THE EUROPEAN SOCIETY OF MEDICINE
Medical Research Archives, Volume 12 Issue 8

CASE SERIES

Bone Regeneration Using an Alloplastic Graft Material that Combines β Tricalcium Phosphate and Calcium Sulphate: A Case Series Report with Histology

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OPEN ACCESS

PUBLISHED
30 August 2024

CITATION
O'Hooley D., et al., 2024. Bone Regeneration Using an Alloplastic Graft Material that Combines β Tricalcium Phosphate and Calcium Sulphate: A Case Series Report with Histology. Medical Research Archives, [online] 12(8). https://doi.org/10.18103/mra.v12i8.5660

DOI
https://doi.org/10.18103/mra.v12i8.5660

ISSN
2375-1924

ABSTRACT

This retrospective case series reports on the use of an established alloplastic bone product composed of a 65:35 ratio of β Tricalcium Phosphate and Calcium Sulphate to facilitate host bone regeneration in a variety of intra-oral sites and clinical indications. The study involved seven patients treated by seven different clinicians operating at five geographical sites. All cases included trephined bone cores harvested at 12 and 33 weeks. These cores were subject to histological analysis using standardized protocols at six separate laboratories. The primary measured outcome was the percentage of residual graft, new bone, and connective tissue at the measured time points. The results of this case series suggest that the alloplastic bone product is 50% resorbed and replaced by new host bone at 12 weeks, with further consistent resorption to 85% at 33 weeks. These results suggest that this alloplastic product can be successfully used in a wide variety of intra-oral bone grafting protocols leading to consistent resorption of the material and its replacement with new host bone, independent of clinician and established histological analytical protocol used.

Keywords: beta tricalcium phosphate, calcium sulphate, socket grafting, delayed implant placement

Introduction

Various types of graft material can be used to facilitate host bone regeneration in implant dentistry, including, autogenous bone, allografts, xenografts and alloplasts.[1-3]

Many factors are involved in decisions regarding which type of osseous graft material to use. Xenograft materials have a significant body of evidence suggesting that they do not fully resorb, leaving particles present which can remain within the soft tissue and in contact with the implant surface, (BIC) contact percentage. This can possibly affect long-term implant survival.[4,5] In addition, complications with xenografts can include chronic inflammation, foreign body giant cell reaction, immune reactions, material displacement, acute and chronic sinusitis and maxillary mycetoma.[6-9]

Although Allografts have been reported to produce a significantly higher proportion of new bone than xenografts[10], both types of graft material may lead to patient objections for either religious or personal reasons related to potential disease transmission via the graft.[11,12] However, alloplastic graft materials along with autogenous grafts have the highest rate of acceptance among patients.[13] This is perhaps reflected in the commercial sphere where alloplastic bone grafts are predicted to grow fastest within the dental bone graft marketplace between 2021-2026.[14]

The increased use of alloplastic graft materials for dental grafting protocols has included the use of both ß Tricalcium Phosphate (ß-TCP) and Calcium Sulphate ($CaSO_4$), both alone and in combination. These two materials have the benefit of being fully resorbed over time, thus they do not leave residual graft particles at the grafted site once host bone conversion is completed.

Calcium Sulphate has been used for over 120 years in medical grafting procedures. It sets hard, producing a stable cell occlusive barrier which prevents soft tissue migration into the graft volume during the healing and organization phases. ß-TCP has also been utilized medically for decades for grafting with many benefits pertinent to its use as a dental graft material. It is osteoinductive and osteoconductive, whilst being completely resorbed as it is replaced by host bone.[15-18]

The benefits of the two materials in combination appear to be due to the synergistic nature of their properties. Calcium Sulphate has a bacteriostatic effect partly due to the acidity of released Ca^{2+} ions during its initial dissolution. This acidity stimulates osteoblasts whilst inhibiting osteoclastic bone resorption.[19,20] $CaSO_4$ however, is not an ideal graft material when utilized in isolation, due to its rate of resorption being faster than host bone formation. This means that it does not act as an effective scaffold within the defect during this critical phase of new bone regeneration. Its osteoconductive properties are thus time limited.[21,22] $CaSO_4$ also has weak osteoinductive properties, with chemical changes and dissolution also leading to porosities that influence neovascularization.[23-25] ß-TCP is a porous substance which undergoes complete resorption over a 9-to 16-month time-period.[26] There is the suggestion that grafting with ß-TCP solely may possibly lead to bone volume reduction over time due to this complete resorption, and this has led historically to its use in combination with less fully resorbable materials such as, for example, hydroxyapatite. Another interesting use has been to expand the total graft volume when autogenous bone is used.

The use of ß-TCP and $CaSO_4$ in combination synergizes their individual properties producing a stable volume, hardening paste that adapts accurately to the contour of the bony defect and develops porosities due to the dissolution of $CaSO_4$. This provides a scaffold for bone regeneration.[27-32]

This self-stabilizing graft material is used without collagen membranes. The direct contact of the graft surface with the periosteum thus not allowing any barrier to periosteal induction of stromal cell-derived factors, with subsequent presence of mesenchymal cells at the bone-healing site. These cells differentiate into osteoblasts. The absence of a collagen membrane, with optimized graft access

to the periosteal blood supply appears to lead to enhanced healing outcomes.[33]

The material used in the cases reported here was EthOss, a graft material composed of 65% ß-TCP and 35% $CaSO_4$. (EthOss® Regeneration Ltd., Silsden, UK). Clinically, 50% new bone has been observed at 12 weeks replacing the graft material and full graft resorption usually occurs over the following 6-12 months depending on the volume of graft present. It has been reported in studies that promotion of osseoinduction as well as three-dimensional scaffold support for new bone occurs with these synthetic graft materials. This synthetic graft has been shown to be biocompatible, osteoconductive and bioresorbable bone graft substitute.[34] Previous histomorphometric analysis has revealed that sites grafted with EthOss were occupied by 50.28% new bone, with 12.27% residual grafting material, and 37.45% connective tissue.[35] The combination of ßTCP and $CaSO_4$ in EthOss™ graft material provides simplicity of use without the requirement for a collagen membrane for guided bone regeneration procedures.[36]

The 7-case series reported here details a multi-center study where trephined bone core samples were taken from intra-oral sites after prior grafting with the alloplastic bone graft EthOss in particulate form.

The seven cases reported here were conducted by 7 clinicians on 7 different patients, 5 male and 2 female, at 5 clinical sites, two cases were conducted in the UK, 1 in USA, 1 in Columbia and 1 in Thailand. Six core samples were taken after early grafting of extraction sockets. One sample was taken after immediate placement into an extraction socket and immediate grafting of the associated radicular cyst via mucoperiosteal flap access. EthOss, a synthetic osseous graft material consisting of 65% ß Tricalcium Phosphate and 35% Calcium Sulphate was utilized in the 7 cases presented in the case studies.

