Innovation in biomaterials for guided bone regeneration

Ralph Day BDS MIHM summarises the key clinical features and benefits of two new products to reach the UK market

associated with the use of autogenous/harvested bone has resulted in synthetic bone graft substitutes becoming an increasingly important component of the surgical armamentarium of dental implantologists and maxillofacial, orthopaedic and spinal surgeons throughout the world.

Calcium phosphates (CaP) have been successfully used in surgical applications for over 40 years, a fact which is extensively documented in the clinical literature.

Synthetic CaP biomaterials have outstanding properties: *similarity in composition* to natural bone mineral; *bioactivity* (ability to form bone

apatite-like material or carbonate hydroxyapatite on their surfaces); ability to promote cellular function, leading to the formation of a uniquely strong bone:CaP interface; and osteoconductivity (the ability to provide an appropriate "scaffold" for bone formation).

CaP biomaterials are able to bind and concentrate circulating endogenous bone morphogenetic proteins and have the potential to become osteoinductive (capable of osteogenesis).

Commercially available synthetic CaP biomaterials differ in composition (hydroxyapatite, beta-tricalcium phosphate, and biphasic CaP) and physical form (particulates, blocks, cements, titanium implant

coatings, composites with collagen or polymers).

MatriBone and Cova

Biomaterials development company Biom'Up specialises in the development of collagen-based medical devices across diverse surgical specialties, including dental, maxillofacial, orthopaedics, spinal, general surgical and cardiothoracics.

Responding to the needs of key opinion leaders in dental implantology and maxillofacial surgery, Biom'Up identified the optimum clinical features and benefits which would define the next generation of GBR products. Following extensive biomaterials research and clinical trials, Biom'Up

obtained CE Mark accreditation during 2008 for its two GBR products, MatriBone and Cova.

Since their launch in 2009, both products have met with increasing acceptance and clinical success with leading dental implantologists and maxillofacial surgeons across Europe. Building on this, Biom'Up has now launched these products into the UK market.

What are MatriBone and Cova?

MatriBone is a granular biphasic ceramic synthetic bone substitute dispersed in a woven matrix of xenogenic collagen (Types I and III).

Biphasic calcium phosphate (BCP) bioceramics belong to a group









State of the art GBR and GTR for Dental Surgeons - enhancing patient outcomes

Biom'Up has developed two unique collagen based products for Dental Surgeons, **Matri™BONE**, a biphasic bone substitute with a resorbable collagen matrix containing a dispersion of HA and β-TCP, for optimal GBR and **Cova™ MAX**, a collagen based resorbable membrane, with unique handling properties, for GTR.

If you would like to learn more about our innovative products then please read the article published in this edition of Dental Practice and visit **www.biomup.com** for further information about Biom' Up. If you would like to evaluate **Matri™BONE** and **Cova™ MAX** then please contact Biom Up's UK distributor **Bluetrac Ltd.**, who will be delighted to provide full product information and technical support:

(T) +44 (0)7885 795467 (E) sales@bluetrac.co.uk (W) www.bluetrac.co.uk

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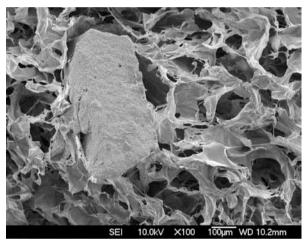
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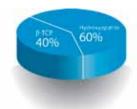
FIG 1 – Composition of MatriBone

of bone substitute biomaterials that consist of a mixture of hydroxyapatite (HA) and β -tricalcium phosphate (β -TCP) of varying HA/ β -TCP ratios, and have close physicochemical similarity to natural bone mineral. By varying the HA/ β -TCP ratio, the resorption profile can be optimised to match the natural osteo-regeneration process.

All Biom'Up collagen products are manufactured using a rigorous scientifically validated extraction process, ensuring that the products present no risk to patients whatsoever of bacterial, viral or prion disease.



SEM MatriBone bone substitute granule and collagen matrix (mag. x100)



Composition of MatriBone bone substitute

To achieve the optimal *in-vivo* resorption profile, Biom'Up bioengineered MatriBone to comprise a dispersed granular biphasic synthetic bone substitute in a collagen (Types I and III) matrix in the proportions (by mass) shown in **Figure 1**.

The key product characteristics are: haemostatic, resorbable, osteoconductive and hydrophilic. Clinical handling features and benefits include:

- Physical structure and stability of the collagen matrix facilitates cellular colonisation throughout the entire volume of the graft
 - Malleable and can be cut to shape before use, enabling accurate placement, minimising wastage
 - Can be placed either in its dry state or reconstituted with physiological saline and/or patient's serum
 - Excellent hydrophilic

- properties allow the spongelike structure to expand up to seven times its dry volume when reconstituted
- Expansile properties ensure that the bone substitute conforms accurately to all irregular bony defects, preventing the unwanted migration of fibroblasts into the graft site, optimising the quality of the regenerated bone stock
- Effective occlusion of the bony defect means that a GTR membrane is often not required
- MatriBone collagen matrix prevents inadvertent particulate migration beyond the intended graft site
- The physical structure and stability of the matrix allows it to serve as a support for adjunctive therapeutic agents such as antibiotics or platelet-rich fibrin (PRF) if required
- Predictable resorption profile, with the collagen matrix typically resorbing in one month, and cellular bony remodelling occurring in three months.

