NHS
Blood and Transplant

Demineralised Bone Matrix

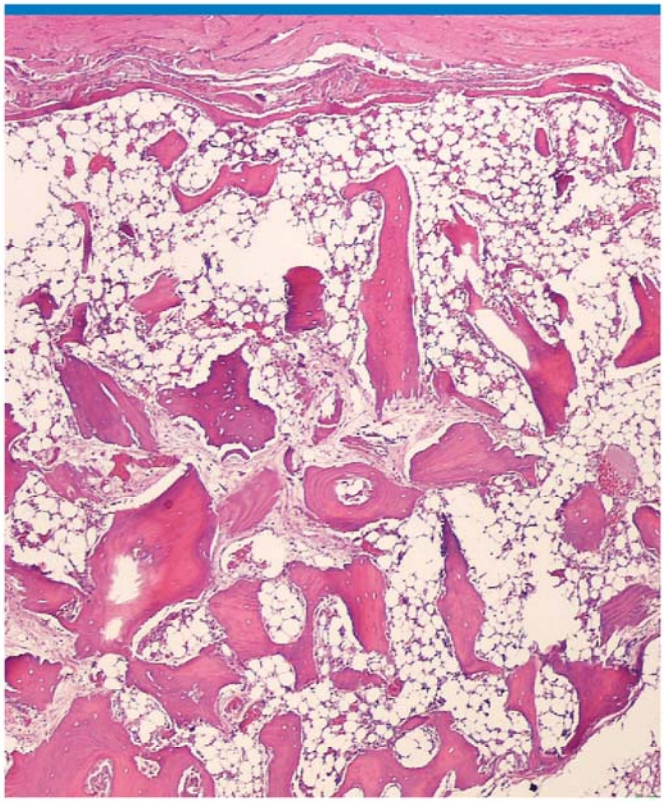
Tissue Services for all your allograft requirements

Demineralised Bone Matrix (DBM)

Demineralised bone is prepared by exposing bone to dilute acid. This gradually dissolves the mineral component of the bone, exposing its protein scaffold. Observations that partly demineralised bone is an effective graft material date from the latter part of he 19th century[2]. However, the modern day interest in DBM as a graft material stems from the seminal work of Marshall Urist in the 1960s[3]. He established that when DBM was implanted into extra skeletal sites, it could form de novo bone.

Why does it work?

The protein scaffold of bone is comprised primarily of collagen, with a small quantity of non-collagenous proteins. These include a group of powerful growth factors called bone morphogenetic proteins (BMPs). BMPs are capable of inducing the formation of new bone by influencing the migration and differentiation of stem cells into bone forming cells. They are thought to originate during osteogenesis, and subsequently become incorporated into the mineralising matrix of new bone. The combination of an osteoconductive scaffold and osteoinductive growth factors is very effective in inducing the formation of new bone.



De novo bone formation induced by NHSBT DBM in an athymic mouse model

DBM putty, provided in a blunt syringe for ease of application and handling

How is it made?

DBM is prepared from cortical bone derived from long bones. The bones are first cleaned of adherent soft tissue and marrow components, and then ground into a fine powder, using a custom-designed grinder which achieves this without generating excess heat. The powder is then sieved to the desired particle size range and demineralised using dilute hydrochloric acid, and rinsed in a buffered saline solution to remove any residual acid. It is then freeze-dried. Some DBM preparations are then mixed with a fluid carrier (glycerol) to facilitate handling and delivery. Depending on the ratio of powder to carrier used, it can be prepared as a flowable gel or mouldable putty. It is then packaged in aseptic conditions into sterile blunt-ended syringes for ease of delivery. The filled syringe is then terminally sterilised and subjected to final quality checks prior to release.

Sterility and safety

Due to the way in which DBM is prepared it is by definition a very safe form of allograft. It undergoes a lengthy processing protocol that includes washing at elevated temperatures and demineralisation. This will deplete any initial contamination. In addition, the bioburden present on the graft is assessed before processing begins, and if it is determined to be too high the graft is not made available for clinical use. At the end of processing, all DBM grafts are terminally sterilised with gamma irradiation. This is a very effective and widely used method of sterilizing tissue grafts. There has never been a documented case of infection being transmitted via a DBM graft.