Six sites had core samples taken at 12 weeks with 1 having the core taken at 33 weeks. IRB approval was not necessary as patients were not identified in the results. For the same reason consent for publication of the individual cases were not required. Where clinical photography was taken and is presented here, consent was obtained for its use within this publication.

The seven patients had an age range from 16 to 59 years old. All patients were reviewed for their suitability of implant surgery and were fit and well at the time of the initial grafting and core sample harvesting.

The STROBE checklist was followed in the preparation and completion of this article.

CASE 1:

A 51-year-old male patient presented with a lower left second premolar tooth that was tender to percussion. The tooth had previous endodontic treatment resulting in a lateral perforation of the root towards the buccal, with extrusion of gutta-percha root obturation material into the unattached buccal mucosa. Examination revealed a large coronal composite restoration with evidence of coronal leakage. A small field CBCT scan revealed a large bony radiolucency associated with the apical third of the lower left second premolar root and extending mesial to the distal wall of the lower left first premolar root, and distally approximately 10mm behind the distal wall of the lower left second premolar. (Figure 1) The prognosis was poor on the tooth related to the lateral perforation, remaining condition of the tooth and the size of the lesion present and it was recommended to extract the tooth, immediately graft the site and following graft healing place an implant to be restored following osseointegration.

Consent documentation was reviewed with the patient and then signed. Local anesthetic (4% Articaine hydrochloride with epi) was administered to both buccal and lingual vestibules from the lower left canine to the lower left second molar. The lower left second premolar was atraumatically extracted, and the socket curetted to remove any residual soft tissue from the socket walls. The bony expansion at the apical third of the socket was identified. A full thickness mucogingival flap was raised mid-crestal

from the mesial of the lower left second molar, around the buccal margin of the lower left first premolar with vertical release distal to the canine. A DASK internally irrigated domed lateral sinus lift diamond bur, (Dentium USA, USA), was used to create the oval access through the buccal bony cortex to the cystic lesion. The cyst contents were sent for histological evaluation and revealed it to be a radicular cyst.

Figure 1: Pretreatment CBCT demonstrating a large cyst associated with the premolar that had prior Endodontic treatment.

After thorough degranulation of both the cyst cavity and socket, each EthOss graft material syringe was held vertically and hydrated with sterile 0.9% saline as per the manufacturer's instructions. A piece of non-shedding sterile gauze was placed at the open end of the syringe to remove excess saline. The syringe was then delivered to the intra-oral site and EthOss graft material expressed into both the cyst cavity and socket. The material was gently compressed to shape it, and a total of 3.5cc of EthOss was added. A sterile non-shedding gauze was held against the material for 3 minutes to allow hardening. The EthOss graft material was tested and resisted pressure and was firm to the touch. The flap margins were then sutured tension free with 4.0 Vicryl Rapide (Ethicon, J&J MedTech, USA) in an interrupted pattern.

The patient returned following 7 months of site healing and graft maturation. The soft tissue over the edentulous area that had been graft demonstrated a lack of inflammation and was keratinized and healthy. A CBCT scan was taken to evaluate the grafted site. (Figure 2) Evaluation of the scan noted the previous defect was filled with dense material and the lesion appeared to be absent. Consent documentation for implant placement was reviewed with the patient and then signed. Local anesthetic (4% Articaine hydrochloride with epi) was administered to both buccal and lingual vestibules from the lower left canine to the lower left second molar. A mid crestal incision was made from the mesial of the 2nd molar to the distal of the 1st premolar and a full thickness flap was elevated to expose the crestal ridge. (Figure 3) The crestal bone had a normal appearance and identification of the previously placed graft material was not visually possible. A core was removed using a surgical trephine bur at the planned implant site for histological analysis. (Figure 4) The site the trephined core was removed was modified to accommodate the planned implant utilizing osteotomy burs (Southern Implants, Irene, South Africa). (Figure 5) A 7x9 mm implant (MAX implant, Southern Implants) implant was placed into the osteotomy (Figure 6 left) and a healing abutment placed in the implant. EthOss graft material was placed over the implant shoulder to the healing abutment to once healed the implant would be completely encased in bone. (Figure 6 middle) The soft tissue was sutured around the healing abutment to get primary closure over the graft material placed. (Figure 6 right) A periapical radiograph was taken to document implant placement. (Figurer 7)

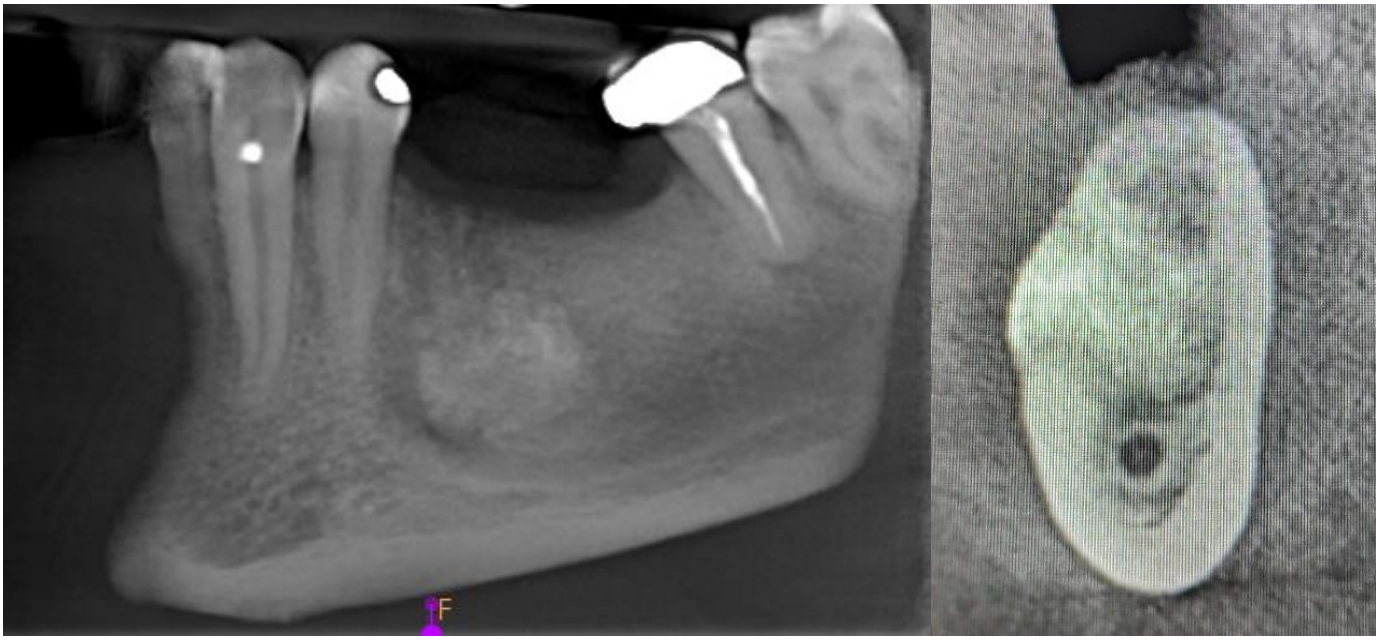

Figure 2: CBCT demonstrating graft fill following graft healing 7-months post treatment.

