Clinical Applications of Bone Allografts and Substitutes

Biology and
Clinical Applications

**SERIES IN ALLOGRAFTS IN BONE HEALING:
BIOLOGY AND CLINICAL APPLICATIONS**
Advances in *Tissue Banking* Specialist Publications

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Editor

Glyn O Phillips

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ALLOGRAFTS IN BONE HEALING: BIOLOGY AND CLINICAL APPLICATIONS

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INTRODUCTION TO THE SERIES

This series* is aimed directly at orthopaedic surgeons, who use or propose to use musculoskeletal allografts in their clinical practice. It is not a subject which comes naturally or easily to this group of clinicians, who seem to be always overloaded with the day-to-day calls of surgical practice. Often, they must rely on infrequent conference talks or specialist review articles for their information. Consequently, it is a field riddled with myths and inconsistencies.

- How are these grafts prepared?
- Are they safe?
- Which are most effective in promoting bone healing?
- Does radiation used to sterilisation damage the bone or weaken the graft when used for structural purposes?
- Which graft should be used for which procedure?
- Are they free of viruses, particularly HIV?
- What does sterility mean in relation to an allograft?
- Do they retain any bone morphogenic protein after tissue bank processing?
- What about their immunogenicity?
- What are the growth factors which assist in the bone healing process?

These are only few of the questions, which have been posed to me during numerous training courses and workshops with orthopaedic surgeons. This series aims to answer these questions and more and do so in an accessible manner. It is a ready reference for any orthopaedic surgeon involved in this work and will point them to even more specialised papers for further detail.

The difficulty in gaining access to authoritative information in this diverse subject is its inter-disciplinary character. At one end of

*The papers in this series are collected from *Advances in Tissue Banking* and *Radiation and Tissue Banking*.

the spectrum is the tissue banker, who is involved with screening potential donors, undertaking serological tests to eliminate potential harmful micro-organisms and procuring the tissues, in association with medical colleagues. Thereafter, there is a series of processing and sterilisation procedures, conducted within a total quality system which documents and ensures complete traceability, which ends with the allograft professionally packaged and ready for the surgeon. At the other end of the spectrum is the surgeon, facing a bewildering array of such grafts. In between there are so many specialities, such that currently the information flow is mainly based on chat and experience between surgeons.

This series aims to bridge this great divide by describing what grafts should be used, what are the factors which influence their ability to promote bone healing and details about the clinical effectiveness of the work carried out up to this time.

The subject is developed stepwise, but each contribution has been prepared by a specialist who has direct experience in practical aspects of the subject.

Volume 1 deals with the biological aspects of bone healing and immunology, the growth factors which control bone repair and specialist factors associated with particular grafts such as demineralised bone.

Volume 2 describes the influence of the components of bone, the biochemistry of collagen, the process of osteoinduction, and factors which might reduce the functioning of these important molecular triggers, and dispels some myths about the effects of radiation.

Volume 3 describes the general clinical use of various allografts, a comparison between autografts and allografts, and an evaluation of the value of bone substitutes compared with human allografts.

Volume 4 describes in more detail specific procedures for application of allografts in various reconstructions: in the knee, the spine, in neurosurgery, total hip and revision hip arthroplasty.

Volume 5 deals with allografts in the treatment of bone tumours and prosthetic composites and evaluating long term results of allograft in the management of bone tumours.

All the contributors have also been authors within the *Advances in Tissue Banking* series and received the accolade of their peers across the subject spectrum. They are, therefore, not narrow specialists and so can present a wide perspective which the series aims to do, and to do so with an authority based on achievement.

It is a pleasure to recommend the series to all orthopaedic surgeons who have an open mind about the subject and are prepared to read and learn.

