Ortopedia Traumatologia Rehabilitacja
© MEDSPORTPRESS, 2008; 6(6); Vol. 10, 576-582

Per-operative Vibration Analysis: a Valuable Tool for Defining Correct Stem Insertion. Preliminary Report.

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SUMMARY

Background. Defining the stem insertion end point during total hip replacement still relies on the surgeon's feeling. When a custom-made stem prosthesis with an optimal fit into the femoral canal is used, the risk of per-operative fractures is even greater than with standard prostheses. Vibration analysis is used in other clinical settings and has been tested as a means to detect optimal stem insertion in the laboratory. The first per-operative use of vibration analysis during non-cemented custom-made stem insertion in 30 patients is reported here.

Material and methods. Thirty patients eligible for total hip replacement with uncemented stem prosthesis were included. The neck of the stem was connected with a shaker that emitted white noise as excitation signal and an impedance head that measured the frequency response. The response signal was sent to a computer that analyzed the frequency response function after each insertion phase. A technician present in the operating theatre but outside the laminated airflow provided feed-back to the surgeon.

Results. The correlation index between the frequency response function measured during the last two insertion hammering sessions was >0.99 in 86.7% of the cases. In four cases the surgeon stopped the insertion procedure because of a perceived risk of fracture. Two special cases illustrating the potential benefit of per-operative vibration analysis are described.

Conclusions. The results of intra-operative vibration analysis indicate that this technique may be a useful tool assisting the orthopaedic surgeon in defining the insertion endpoint of the stem. The development of a more user-friendly device is therefore warranted.

Key words: Total hip replacement, vibration analysis, bone-prosthesis stability, frequency response function

BACKGROUND

The most critical point during total hip replacement (THR) is defining the end point for insertion of the femoral stem. This involves a sense of mechanical stability when applying torque forces to the prosthesis as well as a feeling of the prosthesis being well fixed and not displaceable along the axis of the femur. Excessive press-fitting of a THR femoral component can cause intra-operative fractures with an incidence of up to 30% in revision cases1.

The stability and survival of the implant are directly related to the long term fixation stability of the prosthesis stem 2. Besides the design, material composition and surface characteristics of the implant, the initial per-operative fixation of the stem in the femoral bone has a critical influence on its long term fixation stability. This is especially the case with non-cemented, press-fit fixated stems.

In our centre, custom-made stem prostheses are commonly used to increase the optimal fit in the femoral canal. Correct stem insertion is defined by the senior consultant. Especially because defining the endpoint of the stem insertion is based on feeling, and few models exists for practical training, it remains a delicate point during surgery. A system that can help the surgeon to define the insertion end point, may contribute to better implant stability and hence longer survival of the prosthesis.

Vibration analysis has been tested in cadaver femurs and synthetic composite femurs 3-5. This paper reports the first per-operative use of a non invasive vibration analysis technique for the mechanical characterization of primary bone-prosthesis stability. Two special cases illustrate the potential benefit of this technique.

MATERIALS AND METHODS

THR-eligible patients received full information relative to the surgical intervention and the study objectives. The study protocol was approved by the institutional review board. Patients were enrolled after providing written informed consent.

Thirty patients (12 male and 18 female) were included in this study. The prosthesis stem was intra-operatively custom-made. After reaming of the femoral cavity, a 3D imprint of the cavity was made in the form of a silicone mould. This mould was scanned and its geometry was optimized using a CAD-procedure. Based upon this adapted geometry, a Computer Numerical Control (CNC) milling machine transformed a partially preformed titanium alloy prosthesis stem into the final personalized shape. All prosthesis stems were proximally coated with hydroxyapatite. A standard hydroxyapatite-coated pinnacle cup (Johnson&Johnson, Dupuy) (Warshaw, USA) was used in all cases. The average age at time of operation was 53.9 years (± 7.6 y). The majority of the patients suffered primary coxarthrosis (n=28), and two patients suffered avascular necrosis. All interventions were performed by the senior consultant (MM)

In previous in vitro studies6-9, performed on cadaveric and artificial human femora (Sawbone® nr. 3306, Left Large Composite Femur, www.sawbones.com), it was shown that the evolution of the frequency response function (FRF) can be used to assess the stability of a THR prosthetic stem and to detect the insertion end point. From the in vitro studies, a protocol has been derived to be applied in per-operative conditions.

