One-stage exchange

IT ALL BEGAN HERE

Based on the first implementation of mixing antibiotics into bone cement in the 1970s, the Endo-Klinik has used one stage exchange for prosthetic joint infection (PJI) in over 85% of cases. Looking carefully at current literature and guidelines for PJI treatment, there is no clear evidence that a two stage procedure has a higher success rate than a one-stage approach. A cemented one-stage exchange potentially offers certain advantages, mainly based on the need for only one operative procedure, reduced antibiotics and hospitalisation time. In order to fulfill a one-stage approach, there are obligatory pre-, peri- and post-operative details that need to be meticulously respected, and are described in detail. Essential pre-operative diagnostic testing is based on the joint aspiration with an exact identification of any bacteria. The presence of a positive bacterial culture and respective antibiogram are essential, to specify the antibiotics to be loaded to the bone cement, which allows a high local antibiotic elution directly at the surgical side. A specific antibiotic treatment plan is generated by a microbiologist. The surgical success relies on the complete removal of all pre-existing hardware, including cement and restrictors and an aggressive and complete debridement of any infected soft tissues and bone material. Post-operative systemic antibiotic administration is usually completed after only ten to 14 days.

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This article describes the authors’ experience of the Endo Klinik management strategies. In order to fulfill a one-staged approach, there are essential pre-, peri- and post-operative details, which need to be meticulously followed.

**History**
Based on the first implementation of mixing antibiotics into bone cement by Professor Buchholz in the 1970s, the Endo-Klinik followed a one-stage exchange methodology for PJI in over 85% of all our infected cases up to now. While initially there was little enthusiasm for adding antibiotics to cement, Buchholz was able to decrease the infection rate from around 3% to below 1% by altering the antibiotic content of cement. Based on these findings, it became logical for Buchholz and his Microbiologist Professor Lodenkämper to extend this concept to septic revision THR, which established the basic concept of one stage exchange joint revision. This technique quickly became the standard for PJI treatment at the Endo Klinik.

**ENDO Klinik classification**
Based on the reported limited success rate of implant retention in PJI between three and 64 weeks after primary surgery, we defined two scenarios in our clinical set up: 1) acute infection – occurring within the first three post-operative weeks; and 2) late infection – occurring after the third post-operative week. Consequently the authors aggressively treat an acutely infected TJR with a local debridement, soft-tissue revision and extensive lavage, polyethylene liner exchange, while preserving the initially implanted prosthesis. Systemic antibiotics are used as described by Zimmerli, Trampuz and Ochsner for between three and six months. Late infection, however, is always treated with complete implant removal and one stage exchange, which is possible in around 85% of our PJI cases.

**Diagnosis**
According to current evidence and recent clinical practice guidelines by the American Academy of Orthopaedic Surgeons (AAOS), we follow mandatory pre-operative testing, for every case of a TJR patient with unexplained pain:

- Laboratory monitoring of C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). 19,20
- Knee or hip joint aspiration with prolonged microbiological culture time of at least 14 days, with patients being off antibiotics for a minimum of 14 days. 21
- Synovial fluid analysis of white blood cell count and percentage of neutrophils. 22-24
- Repeated aspiration in cases of initially negative microbial cultures in combination with either obvious infection signs or pre-existing positive culture results.
- Arthroscopic biopsy of the knee joint or open biopsy of the hip joint in cases of persistent negative aspiration results, with obvious infections signs. 25

**Joint aspiration**
The essential and most relevant pre-operative diagnostic test required in any case of a planned one stage exchange, is based on joint aspiration with a precise identification of micro-organisms. The presence of a positive bacterial culture and respective antibiogram is vital in order to individually define the specific antibiotic to be loaded into the cement, which is required to achieve a high local therapeutic level of antibiotic elution. 26-29

This protocol has been adopted as policy in our clinic before every planned TJA revision case. An earlier study demonstrated, that between 4% and 7% of our patients undergoing TJA revision, had a subtle low grade infection by aspiration, without any obvious clinical symptoms or relevant laboratory abnormalities. 30 A standardised protocol of joint aspiration, in combination with CRP and ESR laboratory testing might become a general recommendation in many countries, in order to rule out PJI before TJR revision.

