2 PRESERVED BONE ALLOGRAFTS IN RECONSTRUCTIVE ORTHOPAEDICS

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1. Introduction

Tissue banking experience was achieved over a long period (1963–2001) since the creation of tissue banks in Poland. Thanks to initiative of two outstanding Polish professors: Adam Gruca, director of Orthopaedic Clinic in Warsaw and Kazimierz Ostrowski, director of the Department of Histology & Embryology in Warsaw, organisation of tissue processing and co-operation with orthopaedic clinics, radiation-chemistry laboratories and microbiological units was started. Since 1963, a tissue bank has been operating in Warsaw and around 100 000 grafts of bone, cartilage, dura mater, skin and fascia have been prepared and used in various branches of reconstructive surgery. In 1967, the tissue bank in Katowice, connected to the Blood Transfusion Centre, was created. In 1978, a similar unit was organised in Kielce as the Cryobiological Unit in the local blood transfusion centre. These three units created the first network of multi-tissues banks in Poland. In the 1980s, in several

medical institutions (Cardiosurgery Clinic in Zabrze, Institute — Centre of Health Child, Cardiosurgery Clinic in Kraków) the heart valves and blood vessels banks were organised. Later, two eye tissues banks (in Warsaw and in Lublin) were founded. All of these units are in contact, once a year within the frame of Polish Transplantation Society, when a session on tissue banks is organised. Most of the workers attend the meetings of EATB. Twice, in 1977 and in 1999, worldwide meetings of tissue bank specialists in Poland were organised. Implementation of radiation sterilisation as main sterilisation procedure has been adopted since the very beginning. Some studies performed in our tissue bank were fundamental for allografts radiation-sterilisation (Dziedzic-Goclawska, 1979; Dziedzic-Goclawska *et al.*, 1979; Komender, 1976; Ostrowski *et al.*, 1980; Ostrowski *et al.*, 1996). The Central Tissue Bank established good links of collaboration with orthopaedic units, and that enable us to perform interesting analyses of use of preserved allografts in clinics.

2. Transplantation of Lyophilised and Radiation-Sterilised Bone Grafts

In 1960s and 1970s, lyophilised bone most often was used for orthopaedic reconstructions. Thanks to the good co-operation with several orthopaedic units, records on the follow-up of patients after bone transplantation can be gathered. This analysis is based on 1014 cases of preserved (lyophilised and radiation-sterilised) allogenic bone transplantation, where 27 biological and clinical variables were taken into consideration and detailed results were published earlier (Komender *et al.*, 1991). The following general conclusions may be drawn: more than 91% of operated patients reached full restoration or significant improvement of their condition; after surgery 80.3% of patients reached their full physical fitness; in 5.1% of the patients the results of treatment were unsatisfactory; in cases of benign tumours and congenital changes, the highest number of *"very good"* results of treatment was achieved; unsatisfactory results of treatment most often appeared in post-traumatic deformation and degenerative diseases (Table 1).

Table 1. Transplantation of lyophilised, radiation-sterilised bone allografts. Results of treatment in various diagnoses.

Diagnoses	Result of treatment									
	Very good		Satis-factory		Difficult to estimate		Unsatis-factory		Total	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Traumas	11	1.1	19	1.9	2	0.2	6	0.6	38	3.8
Benign tumours	107	10.6	68	6.7	6	0.6	5	0.5	186	18.4
Malignant tumours	0	0	2	0.2	0	0	0	0	2	0.2
Unspecific inflammations	6	0.6	30	3.0	1	0.1	4	0.4	41	4.1
Specific inflammations	42	4.2	86	8.5	5	0.5	7	0.7	140	13.9
Degenerative changes	34	3.4	38	3.8	3	0.3	7	0.7	82	8.1
Congenital change	141	14.0	213	21.1	11	1.1	17	1.7	382	37.8
Scolioses	25	2.5	73	7.2	7	0.7	4	0.4	109	10.8
Others	9	0.9	18	1.8	1	0.1	2	0.2	30	3.0
Total	375	37.1	547	54.2	36	3.6	52	5.1	1010	100

$Chi^2 = 75.479$; degrees of freedom, 24; $p < 0.01$

A comparative analysis of the distribution of clinical results obtained in this group was carried out using the Chi^2 test (Mainland, 1963). Some correlations and coincidences were presented. In order to find out the meaning of the correlations; the *"indices of coincidence"* were calculated according to Pearson (1904). Pearson's index permits a comparison of coincidence of different pairs of variables even with a various degree of freedoms, thus showing a strong relationship between the variables. As expected, numerous

variables showed significant correlation with the estimated final result of treatment (Komender *et al.*, 2001).

Three sets of indices of coincidence for the *"final result of treatment"*, *"fitness for work"* and *"role of the graft"* are evaluated. A strong relationship was found between: *"rebuilding of grafts"*, *"early estimated result of treatment"* and *"re-operation"* with the *"final result of treatment"*. What concerns the rebuilding of transplanted allografts seems to be the most important and sensitive factor in the post-surgery observation. Less important factors seem to be *"diagnosis"* and *"anatomical localisation"*. When the patients with unsatisfactory results of treatment were analysed, the most often localisation is related to the vertebral column or crus. No significant coincidence was found with *"age"*, *"handicap level"* or other parameters. Numerous patients even in their 70s were operated with the use of preserved allografts and the age seemed having no influence on the final result of treatment.