The prosthesis neck was attached to a shaker (Bruel & Kjaer model 4810) using a stinger provided with a clamping system. The excitation was accomplished with white noise in the range 0-12.5 kHz. The input force and response acceleration were measured at the same point with an impedance head (PCB Piezotronics model no. 288D01) mounted between the shaker and the stinger.

The excitation system used low amplitude vibrations and introduced approximately 0.5W of power into the femur-prosthesis system. The FRF was measured and recorded by a Pimento vibration analyzer (LMS International) connected to a portable computer provided with the appropriate software (Pimento 5.2, LMS International). The vibration analyzer generated the excitation signal, which was amplified and sent to the shaker. The vibration analyzer, portable computer and amplifier were installed in the surgical theatre but outside the so-called laminar flow area.

The surgeon inserted the implant in the femoral canal through repetitive controlled hammer blows. After each blow, the FRF of the implant-bone structure was measured directly on the prosthesis neck in the range 0-10 kHz. The FRF change indicates the evolution of the stiffness of the implant-bone structure and, as a consequence, the evolution of the implant stability. The hammering was stopped when the FRF graph did not change noticeably anymore. Extra blows would not improve the stability of the prosthesis but would increase fracture risk.

The amount of FRF change between insertion steps was quantified by Pearson's correlation coefficient R between successive FRFs. A correlation between the FRFs of successive stages of R=(0.99 +/- 0.01) over the 0-10000 Hz range was proposed as an endpoint criterion.

RESULTS

Thirty cases of non cemented stems were studied in vivo. In twenty-six out of the thirty cases (86.7%), the correlation coefficient between the last two FRFs was above 0.99 when the surgeon stopped the insertion. In the other four cases, when the surgeon decided to stop the insertion because of suspected bone fragility, the final correlation coefficient had attained lower values.

A typical evolution of the FRF graph is shown in Figures 1a-d. Pearson's correlation coefficient (R), calculated for consecutive pairs of FRFs, is presented in Figure 1e. Stage 0 corresponds to the FRF calculated after the stem was introduced in the femur by hand; stage 1 corresponds to the FRF calculated after the first hammer blow series, stage 2, after the second hammer blow series, and so on. The surgeon needed five stages (0…4) to completely insert the stem in this case.

DISCUSSION

This study demonstrates the possibility of per-operative vibration analysis in vivo. The high correlation index between the last two series of hammer blows indicates that FRF analysis corresponds with the feeling of an experienced surgeon. Moreover, two special cases demonstrate that even an experienced surgeon may benefit from an assessment tool for defining the stem insertion end point.

Case 1. During a per-operative experiment, when the stem was quasi fully inserted, the highest peak of the FRF graph slightly shifted to the left (stage B in figure 2a).

After a supplementary hammer blow series, the corresponding FRF graph represented an abnormal shape (stage C in figure 2b). Upon inspection of the bone, a small fracture was observed and the hammering was stopped.

Case 2. An oscillating pattern of the FRF graph was observed during another per-operative hip arthroplasty procedure stages 7, 8, and 9 (Figures 3a and b).

Since the stem was visibly not fully inserted, the hammering would normally have had to continue, but the behavior of the FRF indicated that the stem was blocked and, as a consequence, there was a risk of fracture. The problem was solved by pulling out the stem, adjusting the femoral canal and reinserting the prosthesis. The FRF demonstrated a normal evolution during the reinsertion. The graphs corresponding to the final two stages are shown in Figure 3c. The corresponding Pearson's correlation coefficient attained the value of 0.998.

The small bone fracture described in the first case would have passed unnoticed without the use of vibration analysis. The reported incidence of per-operative fractures shows wide variations with ranges up to 30% in revision surgery1 Those fissures mostly heal spontaneously but stem stability may be compromised.

Besides reduction of the intra-operative fracture risk, insertion of the stem prosthesis results in well-defined contact areas and interface pre-stresses between the stem and the femoral bone. Under actual loading, hip stem displacement and femoral stress distribution will strongly depend upon these initial contact conditions. Hip stem displacement is not only important in view of prosthesis migration, but also in terms of micro movements that must be limited in order to allow interfacial bone formation and in-growth10. Femoral stress distribution has a crucial influence on bone remodeling and, therefore, on the final strength of the bone-implant structure.

Per-operative vibration analysis has, to our knowledge, not been documented up till now. The available information is based on laboratory studies and finite element analyses. In a finite element study 11 the relation between the vibration behavior and the spatial distribution of contact areas is analyzed. In a transient dynamic analysis 12 the successive steps in the insertion process are simulated and the vibration response in each step is modeled by finite element methods.