**Indications**
Generally we see very few arguments against a one stage revision protocol. The minimum infrastructural requirement is based on the pre-operative knowledge of the bacteria in the synovial fluid, in combination with a distinct patient specific plan for localised and systemic antibiotic treatment as recommended by an experienced microbiologist. This is true for both septic knee and hip revisions. An overview of all prerequisites necessary for a one staged exchange is shown in (Fig. 1).

**Contra-indications**
The following criteria should be considered to indicate that a two (or more)-staged procedure is required:

- Failure of ≥ 2 previous one-staged procedures.
- Infection spreading to the neurovascular bundle.
- Unclear pre-operative bacterial specification.
- Non-availability of appropriate antibiotics.
- High antibiotic resistance.
- Sinus tract with unclear bacterial specification.

A relative contra-indication is inadequate soft-tissue coverage of the affected joint. We do however perform a one stage approach in patients undergoing early secondary flap reconstruction by a plastic surgeon, while covering the wound using an interim vacuum assisted closure technique. In severe PJI cases of the knee including a complete loss of extensor mechanism, the authors prefer the use of a one stage arthrodesis nail.

Generally larger osseous defects or associated osteomyelitis have to be treated radically in a one stage approach, including complete resection of the affected bone, demonstrating another possible drawback of this technique.

**Pre-operative preparation and planning**
To undertake a one stage procedure, a positive bacterial culture must be present and a respective profile of antibiotic resistance must be understood. Cemented fixation using
antibiotic loaded cement is considered to be the treatment of choice in order to achieve a high local therapeutic level of antibiotic eluting from the cement. This might be complemented in the future by antibiotic loaded cementless implants or silver coatings.

The success of a one stage approach not only depends on the meticulous removal of all hardware (including cement and restrictors) but also a very aggressive and complete debridement of infected soft-tissue and bone material. This should always include a full synovectomy, including the posterior aspects of the knee or radical debridement of the anterior and posterior capsule of the hip.

In the knee this approach might also include sacrificing the collateral ligaments to perform a complete and radical soft-tissue resection. Thus the definitive pre-operative planning should consider the use of a semi-constrained, or even fully constrained or hinged implants, based on the surgeon’s preference.

**Implants and cement**

- Antibiotic loaded cement with additional antibiotics in powder form to be added intra-operatively is necessary in all cases. Invariably at least two or three mixes of cement (between 80 g and 120 g) are required as are large mixing systems and appropriate cement guns. In patients with a narrow diaphysis extra narrow nozzles allow for appropriate retrograde cementing.

- Industrially pre-manufactured antibiotic loaded cement may be appropriate. However, for the success of any one-staged procedure, the patient specific antibiogram for the final topic cement impregnation is mandatory.

**Operative technique**

- The surgical success relies on the complete removal of all pre-existing hardware material, completed removal of all cement rests, restrictors, cable wires or any other contaminant material. Consequently special instruments should be available (Fig. 2).

- All non-bleeding tissues and related bone need to be radically excised.

- Biopsy material, preferably five or six samples, should be taken as a routine measure from all relevant areas of the operation site for combined microbiological and histological evaluation.

- Completing the debridement often exceeds the amount of resected material seen in a two-staged approach.

- We recommend the general use of pulsatile lavage throughout the procedure, however, after implant removal
and complete debridement, the intramedullary canals are packed with polymeric biguanid-hydrochlorid (polyhexanid) soaked swabs. Furthermore, the swabs are placed over the wound area before re-draping the patient.

- The whole team should re-scrub and new instruments used for re-implantation.
- A second dose of antibiotics should be given after 1.5 hours operating time or if blood loss at this point exceeds 1 l.

