A NOVEL METHOD FOR EARLY DETECTION OF ASEPTIC LOOSENING IN MASSIVE IMPLANTS: A CORRELATION OF RADIOGRAPHIC BONE DENSITY AND TELEMETERED FORCE

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Introduction
Titanium alloy endoprostheses, fixed using a cemented intramedullary stem, are used for femoral reconstruction after bone tumour excision. They give good initial stability with a rapid return to maximal function, but are prone to aseptic loosening in the medium to long term [1]. Follow-up studies using serial radiographs have shown that characteristic bone remodelling occurs with time. Mechanical tests on cadaver femora have shown how the prostheses alters the stresses in the remaining bone. However, only by using instrumented prostheses is it possible to show how forces relate to the fixation change over time in vivo. Instrumented proximal and distal femoral replacements were developed to investigate force transfer in the fixation [2,3,4]. The aim of the present study was to correlate changes in force transfer in the fixation with bone density ratio measured on radiographs; to see whether this bone remodelling pattern could be an early sign for predicting later aseptic loosening and clinical failure.

Materials and Methods

Instrumentation: The massive prostheses contained cavities above the shoulder and at the stem tip to house the strain gauges and electronics in order to measure axial force [2,3]. Power was supplied and data telemetered by inductive coupling.

Patients: Three patients were included in the study: patient A was a 46-year-old man who received a proximal femoral replacement (PFR) after resection of a large clear cell chondrosarcoma in the right proximal femur. Patient B was a 41-year-old woman with MFH of the mid-region of the right femur. She received a distal femoral replacement (DFR) with hydroxyapatite collar to replace 277mm of resected femur. Patient C was a 67-year-old man with several previous failed reconstructions of the left femur. Patient C was informed of the intent for participation in the study. The telemetric and radiographic follow-ups were up to 2.5 years.

Telemetry data: The axial forces were measured at 1, 2, 4, 6 weeks and every two months post-operatively when patients were walking. The ratio of the average peak excursions of axial force at the stem tip to that in the shaft was calculated. This indicates the proportion of axial load transmitted to the intramedullary stem tip.

Radiographic bone density analysis: Radiographs of the stem were taken every 36 months. They were digitized using a laser scanner and the bone adjacent to the stem tip was analysed in 5 zones, with zone 1 nearest the shoulder and zone 5 at the tip of the stem (Fig. 1). Relative bone density for each zone was quantified by a new method [5]. Two regions on the same radiograph were selected, one containing bone and one with soft tissue only. Optical density measurements of the two regions were taken and converted to x-ray intensity by averaging the characteristic curves for 4 types of high speed film. Assuming equal bone density for the two regions of the same radiograph (lateral to medial, shoulder to tip) were calculated, and changes over time were analysed. A two tailed t-test was used to test the significance of the correlation with time or telemetry data.

Results

Telemetry data: The ratio of the stem tip to shoulder force increased with time in all three subjects. It stabilized at about 65% after 1 year for patient A, but continued to increase for patient B and C (reaching 100% in patient C within 1 year) (Fig. 2).

Radiographs bone density

Patient A: The lateral to medial bone density ratio decreased in zone 1 (R²=0.836, p=0.004) but increased in zone 5 (R²=0.966, p=0.007) (Fig.3). The magnitude of the change was about 3 times the root mean squared error for paired observations (0.07, from 8 pairs). Other changes included the growth of a pedicle on the medial side and the formation of a gap at the transection site. The prosthesis has remained fixed for over 10 years to date.

Patient B: For bone mineral content (density multiplied by width), in the implant shoulder region, the lateral-to-medial bone density ratio was decreased. On the medial side, the shoulder-to-tip ratio was increased (R²=0.714, p=0.0083), mainly due to the increase in cortical thickness in the shoulder region. On the lateral side, the shoulder-to-tip ratio did not change significantly. However, there was an increase in bone density (relative to the ischium) on the lateral side of the stem tip (R²=0.587, p=0.045). Bone formed on the hydroxyapatite collar but there was a gap between it and the femoral bone. The prosthesis became loose and was revised after 33 months.

Patient C: The radiographs showed that the fixation became loose very quickly. By 20 months the radiolucent line in lateral zone 1 was over 4mm wide. The prosthesis was revised after 23 months.

Discussion

The radiographic changes were evidenced by the telemetry data which reflected the altered stress distribution. For example, the new bone formation on the medial side near the shoulder was correlate to the increase in compressive stress on that side. The bone density increased in lateral zone 4 because of the stem tilting caused by the varus moment, as the moment in the frontal plane acted in a varus direction [4]. Stress shielding of the lateral cortex below the shoulder occurred with patient A because the load line passes medial to the transection site. Initially most of the load is transferred by the shoulder, and the tip-to-shaft ratio is low. The ratio will change due to early bone remodelling, but remain stable over time if the implant is well fixed. This was shown in patient A. However, if the implant starts to become loose, the load will then transfer to the stem tip, and the ratio will progressively increase until gross aseptic loosening and implant failure occur. This was observed in patients B and C. Thus the early radiometric data could be a useful tool to predict later implant loosening.

In the past, bone density in a particular zone was usually compared longitudinally to show changes over time. In this study, the change of bone density ratio in two zones was analysed. The progressive adverse changes of bone density ratio indicate an early sign of aseptic loosening of the implants. The good correlation between the telemetry and radiographic data, and also the clinical results, has evidently support (4,3).

References

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