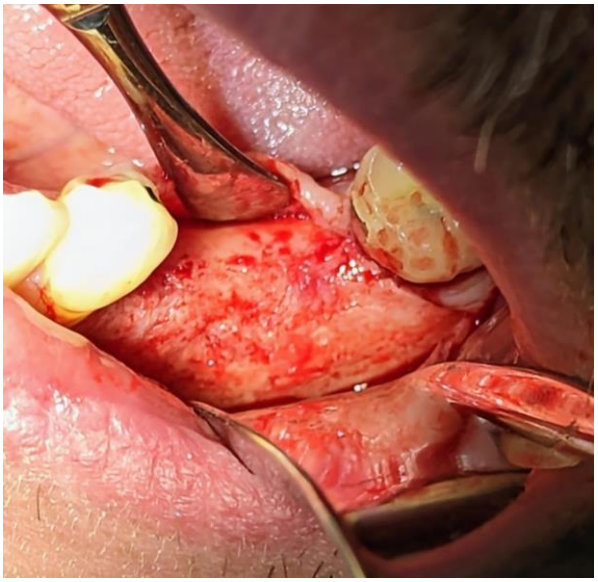

Figure 3: Healed grafted site following flap of the ridge to expose the crestal bone.

Figure 4: Trephine core taken of the grafted site for histological analysis in preparation for implant osteotomy.

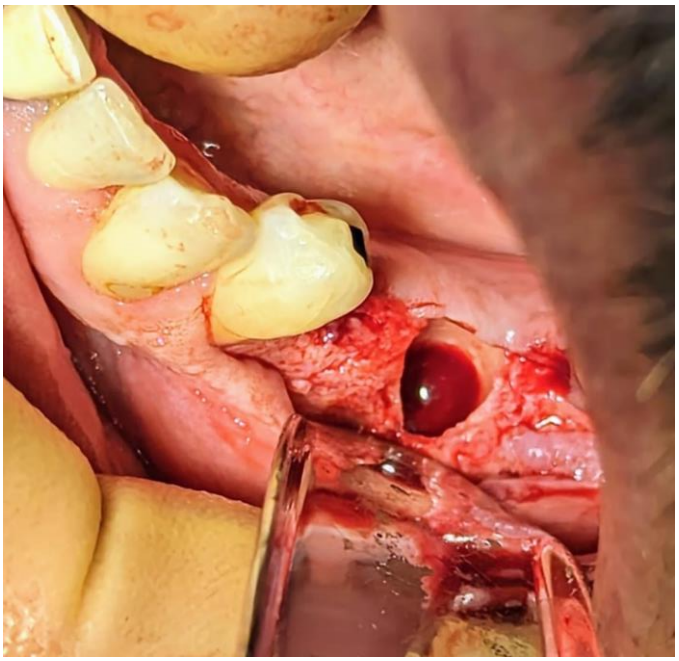

Figure 5: Osteotomy created following trephine core removal.

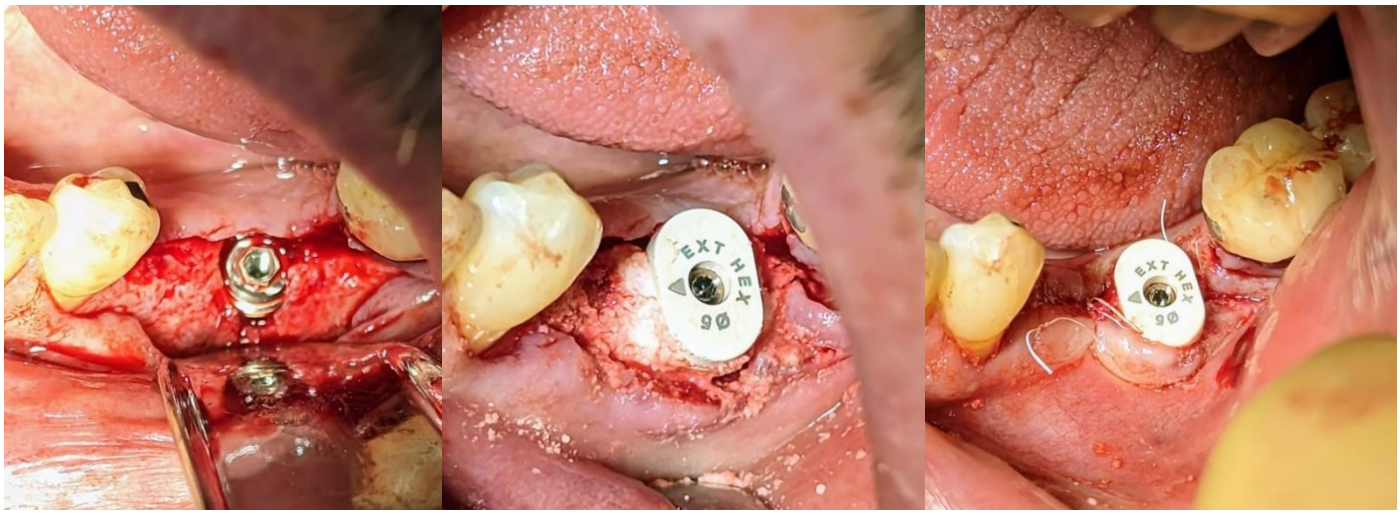

Figure 6: Implant placed in the osteotomy (left), healing abutment placed and EthOss graft placed over the implants shoulder (middle) and soft tissue sutured to close the site (right).

Figure 7: Periapical radiograph of the implant and graft placed over the implants shoulder.