**Re-implantation**

The following should be considered:

- Inadequate bone stock may require the use of allografts, although ideally this should be avoided. The authors prefer to fill large defects with antibiotic loaded acrylic cement, and do not favour the use of any allografts (Figs 3 to 5).
- Alternatively, the use of tantalum-based acetabular wedges or femoral and tibial cones have been implemented in our regular clinical use for over five years. A combined fixation of the cement with the prosthesis and tantalum augmentation is possible. It has been postulated that tantalum has some antibacterial potential; however, this has not been clinically proven.
- The antibiotic-loaded cement is prepared in the meantime, fulfilling the following criteria:
  - Appropriate antibiotics
  - Bactericidal (with the exception of Clindamycin)
  - Powder form (never liquid)
  - Maximum concentration of 10%/PMMA powder
- Antibiotics (e.g. vancomycin) might change the polymerisation behaviour of the cement, causing acceleration of cement curing.

- Current principles of modern cementing techniques should be applied. In order to achieve an improved cement bone interface, the tourniquet should be inflated prior to cementing in TKR cases.

**Post-operative antibiotics**

Associated post-operative systemic antibiotic administration in a one-stage procedure is usually followed for ten to 14 days (with the exception of *streptococci*). While a prolonged administration of intravenous antibiotics for six weeks is common in the two-stage approach. The rational for this prolonged period of time has not been clarified in the literature, but there is clear evidence of relevant systemic and organ-specific complications after prolonged antibiotic administration.

**Post-operative care and rehabilitation**

Post-operative stay in hospital ranges between 12 and 20 days (mean 14) in our clinic. The physiotherapy approach after any one-stage procedure cannot be generalised due to the variety of soft-tissue and bone damage, and the extent of infection, an individual plan is developed in most cases. Compromises between necessary immobilisation due to structural damage and attempts for an early mobilisation, especially in the elderly patients often with many comorbidities, have to be made. However, we recommend early and aggressive mobilisation within the first eight days post-operatively if possible. In TKR patients, a similar mobilisation strategy to the primary situation allows the patients to fulfil an early rehabilitation process. In most patients with adequate bone stock, immediate full-weight-bearing mobilisation is often possible (Figs 4 and 5).
Post-operative complications

Persistent or recurrent infection remains the most relevant complication in the one stage technique. Failure rates with a two stage exchange have been described as being between 9% and 20% in non-resistant bacteria, our experience shows comparative results after eight years of follow-up using the one stage approach.\textsuperscript{10-12,36} As a result, we discuss with patients, at the time of consent, a possible risk of recurrent or new infection in between 10% and 20% of cases.

Although we are unable to present comparative data evaluating the functional outcome of a one-\textit{versus} two-stage approaches, we do not believe that an articulating spacer, or a partial or complete immobilisation of the affected joint, will result in a better functional outcome.

We consider the risk of direct damage to the sciatic or peroneal nerve and main blood vessels as low under the
guidance of an experienced surgeon, even in such an extended aggressive debridement. The general risk of intra- and post-operative fractures should be comparable with the two-staged exchange, however, especially cemented femoral stem revision tend to have a general lower fracture rate, than any uncemented technique.

Outcomes
The two stage approach has become the method of choice for most surgeons worldwide, with reported re-infection rates of in between 9% and 20%.10-12,36 Although advocated as the benchmark procedure, the authors have established and followed the one stage approach in the clinic for over 30 years and in 85% of all our infected TJR patients (Figs 6 and 7).

Accordingly, far more studies have been published and emphasised concerning the two stage revision technique. Quite a few studies evaluating one stage exchange and its techniques are available.5,6,13,14,37-40 Although most reports are from the Endo Klinik, other international institutions have reported their experience using this technique with rates of success being between 75% and 90% depending on the length of follow up.14,34,38,39,41,42

Besides the obvious benefit of eliminating a second major operation, further advantages arise from the reduced duration of post-operative systemic antibiotics in terms of cost, convenience and morbidity. This is rarely prolonged for more than 14 days in the authors setup.

Summary
One stage exchange in PJI is rarely used in the wider orthopaedic community, although it offers some obvious advantages. The key to success is based on a well-defined and detailed protocol, including a meticulous pre-operative aspiration regimen, planning, aggressive intra-operative surgical approach, followed by a cemented implant and relatively short period of systemic antibiotic therapy.

No benefits in any form have been received or will be received from a commer- cial party related directly or indirectly to the subject of this article.

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References