Glyn O. Phillips
Series Editor

PREFACE

The clinical practice of using bone grafts to repair, replace or supplement the bone stock has a long history, dating back to McEwen in 1881. When a group of surgeons, in which Geoffrey Burwell was a leading figure showed that frozen preserved allograft was superior in performance to fresh allogeneic bone, the road was pointed to the more extensive use of bone grafts. However, generally the practice remained a "cottage industry" well into the latter part of the 20th century. This involved orthopaedic surgeons keeping pieces of bone in individual hospital cold store, which had been rescued after surgery, usually femoral heads after hip replacement, and using these as required on an individual basis. There were many exceptions and these surgeons were usually associated with the pioneering tissue banks, which first emerged first in the 1950's. Notable among the early tissue banks was the Bethesda Naval Tissue Bank in the USA, the Wakefield Tissue Bank in the UK, the Bank at Hradec Kralove in Czechoslovakia, the Charite Hospital Bank in Berlin, the Democritos Bank in Greece and bank in Warsaw which celebrated its 40th anniversary in 2004. The explosion came in the 1990's and onwards, with the result that more than one million bone grafts were used in the USA during 2004. This volume reflects the growth of the subject, giving a cross-section of specialised experience.

Despite this remarkable growth the safety of allografts remains a major concern due to microbial and viral contamination of tissues. Existing methods and processing for sterilising tissues are proving, in many instances inadequate. Infections have been transmitted from the graft to the recipient and in the USA, the Centre for Disease Control and other regulatory bodies, have

drawn attention to the need for a reliable end sterilisation method which does not damage the functionality of the final tissue. The International Atomic Energy Agency (IAEA) has given special attention to the widely used method of using ionising radiations for such sterilisation. There is a great deal of misunderstanding about this method and a rigorous approach is needed if the method is to be used to its full potential. Accordingly the IAEA have set out a Code of Practice for this application of radiation, which is described in the first contribution since it is fundamental to the whole field of surgical use of tissue allografts.

The following two contributions document the Polish experience led by Janusz Komender. A tissue bank has been operating in Poland since 1963 and more than 100,000 grafts of bone, cartilage dura mater, skin and fascia have been prepared and used in the various branches of reconstructive surgery. Historically and scientifically this work is important, not the least because they have consistently used radiation sterilised bone grafts. As such they have the widest experience of this type of graft, and their contributions positively dispel the myth that radiation destroys the clinical value of the allograft. Satisfactory graft substitution was observed in 90.8% of all patients. Their second contribution concentrates on the use of deep frozen radiation sterilised bone allografts. They find that such allografts undergo "creeping substitution" (incorporation) in 3 to 6 months. Both contributions give a wealth of experience in the use of radiation sterilised grafts.

There is no real conflict between the use of autografts and allografts, although this debate is still often perpetuated. Autografts are, of course, the gold standard. Shortage of autograft bone and the advisability of introducing a second lesion are factors which ultimately decide which should be used in particular circumstances. The contribution of Sarkar and colleagues from Germany compare the clinical results and organisational aspects of autogenous and allogeneous bone grafting. This contribution shows that using allogeneous grafts does not increase the risk of post-operative infections. In contrast

to the Polish experience these workers do not favour graft sterilisation.

The Russian experience in this field has not been readily available and so the contribution by Professor Kalinin and his colleagues is important since it illustrates the approach in that great country. They have developed a model which contributes to the continuing discussion about allografts versus autografts. They find demineralised bone to be a highly promising transplantation material, a subject further considered in the next contribution.

Demineralised bone is a specialist tissue graft which has mostly been used in maxillofacial surgery. Christian Delloye, from Belgium, however, compares the more general use of freeze-dried mineralised and demineralised bone. The use of freeze-dried bone has not been as popular in Europe as in the USA. As a structural material it is not appropriate since freeze drying significantly weakens the bone, much more so than the effects of radiation. As a leading member of the European Association for Musculoskeletal Tissue (EAMST) Dr Delloye appropriately draws attention to the need to keep strictly to the European Standards when processing his grafts. His conclusion is that freeze dried bone remains a reliable bone substitute.