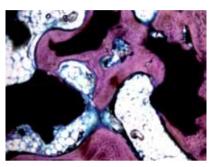
The product is available in four sizes, ensuring a solution for all sizes of bone defect: $12 \times 12 \times 12$ mm, $24 \times 12 \times 12$ mm, $30 \times 30 \times 6$, and $35 \times 60 \times 6$. All MatriBone products are available in two synthetic bone granule sizes, either $80\text{-}200\mu\text{m}$ or 0.5-1.0mm, dependant on clinician preference.

Clinical indications

 In combination with/without Cova GTR membrane for filling bone defects in preparation for



MatriBone pre-implantation: bone substitute granules (black) are surrounded by porous collagenous matrix (x4, modified Paragon method)



MatriBone three months postimplantation: bone substitute granules surrounded by newly formed bone (violet). Good integration with no sign of osteolysis (x5, rabbit model, modified Paragon method)

dental implants

- Peri-implant bone augmentation with/without PRF membrane (Choukroun technique)
- Treatment of peri-implantitis bone augmentation procedures
- Sinus lift Matri Bone with and without Cova GTR membrane
- Filling bony defects, e.g. apicectomy, apical cyst resection
- Reconstruction of the alveolar ridge

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Cova

Cova is a resorbable acellular Type I xenogenic collagen membrane bioengineered to optimise guided tissue regeneration across a range of dental and maxillofacial procedures.

Clinical features and benefits include its ease of use – its optimised mechanical and handling properties make the product easy to place, re-adjust, re-size and suture.

It is transparent before implantation, providing excellent visualisation during implantation – this is not possible with similar

products which are opaque. It becomes opaque once immersed in blood – useful when surgery is invasive and very bloody.

The mechanical properties are exceptional. Should unforeseen complications make it necessary to re-open the wound in the early post-operative phase, Cova can be easily removed for up to one week post-implantation – this is not possible with similar collagen-based GTR products.

It has a predictable resorption profile, as it is manufactured from

virtually pure collagen, providing predictable biodegradation and therefore little inter-patient variation

The collagen matrix resorbs typically in two to three months, in harmony with the natural cellular bony remodelling process, ensuring that it plays its role as a barrier to fibroblast migration. It is available in three sizes, ensuring a solution for all sizes of graft site: 15 x 25mm, 20

x 30mm and 30 x 40.

Clinical indications

- In combination with MatriBone in preparation for dental implants
- Reconstruction of bone dehiscence – in combination with Matri Bone synthetic GBR matrix
- Covering periodontal bone defect bone grafts
- Sinus lift in combination with Matri Bone synthetic GBR matrix

Dr Ralph Day is Managing Director of Bluetrac Ltd, Biom'Up Biomaterials UK distributor. The purpose of this article is to provide an overview of GBR biomaterials science and the experience of clinicians who have used these two new GBR/GTR products since their initial launch in Europe in 2009. For further information, contact Ralph on 07885 795467, e-mail sales@bluetrac.co.uk, or visit www.biomup.com

Clinical case study

The following case study, provided by Dr Robert Fromental (principal, Private Practice in Implantology and Periodontics, Lyon, France), illustrates the use of MatriBone as a synthetic GBR matrix during a lateral approach sinus lift.

This case study describes the treatment of an edentulous area in sector 1 of the maxilla in preparation for implants using a sinus lift and bone graft. A lateral approach is planned and bone defects will be filled using MatriBone as the guided bone regeneration matrix.

The patient is a 60-year-old female non-smoker with no previous medical history to contraindicate the surgical placement of implants. A specialist ENT opinion was obtained which confirmed that there were no contraindications to maxillary sinus lift and bone graft.

The treatment objectives are to carry out a sinus lift via a lateral approach using MatriBone as a guided bone regeneration matrix, with placement of four implants to provide a base for a permanent prosthesis.



Cone beam CT: panoramic and coronal views showing the extent of the bone defect (Sector 1)

Surgical technique



Elevation of
mucoperiosteal flap
(lateral approach),
removal of bone flap
and elevation of the
Schneiderian membrane



Introduction of
MatriBone guided bone
regeneration matrix,
which has excellent
hydrophilic properties
and has been soaked
in serum



Compaction of MatriBone without crumbling and no migration of bone granules



Packing of the post extraction site at 15 and placement of an implant at 14 which is covered with MatriBone



Exposure of the primary implants six months postoperatively following bone graft, with transitional prosthesis insitu at 14



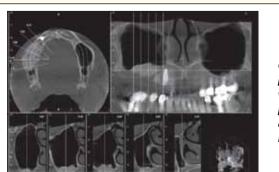
Intra-operative suturing of the implant site





Final prosthesis in-situ, 12 months post-op

Note the excellent healing 10 months post-op



Cone beam CT: panoramic and coronal views four months post-op showing excellent bone integration

Conclusion

This case study clearly demonstrates the excellent handling characteristics and biocompatibility of MatriBone when used in sinus lift procedures. MatriBone is a highly malleable, sponge-like bone substitute making grafting in these types of procedures much easier.

This case study describes a lateral approach, but other approaches may be considered on a case-by-case basis for the placement of single or multiple implants.

A video illustrating this case is available at: http://www.biomup.com/matri-bone-max.html