The core sample was sent for histological evaluation to Milan University. The sample was processed, and slices made and stained with H&E and evaluated under the microscope. (Figure 8) Histologically, high quality bone was noted with thick trabeculae similar cortical bone with minimal residual b-TCP particles present. Further histological analysis of the trephine core under picrosirius/polarized light demonstrated well-structured bone with lamellae clearly defined with collagen appearing deep red marking them as mature fibers and osteons present and defined. (Figures 9, 10) Histogram analysis utilizing Adobe Photoshop noted 33,871 pixels of non-bone and 152,441 pixels of bone to yield 81.8% bone present in the core sample. (Figure 11)

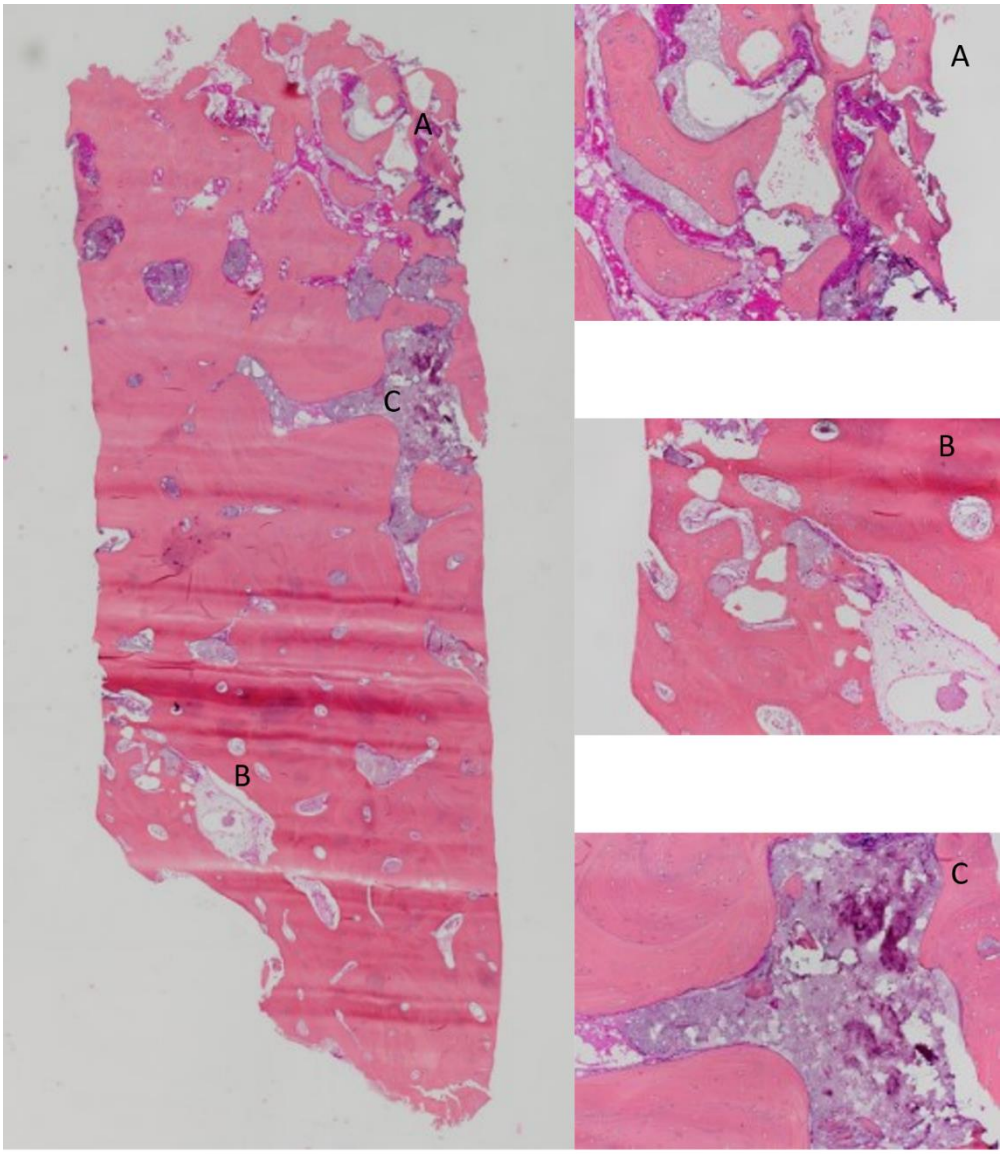

Figure 8: Histological analysis of the trephine core under H&E staining demonstrating high quality bone regeneration with thick trabeculae similar to cortical bone in composition with minimal b-TCP particles present.