Clean room production facility

Product range

DBM Powder

DBM powder is provided with a particulate size range of 250–710mm (or micron). While powder alone is light and electrostatic it can be mixed with the patients blood or bone marrow both to facilitate handling, and to provide the graft with autologous cells which may enhance osteogenesis.

DBM Paste

DBM paste is prepared by mixing DBM powder with glycerol in the ratio 55% DBM to 45% glycerol (v/v). This mixture has a fluid consistency. It is available in 1, 5 and 10cc in a blunt-ended syringe.

DBM Putty

DBM putty is prepared by mixing DBM powder with glycerol in the ratio 65% DBM to 35% glycerol (v/v). This mixture has a solid consistency, and can be moulded into shape. DBM putty is also available in 1, 5 and 10cc in a blunt ended syringe.

Combination with other grafts

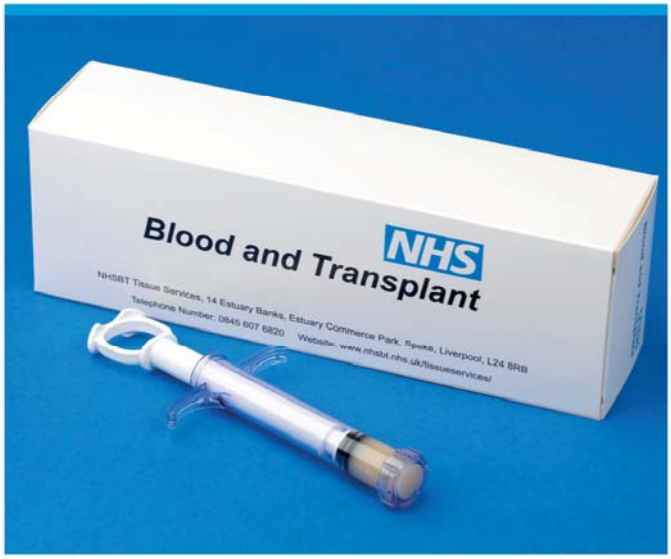
Following removal of the mineral content, DBM has little intrinsic mechanical strength. It is therefore unsuitable for use as a graft alone where structural strength is required. It can however be mixed with mineralised bone allograft to form a composite graft which has both structural strength and osteoinductive potential. NHSBT provide a wide range of mineralised allografts including ground bone (coarse, medium and fine), cancellous chips and struts which can be used alone or in combination with DBM. A summary of grafts available and ordering codes are given in Table 2.

Clinical applications of DBM

DBM has a long history of successful clinical use in applications where bone regeneration is needed.

These include:

- **Oral and maxillofacial** DBM has been demonstrated to effectively induce new bone formation when used for extraction socket filling and alveolar ridge augmentation[4,5]
- **Spine** DBM has been demonstrated to be a reliable allograft when used in spinal surgery for interbody fusion[6]



DBM graft and outer packaging

- **Trauma** DBM has been shown to be as effective as autologous graft when used to promote union in difficult to heal fractures with bone loss[7]
- **Joint replacement** Implantation of DBM, in conjunction with mineralised allograft, has been shown to regenerate lost bone stock in revision hip arthroplasty[8]
- **Tumour repair** When used as a void filler following tumour excision , DBM has been shown to regenerate bone as efficiently as autograft[9]

Indications

DBM is indicated for the filling of gaps in bone, or for bone surface augmentation in non-weight-bearing sites.

Contraindications

The removal of the mineral content of DBM compromises its structural properties. It is therefore not appropriate as a sole graft where structural support is required. For these indications a combination of DBM with mineralised allograft may be appropriate.

Supply and storage

All DBM grafts supplied by NHSBT Tissue Services can be stored at room temperature until the expiry date shown on the label. Under the terms of the Human Tissue Act, DBM grafts are not considered to be 'relevant material,' and therefore a licence to permit storage is not required.