The orthopaedic surgeon needs to be supported with other grafts, apart from bone. Cartilage is one of the most important of these. Despite the advances in tissue engineering, allogenic rib cartilage offers excellent properties and enables the surgeon to shape the implant as required, particularly for reconstructions of the face. The contributions of Sladowski and colleagues demonstrate that cartilage offers long term support for soft tissues and degradation does not occur within the first four years. Experience of using more than 2500 such grafts is described, with positive results in 75% of cases.

Despite the advances in using human bone allografts, it must often be conceded, either because lack of availability or shortage of these grafts at the desired time that bone substitutes must be considered. Professor Aho from Finland provides an excellent

survey of what is now available. Moreover, he evaluates their clinical effectiveness. He concludes that most of these substitutes can be used as fillers for reconstruction of moderately sized (1–4 cm in diameter) cystic lesion in the human skeleton. Only a few can be used as a replacement of a weight-bearing skeletal part.

The volume, therefore, provides an international expert evaluation of the use of bone, bone substitutes and related allografts, and describes the practices and clinical results in particular procedures. It will provide a ready reference for anyone wishing to carry out a quick survey of the subject.

Glyn O. Phillips
Editor

LIST OF CONTRIBUTORS

J. KOMENDER

Department of Transplantology
Orthopaedics and Neurosurgery Central Clinical Hospital
Military Medical University in Warsaw, Poland

A. KOMENDER

Department of Transplantology
Orthopaedics and Neurosurgery Central Clinical Hospital
Military Medical University in Warsaw, Poland

H. MALCZEWSKA

Department of Histology & Embryology
Medical University in Warsaw
Orthopaedics and Neurosurgery Central Clinical Hospital
Military Medical University in Warsaw, Poland

W. MARCZYNSKI

Institute of Traumatology
Orthopaedics and Neurosurgery Central Clinical Hospital
Military Medical University in Warsaw, Poland

WOJCIECH MARCZYNSKI JANUSZ KOMENDER

Institute of Traumatology
Orthopaedics and Neurosurgery of Central Clinical Hospital
Military School of Medicine in Warsaw, Poland

JANUSZ KOMENDER

Bank of Human Tissues Medical Academy in Warsaw, Poland

M.R. SARKAR

Klinik für Unfall-, Hand- und Wiederherstellungschirurgie
Chirurgie III, Universität Ulm, Germany

M. SCHULTE

Klinik für Unfall-, Hand- und Wiederherstellungschirurgie
Chirurgie III, Universität Ulm, Germany

G. BAUER

Klinik für Unfall-, Hand- und Wiederherstellungschirurgie
Chirurgie III, Universität Ulm, Germany

E. HARTWIG

Klinik für Unfall-, Hand- und Wiederherstellungschirurgie
Chirurgie III, Universität Ulm, Germany

A.V. KALININ

Russian Research Institute of Traumatology and
Orthopaedics, named after R.R. Vreden
Baikov Str. 8, 195427 St. Petersburg, Russia

V.I. SAVELIEV

Russian Research Institute of Traumatology and
Orthopaedics, named after R.R. Vreden
Baikov Str. 8, 195427 St. Petersburg, Russia

A.A. BULATOV

Russian Research Institute of Traumatology and
Orthopaedics, named after R.R. Vreden
Baikov Str. 8, 195427 St. Petersburg, Russia

Ch. DELLOYE

Catholic University of Louvain
St-Luc University Clinics
Brussels, Belgium

D. SLADOWSKI

Department of Transplantology
Warsaw Medical University, Poland

A. KOMENDER

Department of Transplantology
Warsaw Medical University, Poland

J. KOMENDER

Department of Transplantology
Warsaw Medical University, Poland

H. MALCZEWSKA

Department of Histology & Embryology
Warsaw Medical University, Poland

A.J. AHO

Department of Surgery
The Turku University Central Hospital
The Biomaterial Project, University of Turku
Turku, Finland

J.T. HEIKKILÄ

Department of Surgery
The Turku University Central Hospital
The Biomaterial Project, University of Turku
Turku, Finland