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The effect of bone growth onto massive prostheses collars in protecting the implant from fracture

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ABSTRACT

Limb-sparing distal femoral endoprotheses used in cancer patients have a high risk of aseptic loosening. It had been reported that young adolescent patients have a higher rate of loosening and fatigue fracture of intramedullary stems because the implant becomes undersized as patients grow. Extracortical bone growth into the grooved hydroxyapatite-coated collar had been shown to reduce failure rates. The stresses in the implant and femur have been calculated from Finite Element models for different stages of bone growth onto the collar. For a small diameter stem without any bone growth, a large stress concentration at the implant shoulder was found, leading to a significant fracture risk under normal walking loads. Bone growth and osseointergration onto the implant collar reduced the stress level in the implant to safe levels. For small bone bridges a risk of bone fracture was observed.

1. Introduction

Limb-sparing surgery using a massive endoprothesis has been accepted as the best choice for treatment of malignant bone tumors of the peripheral skeleton [1–3]. Longevity of the reconstruction is, however, a major concern, especially in young and active patients who place high demands on their prostheses [4]. These patients undergo neo-adjuvant chemotherapy and this has been shown to reduce recurrence of the cancer and the development of metastasis, but at the same time impairs normal bone formation. A study of custom-made distal femoral endoprotheses reported aseptic loosening as the principal mid-term mode of failure, with a 67% probability of a patient avoiding aseptic loosening for ten years [5]. In this study young patients in whom a high percentage of the femur has been replaced had the poorest prognosis for implant survival. Other studies have also shown aseptic loosening to be the major complication, with rates of loosening of distal femoral prostheses reported to be between 3% and 29% at four to ten years [5–11].

Extracortical bone bridging and osseointegration at the shoulder of the implant may reduce the risk of aseptic loosening by improving stress transfer within the cement mantle [12–16]. The formation of a pedicle of bone from the transection site onto the implant shaft has been observed in these implants and has been found to form on the medial-posterior aspect of the femur [17]. This corresponds to the site on the femur that is under compressive load. The pedicle increases in size by direct ossification. A study by Unwin et al. [18], showed the frequency and variation in the lengths of pedicle in each quadrant of the implant shoulder. Pedicle formation was shown to be more extensive on the medial and posterior quadrants with formation in the posterior quadrant being longer in length. Although bone formation in the lateral quadrant appears to result in good ossification, the frequency of occurrence is lower compared to the medial and posterior quadrants.

A number of animal and clinical studies have shown that extracortical bone-bridging can occur at the shoulder of massive bone tumor implants [19–23]. However, bone ingrowth with direct extracortical bone-implant contact in bone tumor implants retrieved from humans has only been identified in one study [24]. Extracortical bone growth into the grooved hydroxyapatite-coated collar was quantified using radiographs and histologically. Osseointegration into the collar was seen to have occurred in 66% of the patients. In these patients the success was 98% at 18 years. However, in patients where osseointegration did not occur, the failure rate was 25%.

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Fig. 1. X-ray of fractured stem showing fracture at the shoulder of an implant with no evidence of bone ingrowth for tibia in lower leg.

Osseointegration may be even more important in young adolescent patients where the implant is inserted into a growing bone. Due to the small size of the bone, the implant becomes undersized as patients grow. The increase in the diameter of the endosteal cavity may lead to a loose implant. As loads increase as the patient grows, the stem may be too small to withstand the imposed loads and fracture may occur. An example of fracture in this region is shown in Fig. 1, where fracture of the stem at the junction of the implant shaft is seen. If osseointegration into the HA collar does occur then load distribution from the implant onto the bone may bypass the stem. Using Finite Element Analysis (FEA), this study investigates the effect of bone growth onto the implant collar in the distal femur and the way in which this redistributes the stresses through the implant and bone. Quantifying the expected stresses for daily activities such as walking and comparing to the material strength improves the understanding how extensive osseointegration of the collar would protect the stem from failure. The stresses at the stem-collar junction of the implant and in the bony bridge are considered. This contribution investigates the hypothesis that with increased bone ingrowth in the HA collar of a femoral implant, there will be a reduction in the stress (concentration) at the implant stem junction, reducing the implant fracture risk with more physiological stress transmitted between bone and implant.