The sequence of variables is different when they are compared with the *"fitness for work"* after surgery. This coincides with *"age"*, *"diagnosis"* and *"physical efficiency"*. Such characteristics as: *"complications intra- or post-surgery"*, *"wound healing"*, etc. do not show any significant relationship with *"fitness for work"*. The sequence of variables is different when they are compared with the *"role of the graft"*. A very strong coincidence is expressed with *"performed re-operation"* and with the *"rebuilding of graft"*. Reoperation is always an unfavourable incident in course of treatment and if surgeon is obliged to remove the allografts, a positive clinical effect can rarely be expected. Impaired graft substitution is also a rather bad prognostic factor. A comparison of coincidence indices shows how significant *"rebuilding of the grafts"* is in post-surgery estimation. Lyophilised bone allografts are not so readily used now.

3. Transplantation of Deep-Frozen and Radiation-Sterilised Allogenic Bone Grafts

In 1980s and 1990s, deep-frozen bone allografts are most often use for transplantation in humans. In the Institute of Traumatology,

Orthopaedics and Neurosurgery of the Military Medical Academy in Warsaw, during 1981–1995, biostatic bone allografts, frozen and radiation-sterilised were transplanted into numerous patients (Kwiatkowski and Ratynski, 1999; Marczynski *et al.*, 1999). The results achieved in group of 596 female (53%) and 529 male (47%) are presented here. The mean age of patients was 36 years and varied from 2 to 70 years. The grafts were most often used in the second decade of life for 336 patients (30%), or in the third decade for 247 (22%). The indications for bone transplantations varied, 32 diagnoses were categorised into five groups: bone union failure in 401 cases (36%), congenital anomalies in 307 cases (27%), benign tumours in 133 (12%), 68 (6%) of post inflammatory changes and arthroses, 216 (19%) of bone necrosis and others, with: hip joint hypoplasia in 168 cases (15%), scolioses in 146 cases (13%) and solitary cysts in 135 cases (12%). Various types of grafts were used, depending on indications: chips 663 (59%), bars 270 (24%), slices of bone 168 (15%) and solid, large grafts 22 (2%). The manner in which the graft was implanted depended on the diagnosis and location of the pathological change. The grafts were implanted as follows: without covering by periosteum in 517 cases (46%), in incomplete intraosseus apposition of grafts in 292 cases (26%), intraosseus in 213 cases (19%), in subperiosteal position 56 cases (5%) and by intramuscular implantation 45 grafts (4%). In spinal reconstructions, bars were often used — 198 cases (63%), while in femur surgery, chips were mainly used (184 — 78%). In hip surgery, slices of bone were most frequently transplanted (136 — 58%), while chips dominated in reconstructions of the crural bone (148 — 78%).

The result of treatment was analysed 2 to 11 years after surgery. The progress of rebuilding of bone grafts was evaluated in physical and X-ray examinations that were carried out at regular intervals after operation. Analysis shows that by the 3rd month, 517 (46%) grafts were completely rebuilt; the patients of this group were mainly in the second decade of life. Within 6 months after operation, a further 416 (37%) grafts were rebuilt, by the 9th month 101 (9%), and by the 12th month 22 (2%). Within next the 12 months, a further 54 (4.8%) were rebuilt. However, 10 grafts (0.8%) became sequestered with no sign of rebuilding. The number of grafts rebuilt

Table 2. Transplantation of frozen radiation-sterilised bone allografts. Rebuilding of grafts introduced in various position.

Position of graft	Rebuilt grafts		Total	
	n	%	*n*	%
No periosteal cover	466	90.1	517	100
Incomplete intraosseus	251	86.0	292	100
Intraosseus	187	87.8	213	100
Subperiosteal	56	100	56	100
Intramuscular*	0	0	46	100

*all grafts were resorbed

and those in the process of being rebuilt was 1022 (90%). All grafts implanted in muscles were partially or completely reabsorbed (Table 2).

The rebuilding of grafts varied, depending on numerous factors such as: diagnosis, site of grafting, age of the recipient, type, size and the way of the graft introduced. Grafts of spongy bone were rebuilt within 3 to 6 months, grafts of compact bone, in the form of bars were rebuilt within 6 to 24 months. A comparison of age and of graft substitution shows highly effective substitution in the first decade of life 96%. In the second decade, their effectiveness was also high (95%). In the subsequent decades of life, substitution of grafts diminishes. Satisfactory graft substitution was observed in 1022 cases (90.8%) of all patients. The number of transplantations that were estimated to be unsatisfactory was 103 (9.2%).

4. Conclusion

The application of allogenic, biostatic frozen grafts reduce the extent and duration of operations, and the *"creeping substitution"* of implanted bone lasts 3 to 8 months, thus progress of the graft substitution depends on its structure and the position of transplants. Observation of results of bone allografts application is still progressing and now the group of patients under observation

is over two thousand. Development of surgical techniques, new generation of antibiotics and new technology of tissue banking certainly will influence the clinical results.

5. References

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