results, but additional data are required about its long term structural integrity.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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