2. Methods

2.1. FE model

Finite Element models of the femoral bone and implant for different stages of bone growth onto the implant collar were developed with a rotationally symmetric geometry (Fig. 2(a)) to approximate the observed clinical conditions for a cemented implant. The preferential pedicle growth in different quadrants (medial and posterior quadrants [18]) seen in Fig. 3 was not investigated as limited information on the changing geometry was available and

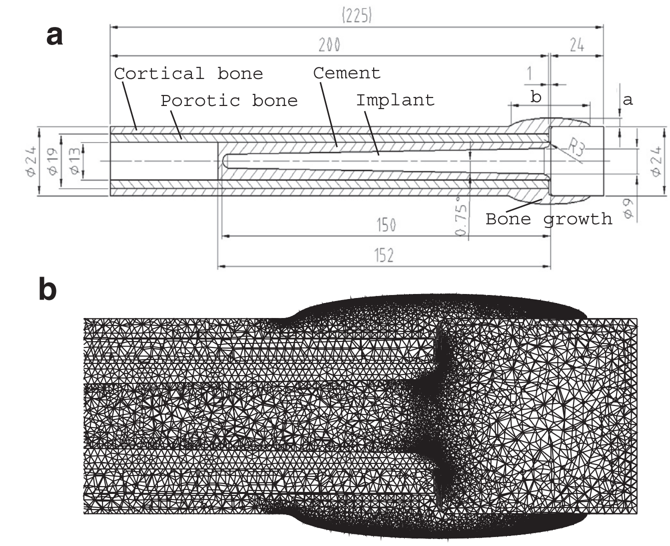

Fig. 2. (a) Schematic of Finite Element model geometry (all dimensions in mm); bone formation onto implant collar with dimensions (a and b); (b) FE mesh for 75% growth.

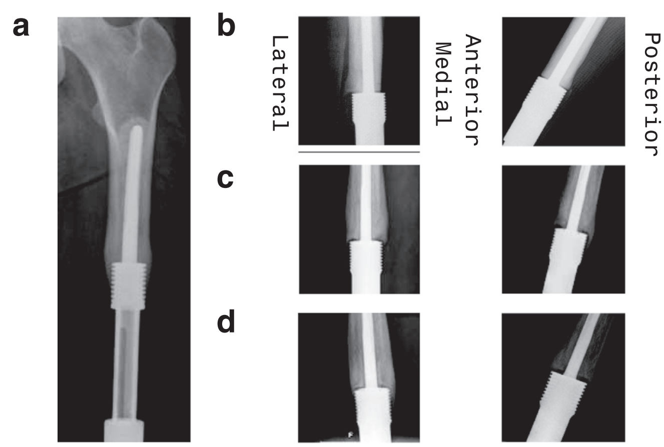

Fig. 3. (a) M-L radiograph of patient taken 12 years after prostheses implanted at age of 7 years; M-L views [left] and A-P views [right] of set of X-rays from implanted femur for different patient taken: (b) immediately post surgery; (c) one year post surgery; (d) two years post surgery.

to limit the number of parameters. As structural failure of the implant stem is expected to occur near the transection site at the stem-collar junction, only the porous collar and stem of the implant and the distal femur were modeled. Thickness of the diaphysis was assumed to have the same outer diameter as the implant collar, i.e., 24 mm. As a result of bone remodeling, particularly in young adolescent patients where growth occurs around the implant stem, less dense or porotic bone forms at the inner diameter of the cortical shell adjacent to the cement after some time [17]. This less dense layer was included with a thickness of 3 mm and models the enlarged endosteal cavity of the bone. The cement was modelled to conform to the shape of the bone on one side and the shape of the implant on the other as is realistic due to cement pressurization. Although known to vary in thickness according to the relatively rough inner bone surface, the cement was modelled as a uniform layer of 2 mm thickness at the distal end. The geometry and dimensions of the implant stem and collar were modelled to mimic the Stanmore extendable prostheses and was either cylindrical with a diameter of 9 mm or included a 0.75° taper in