Survival and failure modes of pediatric distal femoral expandable endoprostheses: a multi-institutional study

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Background

Current State

- Managing limb length discrepancy is a challenge following limb salvage surgery in the pediatric patient. Use of an expandable endoprosthesis enables limb length equalization over time, but there is limited evidence regarding expandable endoprosthesis survivorship and outcomes[1].
- Survival, modes of failure, and mean limb-lengthening for the distal femoral expandable Compress® Compliant Pre-Stress (CPS) device device have not been reported.

Questions/Purposes
At minimum 2-year follow-up:

- (1) What is the survivorship rate of the distal femoral expandable Compress® endoprosthesis spindle?
- (2) How many limb-lengthening surgeries do patients undergo and what is the mean total length of expansion?
- (3) What is the rate of failure and what modes of ISOLS failure are most prevalent?

Level of Evidence: Level IV, therapeutic study.

Methods

- Institutional Review Board approval was received for a multi-institution retrospective study of pediatric patients with a primary distal femur bone sarcoma reconstructed with a Compress® Compliant Pre-Stress (CPS) device (Biomet Inc, Warsaw, IN, USA) expandable osseointegrative endoprosthesis.
- Patients had minimum 2-year follow-up or reached a primary end point (death due to disease or removal of the CPS spindle) before 2-years.
- Electronic medical records were assessed with respect to age; gender; diagnosis; receipt of chemotherapy; resection length; spindle survival; implant survival; International Society of Limb Salvage (ISOLS)[2-3] endoprosthetic failure classification; number of operations; expansion length; residual limb length discrepancy; limb preservation rate; and patient survival.
- Statistical analysis was determined using the log-rank test and Kaplan-Meier technique in Stata® (STATACorp LP, College Station, TX, USA).

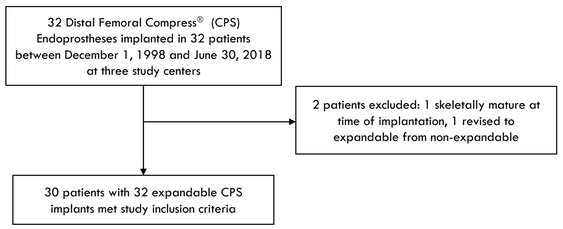

Fig. 1: Inclusion and exclusion criteria

Patient Cohort

Table 1: Patient demographics (n=30)

Characteristic	Number
Age at index surgery (years)	10.6 (5-15)
Sex	
Female	9
Male	21
BMI (kg/m^2)	22.5 (14.5-34.5)
Resection length (cm)	19.8 (14.5-30)
Tumor diagnosis	
Osteosarcoma	28
Ewing sarcoma	2
Perioperative treatment	
Neoadjuvant chemotherapy	29
Adjuvant chemotherapy	28
Follow-up (months)	83.7

Expandable CPS Survival and Outcomes

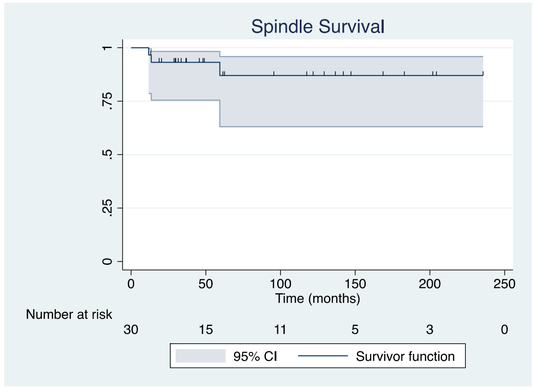

Fig. 2 : Kaplan-Meier survival curve for CPS spindle survival. 2-year spindle survival is 93% (95% CI, 75-98%). 5-year spindle survival is 90% (95% CI, 63-96%) at 5-years.

Spindle survivorship was 93% (95% CI, 75-98%) at 2-years and 90% (95% CI, 63-96%) at 5-years [Fig. 2]

- Spindle aseptic loosening rate was 3% (n=1)
- One spindle sustained rotational failure that did not require surgical revision.

Eighteen (60%) patients underwent 48 lengthening procedures

- Average overall expansion length was 3.5 cm (range 1.0 to 9.1) over a mean of 3.9 surgeries (range 1-9).

Twenty-four patients (80%) sustained one or more ISOLS failure [Fig. 3]

- 14 soft-tissue failures (47%, Type 1); two aseptic loosening (7%, Type 2); 12 structural failures (40%, Type 3); seven prosthetic joint infections (PJI, 23%, Type 4); and two local tumor progression (7%, Type 5).
- Mean time to first ISOLS failure was 42.6 months (range 1.7-126.7).
- Failure of the expandible portion occurred in 17% (n=5) at mean time to failure 41.3 months (range 4.1-90.9).

Twenty-four patients (80%) had 61 unplanned surgical procedures

- One for aseptic failure, 18 for infection, and 26 for arthrofibrosis.

Seven patients (23%) had prosthetic joint infections

- Mean time to infection 42.6 months (1.7-126.7).

Three patients (10%) underwent above knee amputations

- One each for PJI, arthrofibrosis, or local tumor recurrence; 5-year overall limb preservation rate was 90%.

Eight patients (26%) died due to metastatic disease

- Overall patient survival rate of 76% at 5-years.

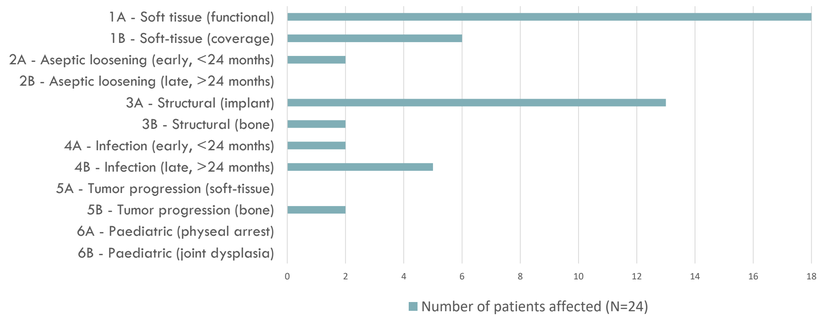

Fig. 3: Types of ISOLS failure affecting expandable endoprostheses (n=30)

Discussion and Conclusions

- Spindle survival of the expandable Compress® endoprosthesis in this pediatric oncology population is comparable to non-expandable Compress® implants[4-5].
- Expandable implants are associated with higher rates of prosthetic joint infection, arthrofibrosis and unplanned operative procedures than traditional non-expandable CPS devices[4]. The benefit of approximating limb-length equality in a growing child comes with a high rate of ISOLS failures requiring unplanned surgical revisions.
- Overall limb preservation rate was high at five-year follow-up.
- Serial lengthening provides meaningful approximation of limb-equality. The percentage of our patients who underwent an expansion surgery (60%) is comparable to previously published rates (51.3%)[1], with a similar number of expansions (3.9 versus 4.0) but more conservative expansion length (3.5 cm versus 4.65 cm).
- Our study is limited by a relatively small sample size due to the rarity of osseous tumors in the pediatric population and because we examined only one anatomic location for implantation, however, the cohort is strengthened by including patients from three study centers.
- Future studies are needed to determine longer term follow-up, functional outcomes, and patient-reported outcomes.

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