Editorial

Boneloc®—the Christiansen experience revisited

In the 1970s the Scandinavian orthopedic community was faced with a large-scale clinical failure in the form of the Christiansen prosthesis. This experience was an embarrassing parenthesis in the evolution of total hip arthroplasty. But it taught us that the laboratory is not real life and that a new concept should be marketed only after the clinical performance of the developed product is documented.

Have orthopedic surgeons learnt the lesson? Apparently not.

We are now witnessing how a new bone cement, Boneloc®, has been marketed without documentation of its clinical performance, even in the short term. The available documentation consists of a large series of in vitro tests and a reasonable number of biological experiments in dogs, none of which, however, spans more than 12 weeks in a non-weight-bearing situation (see Reference list in Kindt-Larsen et al. 1995). As clinical results emerge, it is clear that the cement has more rapidly caused worse clinical problems than the Christiansen total hip ever did (Havelin et al. 1995, Riegels-Nielsen et al. 1995, pp 215–217 in this issue, Suominen 1995). The problems have mainly been on the femoral side—an anatomic location where loosening with conventional cements is distinctly unusual in the first postoperative 10-year period.

Two fundamental questions must be considered in any decision about whether to change from an established to a new concept: Is there a clinical need to develop a new concept? If so, what is the fundamental weakness of the current concept?

John Charnley was fully aware, 25 years ago, that curing cement gives off heat and toxic chemicals and that the biocompatibility of the polymer is not optimal, for instance when compared to, metals (Charnley 1970). This naturally was a cause for concern at the time. But over 25 years of clinical experience shows very clearly that bone cement must have some inherent properties which compensate for its biological shortcomings. In all probability, its ability to create immediate microstability is one of them. Another may well be the time-dependent properties of the polymer. Today, the clinical need to develop a new bone cement is in no way pressing, but we should be very careful not to destroy what we have built up.

Boneloc® is marketed as a cold-curing cement that, in addition, reduces the MMA monomer leakage. What evidence is there that the acute trauma is the fundamental deficiency in bone cement? The answer is probably given by a look at clinical reality itself. In the 1970s it was generally recommended that the cement should be inserted late, usually not until 2.5–4 minutes after the start of mixing, to reduce the chemical trauma. Reaming was not extensive. Today, the same cement is injected into the bone, pressurized, and often inserted early and cooled. All of these measures help to increase the amount of cement inserted (and thereby the rise in temperature) and prolong the time for monomer release. If these factors were to dictate the long-term performance of bone cement, then one would expect fibrous membranes to be more prominent and prosthetic loosening to be more frequent than before. The opposite is true. There is little evidence that acute trauma is the reason for the implant loosening and a bone cement founded on this belief may very well attempt to cure a disease that most often does not exist.

This is not to say that the acute trauma does not exist. Of course it does. A reduction can do nothing but good, *everything else being equal,* and Boneloc® represents a novel way of lowering the exotherm and MMA monomer leakage simultaneously (Kindt-Larsen et al. 1995, Wykman and Sandersjöö 1995, pp 218–219 in this issue). The problem is that everything else is not equal. One cannot alter a single factor in bone cement—e.g., the exotherm—without also affecting other parameters, for instance the nature of the polymer which, in the case of Boneloc®, is indicated by a greater postoperative prosthetic migration (Thanner et al. 1995, pp 207–214 in this issue). Although many laboratory tests have been carried out, and although these indicate that in specific laboratory settings some of the tested properties are similar to those of other cements, the fact is that Boneloc® has not worked in clinical practice, and this is, after all, what counts. It is questionable whether the long-term performance of implant materials can be ascertained by a short-term laboratory experiment.

National registers have an important part to play in monitoring the results of THR. In the Norwegian Register, Boneloc® was found to be inferior after

only 0–3 years of use (Havelin et al. 1995). The Norwegian Orthopaedic Society recommended stopping the use of Boneloc® and should be praised for this rapid action.

It can then be argued that the new Boneloc® II has overcome all of the disastrous features of Boneloc® I. This is for the developer to demonstrate. It cannot be in the interest of our patients, nor can it be an obligation on the part of the orthopedic community, to support a venture which may well be founded on a faulty analysis.

While it is not difficult to recommend that the use of Boneloc® should be stopped, it becomes an ethical dilemma to recommend actions in those presumably very few prospective randomized studies already started to compare Boneloc® II with established bone cements. It would probably be unethical to discontinue such studies before conclusions can be drawn, if only out of respect for those patients already subjected to Boneloc® I. Depending on the size of the patient material, one alternative is to put the studies on hold while awaiting the 1–2 -year results, another is to have several teams pool their data. Considering the dismal performance of Boneloc® I, it is possible that Boneloc® II will differ from established cements even after this short period of follow-up. It should be the obligation of the research teams dealing with these randomized studies to present their results, without delay, preferably in this journal.

It is good medicine to remind oneself that a cemented THR is a routine operation with an excellent prospect of lasting the lifetime of the vast majority of patients, if properly performed. With this background, the failures of the Christiansen and Boneloc® concepts must not be seen only in a technical perspective; they demonstrate very clearly that the practice of THR has an ethical dimension, and that the ethics of testing new concepts should be discussed: For whom is a new THR of value? On whom should it be tested?

Clinicians should not allow themselves to reduce the problem to one of randomization or the probability that results will sooner or later show up in national registers. The ethical responsibility rests heavily on the shoulders of the clinician to make a correct analysis of the need for a new product, before he begins to use it.

If wrong, the patient has to pay the cost.

References

Charnley J. Acrylic Cement in Orthopaedic Surgery. Chruchill Livingstone, Edinburgh and London, 1970.

Havelin L I, Engesæter L B, Espehaug B, Vollset S E. The effect of cement type on early revision of 8,579 primary Charnley prostheses. The Norwegian arthroplasty register. J Bone Joint Surg (Br), accepted for publication.

Kindt-Larsen T, Smith D B, Jensen J S. Innovations in acrylic bone cement and application equipment. J Appl Biomat 1995; 6: 75–83.

Riegels-Nielsen P, Sørensen L, Andersen H M, Lindequist S. Boneloc® cemented total hip prostheses. Loosening in 28/43 cases after 3–38 months. Acta Orthop Scand 1995; 66 (3): 215–7.

Suominen S. Early failure with Boneloc® bone cement. 4/8 femoral stems loose within 3 years. Acta Orthop Scand 1995; 66 (1): 13.

Thanner J, Freij-Larsson C, Kärrholm J, Malchau H, Wesslén B. Evaluation of Boneloc®. Chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties. Acta Orthop Scand 1995; 66 (3): 207–14.

Wykman A G M, Sandersjöö G A. Low polymerization temperature with Boneloc®. In vivo measurements in 11 hip replacements. Acta Orthop Scand 1995; 66 (3): 218–9.

Lars Linder