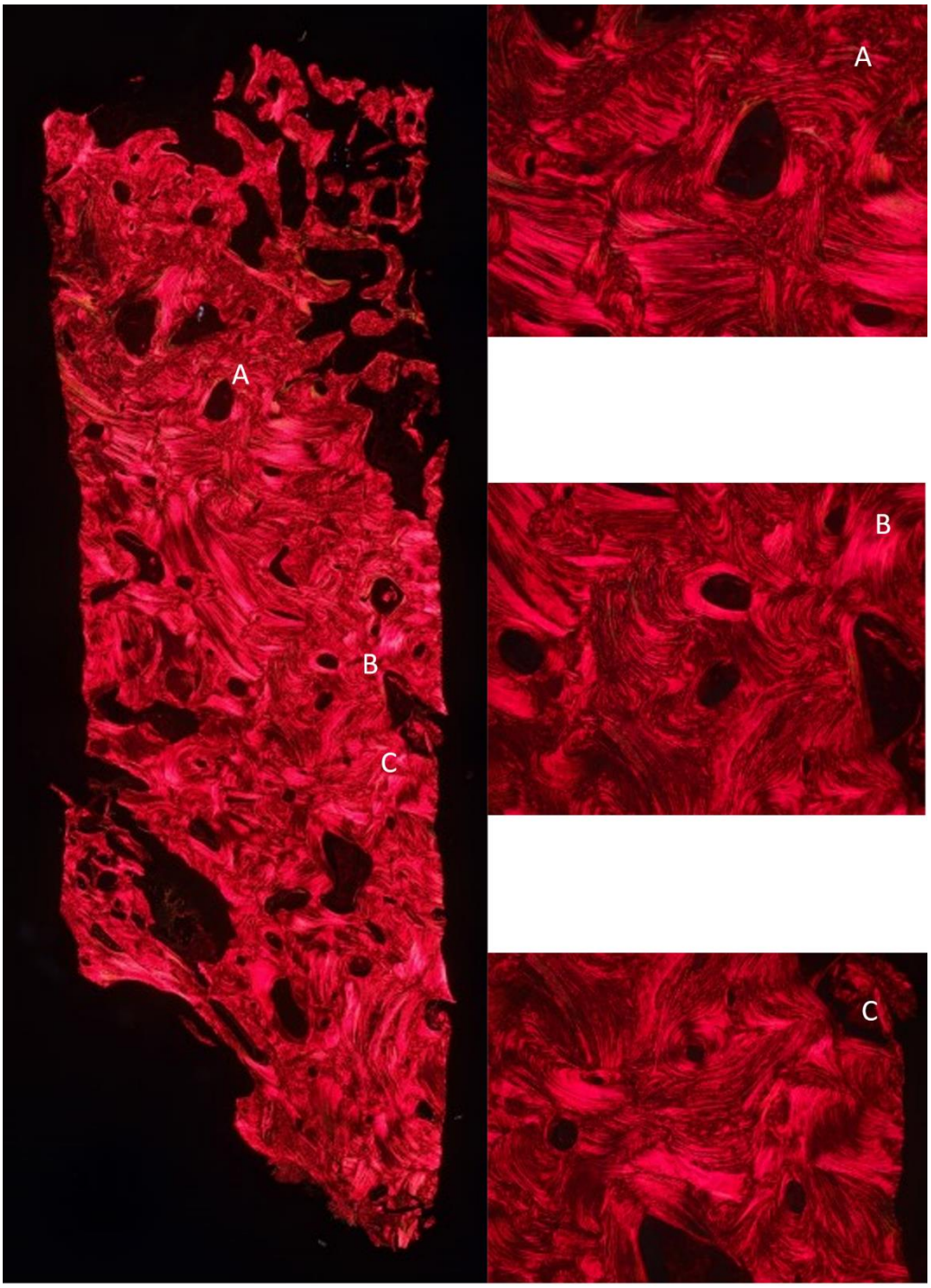

Figure 10: Histological analysis of the trephine core under picrosirius red/ polarized light demonstrating well structured bone that is characteristic of compact bone with tiny lamellae.

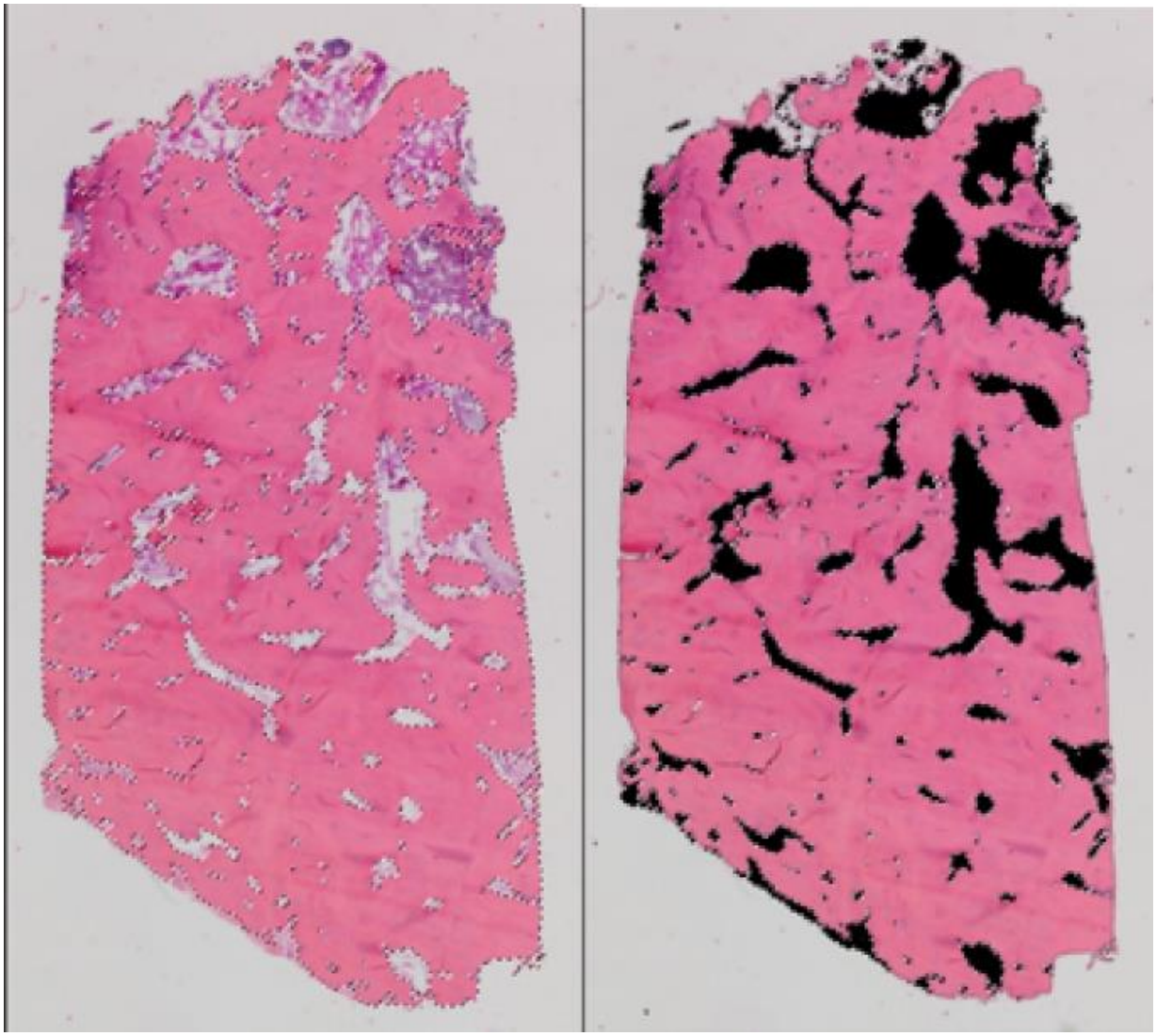

Figure 11: Histological analysis of the trephine core central section of the EthOss grafted area with H&E staining demonstrating no appreciable residue of the b-TCP, with very dense bone with no noted connective tissue present.

CASE 2:

A 56-year-old male presented with a failing mandibular left 1st molar that upon evaluation was deemed non-savable and extraction was recommended with socket grafting to preserve the site in preparation following healing of implant placement. The patient was a non-smoker, and no medical issues were noted in their history. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. EthOss graft was placed to fill the extraction socket and a pericardium membrane (Jason Membrane, Botiss Biomaterials, Berlin, Germany) was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with 5-0 PTFE sutures. At 12-weeks post graft placement in preparation for implant placement, the area was flapped, and a core sample taken from the site for histological assessment. Histological analysis was performed by Dr. Hari Prasad, University of Minnesota, USA which reported 51% new bone and 11% residual EthOss particles. (Figure 12) Histolmorphometry was performed by histologist and identified respectfully that the distal area had 50% new bone and the mesial area had 51% new bone with 11% in both areas. (Table 1)