In order to comply with the HTA traceability requirements, each Trust is required to have a signed service level agreement with the NHSBT before tissue can be supplied. This is to ensure compliance with the legal requirement for traceability of the tissue after it has been issued. In most cases, a signed SLA with NHSBT will already be in place. NHSBT has considerable expertise in the HTA requirements and our customer service team will be able to advise and help with this as necessary.

On request, all grafts are issued on next-day delivery, although same-day delivery for a small additional charge is available for emergency requests. It is a requirement of the UK Human Tissue Act that appropriate traceability systems are in place to ensure that tissue can be tracked from the donor to recipient. NHSBT Tissue Services has service level agreements set up with most hospitals in the UK to facilitate this.

Mineralised bone allografts

In addition to DBM, we provide a range of different mineralised bone allografts. These range from large structural allografts such as hemi-femurs or cortical struts, to morsellised cortico-cancellous grafts. With the exception of whole femoral heads donated by living donors, and massive allografts, all mineralised allografts are processed to deplete marrow content. Massive allografts are partially marrow depleted. Marrow depletion is accomplished by a multistep procedure that utilises a combination of washing with water, solvents and active oxygen compounds together with centrifugation, and has been demonstrated to remove at least 99.9% of donor marrow content.

DBM paste provided in a blunt syringe for ease of application and handling

Slice of mineralised, cleaned and freeze dried bone from a femoral head

Product codes and ordering information

DBM grafts are provided directly from our national tissue bank in Liverpool. Our dedicated customer services team are available 24 hours a day, 7 days a week to advise and assist with your requirements.

The following is a summary of allografts available; please see our website a for full product list and more details.

More information is available on the NHSBT Tissue Services website nhsbt.nhs.uk/tissueservices Alternatively you can call us on 0845 607 6820 or email at tscustserv@nhsbt.nhs.uk

Table 2 Demineralised Bone Matrix

	Product Code	Type of graft	Specification	Pack size
DBM powder particle size range of 250 – 710mm jar containing:				
	TP5015	DBM	Powder	1cc
DBM pastes 55% DBM by volume single blunt ended syringe containing:				
	TP5012	DBM	Paste	1cc
	TP5013	DBM	Paste	5cc
	TP5014	DBM	Paste	10cc
DBM putty 65% DBM by volume single blunt ended syringe containing:				
	TP5009	DBM	Putty	1cc
	TP5010	DBM	Putty	5cc
	TP5011	DBM	Putty	10cc

Table 3 Bone allografts

	Product Code	Type of graft	Specification	Pack size
	Unprocessed bone (fresh, frozen)			
	T0001	Whole Femoral Head	Fresh Frozen	1 whole femoral head
	T0002	Whole Femoral Head, irradiated	Fresh Frozen	1 whole femoral head
	Marrow depleted bone (frozen, all irradiated)			
	T0003	Whole Femoral Head		1 whole femoral head
	T0008	Half Femoral Head	Sectioned longitudinally	1 half femoral head
	T0015	Mixed granules	Ground, cortico-cancellous, granules, >6.7mm	70 or 35cc packs
	T0036	Cortical strut	Half femoral shaft, sectioned longitudinally	1 strut
	Marrow depleted bone (freeze-dried, all irradiated)			
	T0007	Half Femoral Head	Sectioned longitudinally	1 half femoral head
	T0013	Femoral slice	longitudinal slice, 6mm thick	1 slice
	T0026	Coarse ground	Ground, cortico-cancellous granules, >4mm	35 or 15cc packs
	T0027	Medium ground	Ground, cortico-cancellous granules, <4mm	35 or 15cc packs
	T0183	Fine ground	Ground, cortico-cancellous granules, <2mm	35 or 15cc packs
	T0037	Cortical strut	Half femoral shaft, sectioned longitudinally	1 strut
	T0049	Cancellous cubes	1cm^3 cubes of cancellous bone	5 cubes
	T0052	Cancellous chips	6x6x30mm chips of cancellous bone	5 chips
	T0095	Tricortical wedge	Iliac crest section, 30x15mm	1 wedge

References

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