From a clinical point of view the documentation of feasibility and value of per-operative vibration analysis may be considered as a step forward. Our study has, however, not correlated the findings of the per-operative vibration analysis with the clinical outcome, such as pain relief and functional improvement, and long term follow-up is required to identify possible differences in prosthesis stability and prosthesis survival rate. Routine use of this technique could lead to considerable savings in health care budgets since, in case of an intra-operative femoral fracture, the operation time is considerably longer. If there is only a minor fracture, the surgeon can solve this with tension band wiring alone. However if the fracture leads to instability of the femoral stem, the femoral stem has to be replaced by a longer cementless stem or a cemented stem. As full weight bearing is not allowed after an intra-operative femoral fracture, rehabilitation is slowed down and the hospitalization time can be considerably longer than following an uneventful THR procedure. Secondly, vibration analysis could lead to a more accurate press-fit of the femoral stem, thus improving the initial stability. Better stability leads to better osteointegration of

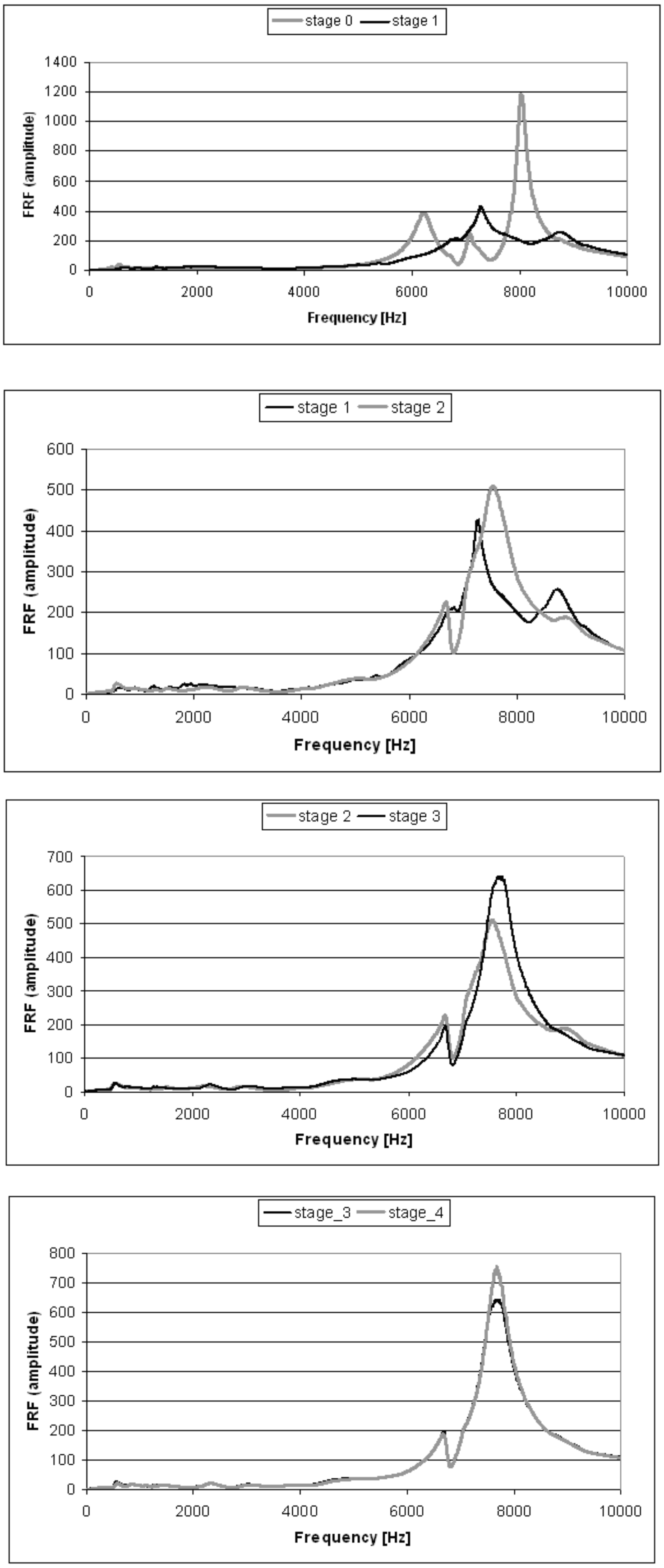

Fig. 1. Non cemented stem. a-d: FRF graphs for successive insertion stages

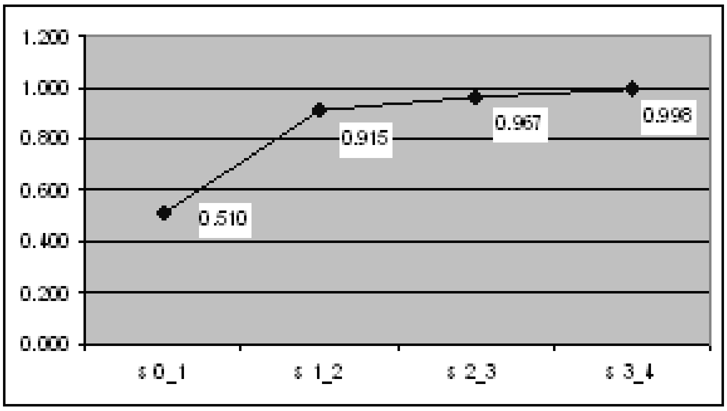

Fig. 1. Non cemented stem. e: Pearson's correlation coefficients calculated for the FRF pairs presented in Fig. 1 a-d

the uncemented stem and should decrease the incidence of aseptic loosening of the stems at long-term follow-up. As the number of THR procedures performed yearly is still increasing, prolonging the survival should decrease the potential number of femoral stem revisions. Revision hip surgery is associated with longer operation times and longer hospitalization times.

The experimental setting used in this study is, however, rather cumbersome and requires the presence of engineers, computer systems and wiring in the operating theatre. This setting can be used in a teaching hospital but more general application can only be envisioned when a wireless and more practical system is developed.

A more extensive study allowing comparison of the incidence of per-operative micro fractures in

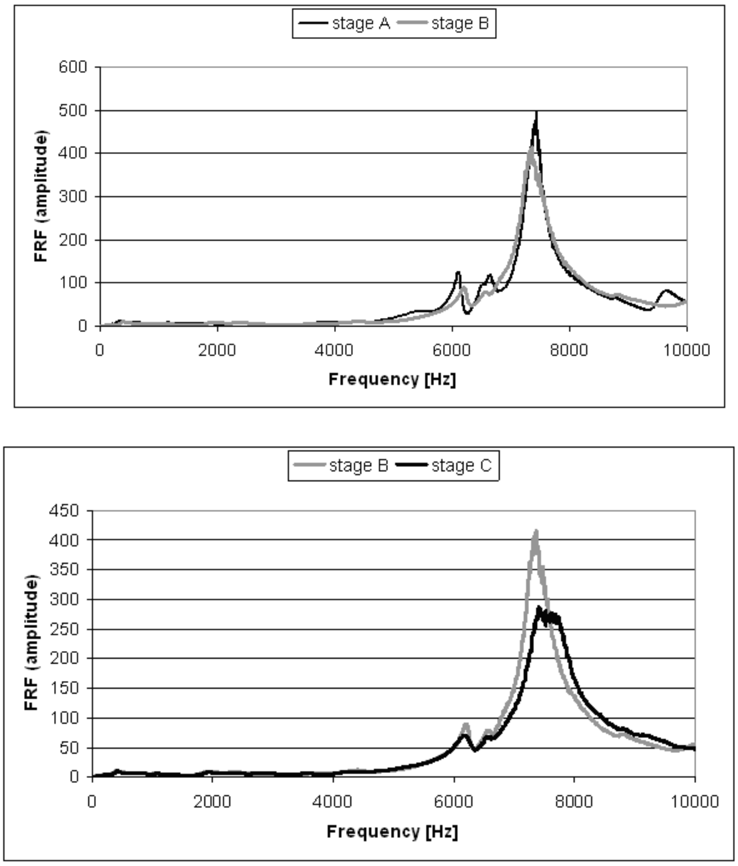

Fig. 2. Per-operative fracture. a: FRF corresponding to the insertion stages and B (left shift). b: FRF corresponding to the insertion stages B and C (minor fracture)