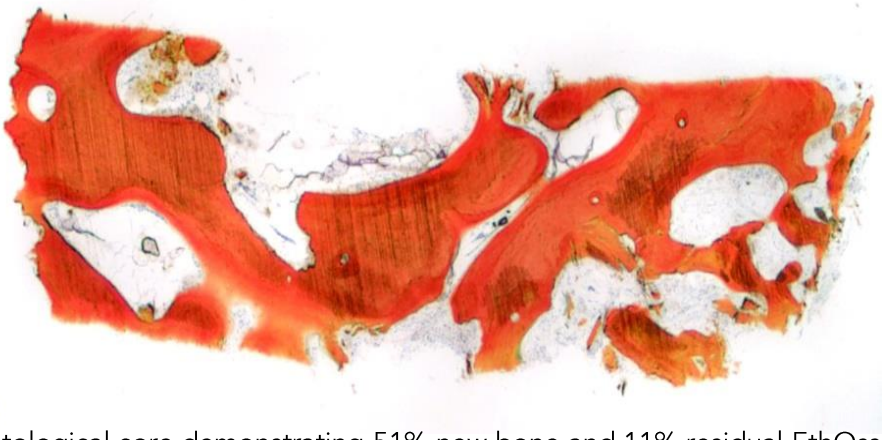

Figure 12: Case 2 histological core demonstrating 51% new bone and 11% residual EthOss particles. (Courtesy Dr. Robert A. Horowitz)

Specimen Identification	Total Area	Vital Bone Area	NonVital Bone Area	Non-Bone Area	Percent Spec= Bone	Percent Total Bone=VITAL	Percent ALLOGRAFT= NONVITAL	Percent Marrow or Fibrous Tissue	Percent Spec = Non Bone
04/17--01	720650	365013	0	79945	51	100	0	38	11
R Hertzson	#19 M	EthOss							
04/17--01A	863797	433811	0	97855	50	100	0	38	11
R Hertzson	#19 D	EthOss							

Table 1: Case 2 histological report of the core sample.

CASE 3:

A 56-year-old female presented with a failing maxillary right 2nd molar that upon evaluation was deemed non-savable and extraction was recommended with socket grafting to preserve the site in preparation following healing of implant placement. The patient was a non-smoker, and no medical issues were noted in her history. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. EthOss graft was placed to fill the extraction socket and a pericardium membrane (Jason Membrane, Botiss Biomaterials, Berlin, Germany) was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with monofilament sutures. At 12-weeks post graft placement, the area was flapped, and a core sample taken from the site for histological assessment. (Figure 13) Histology was performed in the Cell Tissue department at Freiburg University (Baden-Württemberg, Germany) by Drs Heiner Nagursky and Annette Linder. Histological analysis reported the core sample had 48.12% newly formed bone and 8.11% residual EthOss particles.

Cases 4-7 were histologically analyzed utilizing Adobe Photoshop® to generate a black image mask to highlight non-boney tissue. The subsequent selections represented bone tissue. The Histogram tool within Photoshop was used to calculate the pixels of each selection. The pixel data was then used to quantify the percentage of bone tissue within the sample.

CASE 4:

A 59-year-old female patient with no disclosed medical history and a non-smoker presented with issues with the mandibular right 1st molar. Examination noted the tooth had a poor prognosis and extraction was recommended with socket grafting and later implant placement following site healing. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. EthOss graft was placed to fill the extraction socket and a pericardium membrane (Jason Membrane) was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with Vicryl sutures (Ethicon, Raritan, NJ, USA). At 12-weeks post graft placement, the area was flapped,

and a core sample taken from the site for histological assessment. (Figure 14) Histology was performed by Prof, Charles Mangham in the Tissue department at the University of Manchester, UK. Histogram analysis utilizing Adobe Photoshop noted 32,068 pixels of non-bone and 98,447 pixels of bone to yield 75.4% bone present in the core sample.

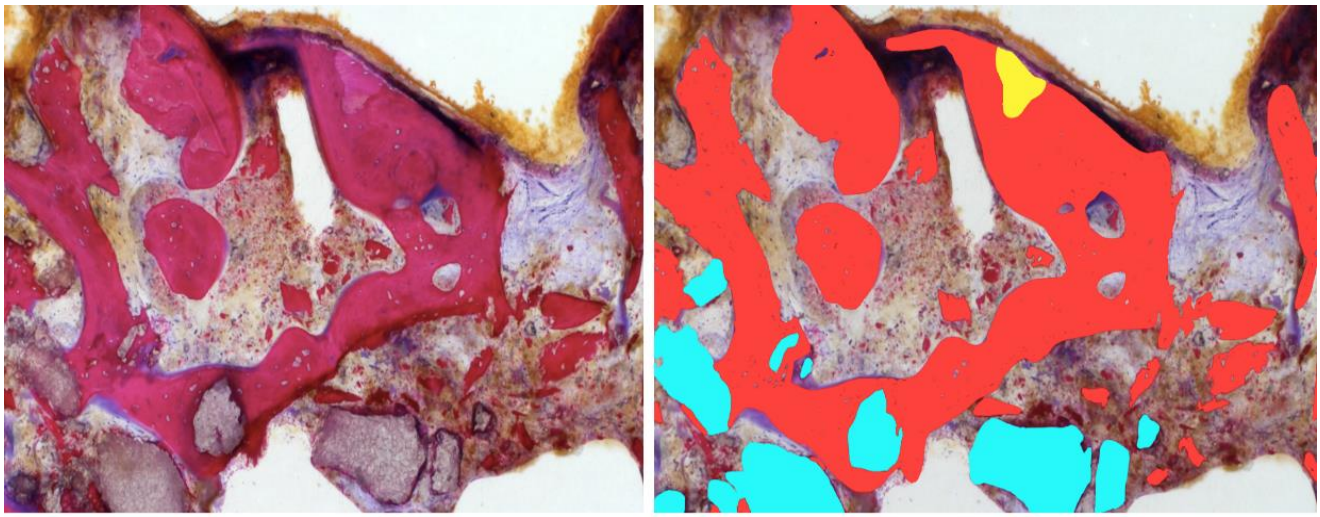

Figure 13: Case 3 histological core demonstrating 48.12% newly formed bone (red) and 8.11% residual EthOss particles (blue). (Courtesy of Dr. Minas Leventis)

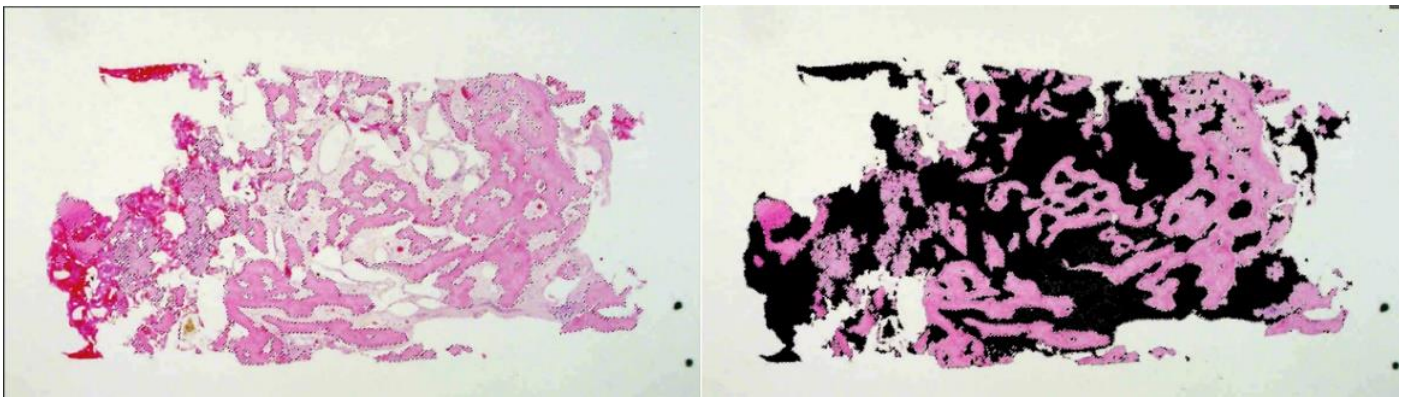

Figure 14: Case 4 histological core following histogram analysis demonstrated 75.4% bone in the sample. (Courtesy of Dr. Peter Fairbairn)

