From Laboratory to Clinic

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Summary

Aseptic loosening of total hip prostheses is still an unresolved problem, although the results of total hip arthroplasties have improved tremendously the last decade. Several mechanisms have been postulated to explain the failure of cemented total hip arthroplasties. Two dominant failure scenarios of cemented reconstructions can be identified: the accumulated-damage failure scenario; the cement and interfaces are not strong enough to resist the long-term dynamic loads, and the particulate-reaction failure scenario: the cement-bone interface gradually disintegrates due to the migration of wear particles. It is believed that the initiation of the failure process is caused by mechanical events. Therefore, a new prosthetic hip design was developed with low and equally distributed stress patterns in the cement and at the interfaces, to reduce the aseptic loosening rate. The studies of this thesis were performed to highlight all aspects of this development, from the innovation process to the clinical introduction of the new cemented total hip prosthesis, in the context of so-called 'stepwise introduction'. In Chapter 2 and 3, an optimization process of the components and the cement mantle is described. This innovation process resulted in the Scientific Hip Prosthesis (SHP). In Chapter 4, the operative procedure for the SHP is described. It is demonstrated that templating of preoperative radiographs, which pre-plans the selection of size and desired position as a part of the operative procedure, is accurate in 40% to 70% of the cases. Although preoperative planning is not an accurate method to determine the implant size exactly, it will inform the surgeon on the size category, its position, level of the osteotomy and relevant anatomical details.

In most hospitals plain radiographs and 'the ruler and pencil method' are used to evaluate total hip arthroplasties during follow-up. In Chapter 5, a method of measurement based on the averaged vertical stem migration in a group of patients over time is described, and its accuracy is estimated. The measurement error was calculated to be 9.8 mm. It was concluded that stem migration can not be measured on plain radiographs with adequate accuracy with the ruler and pencil method.

The clinical results of the SHP were evaluated in 2 studies. The first study (Chapter 6) describes a single-surgeon (author) series. The mid-term results (minimum 5 year follow-up) showed good or excellent clinical results in almost 90% of the

cases. The survival rate for aseptic loosening was 97.6%, which is similar to other frequently used prostheses. No deterioration during follow-up was noticed, and it was concluded that the SHP and the instruments are safe and applicable in the hands of one (author) surgeon. The second study describes a *multi-surgeon* (non-author) series (Chapter 7). The short-term results for patients operated for primary arthrosis were comparable to the single-surgeon series: the clinical results were good or excellent in 92.5% of the cases, and the survival rate for aseptic loosening was 99.3%. However, patients operated for other reasons, especially those with abnormal bone stock, showed inferior results. In both studies, all unwanted events were registered and the adverse event rate per procedure was calculated: 0.3 in the single-surgeon series versus 1.2 in the multi-surgeon series. Inappropriate cementing was one of the most frequently recorded adverse event in the multi-surgeon series. This was probably caused by the simultaneous introduction of a new cementing technique (tertiary cementing technique) and the new prosthesis.

When a new implant or technique is introduced in the clinic, technical difficulties might be expected because the surgeons and surgical teams have to adapt to new surgical instruments and prosthetic characteristics. In Chapter 8, the learning process of the SHP procedure is described. Performance curves, using different parameters were analysed and discussed in the context of a learning theory of skilled behaviour. In general, in the single-surgeon series no significant performance improvement could be detected during the period studied. The results of the multi-surgeon series were, in general, inferior to the single-surgeon series, but a significant improvement in performance occurred during the period studied, mainly by an improvement in the performance of the residents. The surgeon of the single-surgeon series was involved in the development of the prosthesis and learned most of the operative technique and characteristics of the implant in the laboratory. In terms of the learning theory; he passed the cognitive phase prior to the clinical introduction of the prosthesis. The surgeons of the multi-surgeon series went through the cognitive phase, during which most improvement in performance can be obtained, simultaneously with the clinical introduction of the new hip prosthesis. A pre-clinical phase during which the surgeons are instructed and practice was advocated.

The innovation process resulted in an optimized prosthetic design, which in the laboratory proved to reduce cement and interface stresses considerably. Patient and prosthetic characteristics, the cementing technique and the learning process affected the translation of the superior design features from the laboratory to the clinic. Relatively to its peers, the SHP proved to be an adequate design. However, the high expectations invested in an extensive scientific preparation and laboratory-testing phase did not bear fruit in a superior product. Which indicates that total hip arthroplasty is still an art, much more than a science.