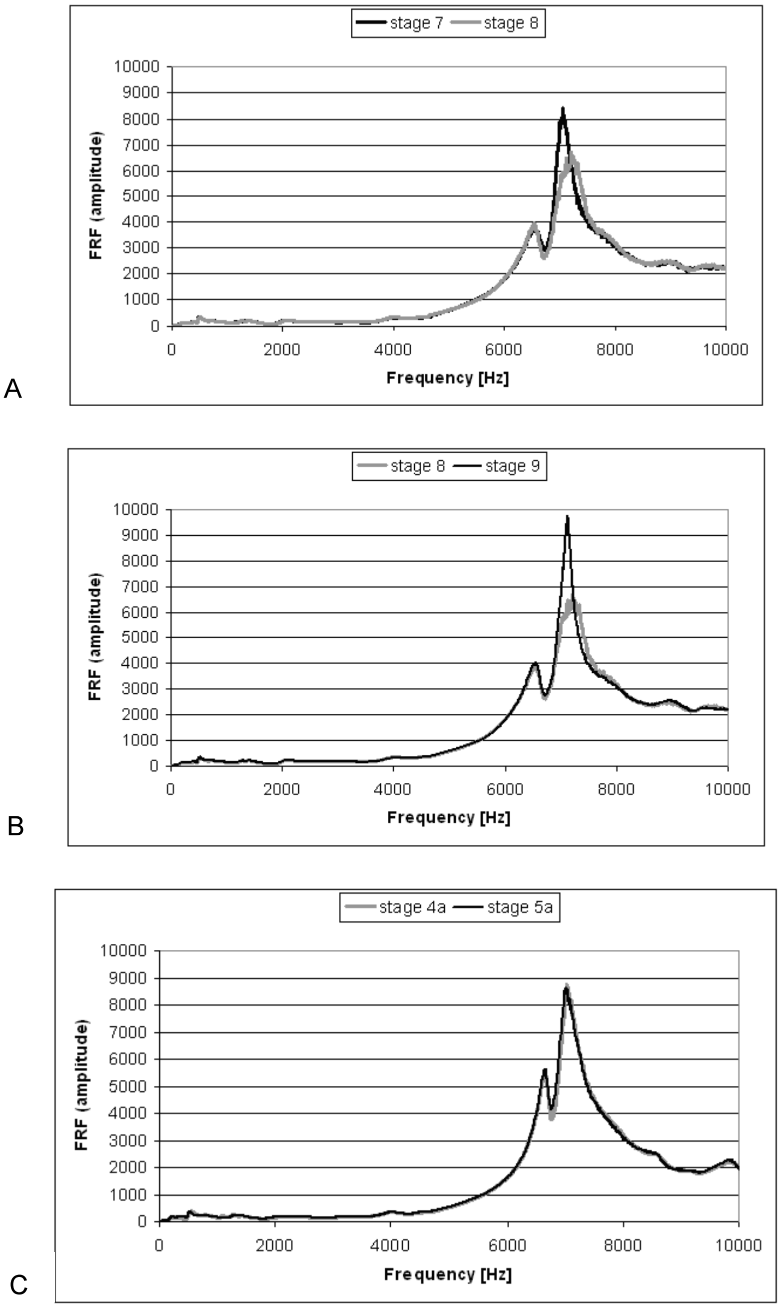

Fig. 3. Correction of the femoral canal. a: FRF corresponding to insertion stages 7 and 8 (normal right shift). b: FRF corresponding to insertion stages 8 and 9 (abnormal left shift). c: FRF corresponding to final insertion stages 4a and 5a (reinsertion)

interventions guided by per-operative vibration analysis with that associated with non-assisted interventions, and a long follow-up aimed at determining the stability of the stem prosthesis is warranted.

CONCLUSIONS

1. Total hip replacement has been described as "The operation of the century"13 because an increasing number of patients benefit from regaining mobility and pain reduction. Although the intervention and the materials have been vastly improved over the years, the definition of the endpoint of the insertion still relies on the feeling, and thus the experience, of the surgeon. Routine use of vibration analysis could avoid intra-operative fractures, which occur more frequently than reported.
2 Vibration analysis for defining the insertion endpoint is not solely reserved for teaching hospitals

but would represent a valuable tool for all orthopedic surgeons.

3. A modified user-friendly device could be used for both the insertion of the stem and the cup, which could reduce the total operation time.
4. This study demonstrated that in vivo use of vibration analysis is possible. There is an urgent need for the development of a more user-friendly, wireless device.

ACKNOWLEDGEMENTS

This research was partially funded by a grant from the K.U.Leuven research council (project OT/ 03/31 – "HipHub").

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Liczba słów/Word count: 2780 **Tabele/Tables:** 0 **Ryciny/Figures:** 3 **Piśmiennictwo/References:** 13

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Otrzymano / Received 14.07.2008 r.
Zaakceptowano / Accepted 26.10.2008 r.