Effects of Terminal Sterilization on Mineralized Allograft

A review of in vitro studies and clinical literature on terminal sterilization methods for allograft bone reveals several key findings. The research indicates that while gamma irradiation is a common sterilization method, it can significantly degrade the quality of allografts.

DISCLAIMER

The following page contain summaries of published data as interpreted by Geistlich. Although we try to reflect to the best of our knowledge the results and conclusions of the cited studies, errors cannot be excluded. We explicitly emphasize that the authors of the cited studies cannot be held responsible for the content of the summaries.

Other Relevant Studies

Aseptic Processing Preserves Allograft Bone Integrity: An Alternative to Gamma Irradiation

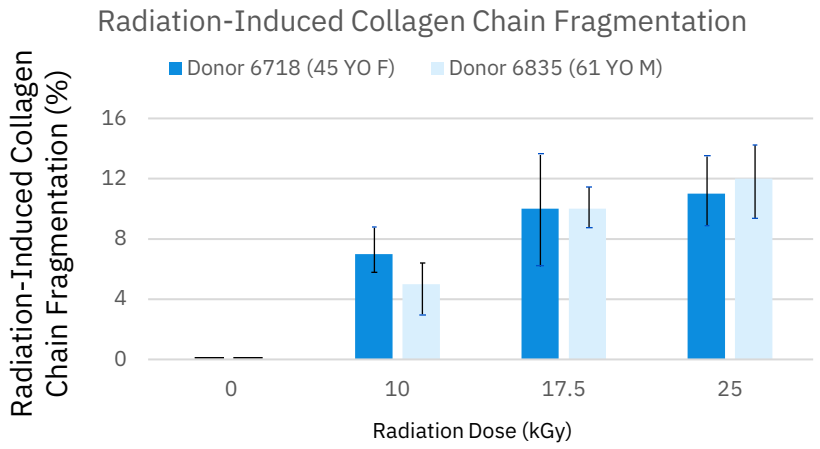
Gamma Irradiation Significantly Reduces Graft Strength

Irradiated cortical bone failed

6-10X

faster than non-irradiated controls

Collagen Damage Is Dose-dependent



Gamma irradiation causes collagen degradation leading to →

- **Reduced toughness**
- **Impaired osteoinduction**
- **Poor remodeling**

Ina et al. (2022) Clin Orthop Relat Res, 480(6), 1208–1219.
Crocker et al. (2024) Cell Tissue Bank (2024) 25:735–745
Lietman et al. (2000) Clin Orthop Relat Res, 375, 214–217.
Nguyen et al. (2006) Cell Tissue Bank, 8(2), 93–105.
Munting et al. (1988) Acta Orthop Scand, 59(1), 34–38.

Key Message

These findings support that compared to standard-dose gamma irradiation, aseptic processing and low-dose sterilization methods better preserve mechanical strength, biological activity, and remodeling potential—key factors for long-term graft success.

Study results

- **Significant Strength Reduction:** At the 25 kGy dose, bone grafts failed up to 10 times faster than non-irradiated controls, and they failed six times faster compared to grafts irradiated at a lower dose (17.5 kGy).
- **Dose-Dependent Decline:** Gamma irradiation, particularly at the standard 25 kGy dose, causes a clear, dose-dependent decrease in the fatigue life of cortical bone.
- **Brittle Fracture and Collagen Damage:** The loss of mechanical strength is associated with a change in fracture patterns from ductile to brittle. This is attributed to the scission of the collagen backbone caused by the radiation.

Review of Peer-reviewed Publications

Research Spans Decades

To assess the effects of terminal sterilization on allograft bone integrity, a literature review of in vitro studies and clinical findings was conducted. The research, spanning decades, has investigated these effects, revealing key findings across various testing methods and publications.