CASE 5:

A 16-year-old male presented with pain on the mandibular right 1st molar. That upon exam it was determined that tooth would require extraction due to the extent of decay present and being non-restorable. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. Implant placement would be delayed until after graft healing had completed. EthOss graft was placed to fill the extraction socket and a pericardium membrane (Jason Membrane) was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with Vicryl sutures (Ethicon, Raritan, NJ, USA). At 12-weeks post graft placement, the area was flapped, and a core sample taken from the site for histological assessment. (Figure 15) Histogram analysis utilizing Adobe Photoshop noted 100,205 pixels of non-bone and 134,028 pixels of bone to yield 57.2% bone present in the core sample.

CASE 6:

A 52-year-old male patient with no disclosed medical history and a non-smoker presented with issues with the maxillary left 2nd premolar. The examination noted the tooth had a poor prognosis and extraction was recommended with socket grafting and later

implant placement following site healing. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. EthOss graft was placed to fill the extraction socket and a pericardium membrane (Jason Membrane) was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with Vicryl sutures (Ethicon). At 12-weeks post graft placement, the area was flapped, and a core sample taken from the site for histological assessment. (Figure 16) Histology was performed by Pathology department at the University of Chulalongkom, Bangkok, Thailand. Histogram analysis utilizing Adobe Photoshop noted 37,875 pixels of non-bone and 42,285 pixels of bone to yield 58.5% bone present in the core sample.

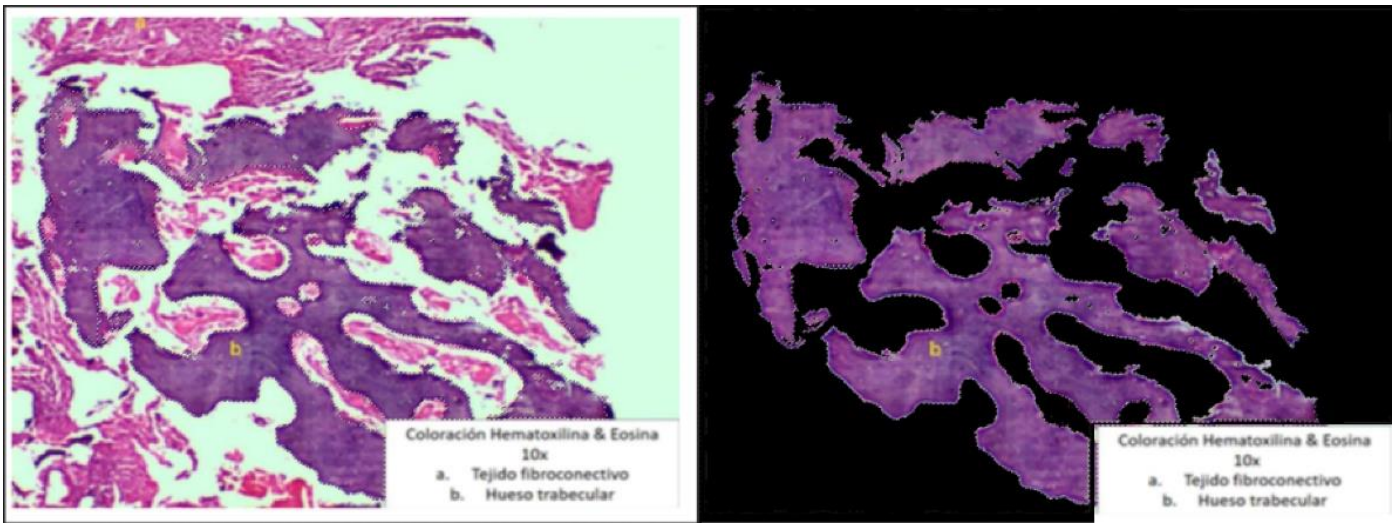

Figure 15: Case 5 histological core demonstrated 57.2% bone in the sample. (Courtesy of Dr. Venessa Suarez)

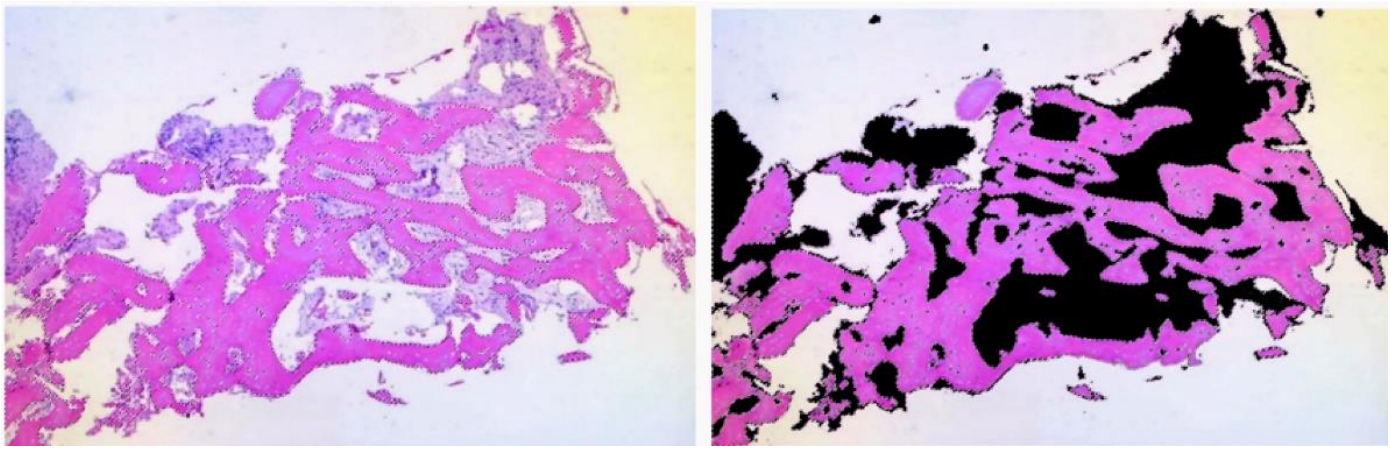

Figure 16: Case 6 histological core demonstrated 58.5% bone in the sample. (Courtesy of Dr. Tachakorn Kutiyaratana)

