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## Femoral Head Allograft Desinfection System Using Moderate Heat

The employment of a reliable thermal viral inactivation process, which minimally manipulates tissues, for surgically retrieved femoral head allografts addresses the increased concerns with virus transmissibility while minimizing the loss of biological properties. Our investigations have shown that heat treatment at a minimum of 80°C for a minimum of 10 minutes provides safe, good quality cancellous bone allografts and increases the cost-effectiveness and simplicity of managing a hospital frozen femoral head bone bank.

Human femoral head centers were contaminated with different vegetative bacterial and viral suspensions. A core temperature of 80°C for 10 minutes was sufficient to fully inactivate  $3 \times 10^6$  ml. *Staphylococcus aureus* and *Streptococcus faecalis*, and  $>5 \log_{10}$  steps of cytomegalia (herpes group), polio (enterovirus), and yellow fever (arbovirus) viruses.

Several biomechanical and biological properties of bone following a one-hour treatment in a water bath set at 80°C were investigated. Employing compression and tension tests, 80°C treated human and porcine cancellous bone blocks showed reductions in properties ranging from 8–19% compared to untreated control groups. Osteointegration at 3 months following treatment of explanted and then reimplanted autograft rat diaphyseal segments was 15% less than untreated controls.

Subsequently, a thermal desinfection system for femoral heads from living donors (Lobator Marburg Bone Bank System, Teios GmbH, Marburg, Germany) was developed. A minimum of 82.5°C is reached for a minimum of 15 minutes in the femoral head center, with a peak temperature of 87°C. Three highly relevant viruses were tested at independent research centers using the Lobator sd-1: HIV-1, BVDV (specific model virus for HCV), and CPV (specific model virus for parvovirus 319 and thermal model virus for HBV). The reduction steps ( $\log_{10}$ ) were: HIV:  $>8.5 \pm 0.3$ , BVDV:  $>5.21 \pm 0.25$ , CPV:  $>9.06 \pm 0.29$ . The kinetics of inactivation

curves for all three viruses indicated that the desinfection process was robust and effective; no viruses were detectable after 62 minutes of the 94 minute process. A microbiological study performed on 2458 consecutive human femoral head allografts found a primary contamination rate of 9% for femoral heads recovered under intra-operative conditions. After processing with the desinfection system bacterial retesting of these same heads revealed a contamination rate of 0.12%; these secondary post-processing contaminations were due to the lab technician learning curve.

Since 1993, orthopaedic and trauma departments in more than 400 hospitals in Europe, Canada and Asia are using the Lobator Marburg Bone Bank System for in-house processing of their surgical femoral head allografts. More than 80 000 femoral heads have been processed to-date. A prospective clinical trial is in progress at the Marburg University Hospital Trauma Center (Germany). One year follow-up results on more than 1500 patients indicate that the complication rate is not higher than those reported in the literature using untreated frozen cancellous bone allografts. A separate retrospective clinical study (Endo-Klinik Hamburg, Germany) involving 236 consecutive patients who had undergone bone grafting at the acetabulum during revision hip arthroplasty found no statistically significant differences in failure rate between patients treated with Lobator-processed grafts versus those treated with gamma irradiated grafts after mean follow-up times exceeding 4 years.

The latest European and German surgical bone banking guidelines have incorporated the use of independently validated thermal viral inactivation methods in place of repeat serological testing of donors. In comparison to allograft femoral heads sourced outside the hospital, and synthetic or xenogenic bone materials, the unit cost to maintain an in-hospital femoral head bank, employing the Lobator Marburg Bone Bank System, can offer significant economic advantages to the hospital.

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### Bibliography

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