Case 7:

A 53-year-old female patient with no disclosed medical history and a non-smoker presented with issues with the mandibular left 1st molar. Examination noted the tooth had a poor prognosis and extraction was recommended with socket grafting and later implant placement following site healing. The tooth was extracted under local anesthetic and the socket curetted of any soft tissue and potential pathology that could affect the graft that would be placed. It was noted a large defect was present close to the inferior alveolar nerve (IAN). EthOss graft was placed to fill the extraction socket and a collagen sponge was placed under the soft tissue to cover the graft material. The soft tissue margins were closed with Vicryl sutures (Ethicon, Raritan, NJ, USA). At 12-weeks post graft placement, the area was flapped, and a core sample taken from the site for histological assessment.

(Figure 17) Histology was performed by Dr. Paolo Savadori at the University of Milan (Italy). Histogram analysis utilizing Adobe Photoshop noted 61,907 pixels of non-bone and 87,206 pixels of bone to yield 58.5% bone present in the core sample.

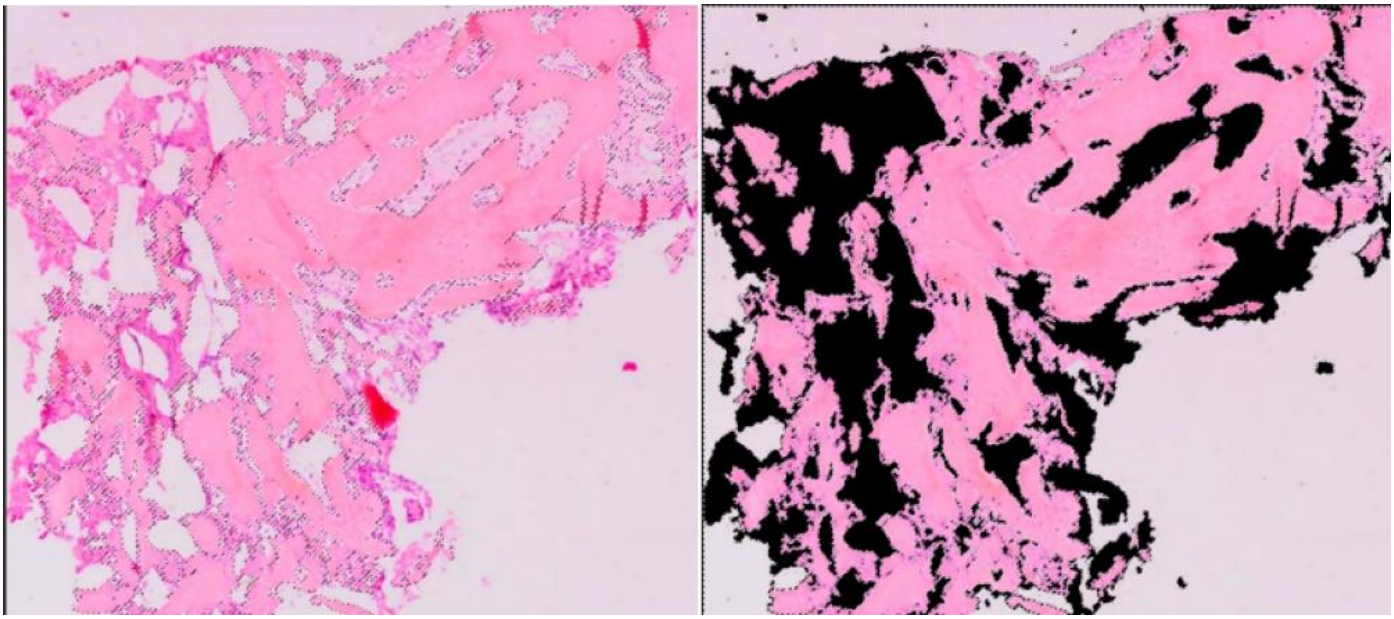

Figure 17: Case 7 histological core demonstrated 58.5% of bone present in the sample. (Courtesy of Dr. Stuart Kilner)

Discussion

For all cases, a standard tooth extraction protocol was followed, where, if present, multiple roots were sectioned first using highspeed or speed increasing handpieces and diamond burs. Periotomes (Helmut Zepf Medizintechnik, GMBH), (Hu-Friedy Group, USA) or (Karl Schumacher, USA), were used to section the coronal periodontal ligament fibres, and luxators (Directa AB, Sweden), plus forceps (Dentsply Sirona, USA) or (Devemed, GmBH), were used to remove the roots with minimal trauma to the sockets. The sockets were then assessed carefully via magnified direct vision and using periodontal probes (Hu-Friedy, USA) or (Nordent Manufacturing Inc, Canada). All seven sockets were judged intact.

Thorough degranulation was carried out using either sharp curettage alone with Lucas curettes (Hu - Friedy, USA), or (TK Plus, USA), or in combination with EthOss degranulation burs (EthOss Regeneration Ltd., Silsden, UK).

For the remaining radicular cyst case, a full thickness muco-gingival flap was raised with a mid-crestal incision and both mesial and distal releasing incisions at the lower left second premolar to second molar site. The location of the mental foramen and neurovascular bundle was carefully exposed using blunt dissection and visualized directly. A Swann-Morton 15 blade (Swann-Morton Limited, UK) was used for the incision. The radicular cyst was accessed via an ovoid osteotomy through the buccal cortical mandibular bone and through the extraction socket of the second premolar. The premolar was extracted using a similar protocol to the other six cases. The ovoid osteotomy was created using the novel use of the DASK Sinus Lift Kit domed internally irrigated diamond bur, (Dentium USA, USA).

For the immediate socket graft cases and the radicular cyst graft case after thorough degranulation had been completed, the EthOss graft material was mixed according to the manufacturer's instructions. The EthOss syringe cover was removed, and the syringe was filled to the specified marker with 0.9% sterile saline to hydrate the graft particles, the syringe cover replaced, then the syringe shaken to ensure complete diffusion of the saline through the graft material. A dry, non-shedding, sterile gauze was then applied to the syringe nozzle and the plunger depressed to

extrude excess saline from the hydrated graft volume. The syringe was then transferred to the surgical site and the hydrated material extruded into the area to be grafted. For the six immediate socket grafting cases, 1cc of EthOss was placed. For the radicular cyst case, 3.5cc of EthOss was placed in total. For all seven cases, a piece of dry, non-shedding, sterile gauze was placed over the graft material and gentle pressure was exerted to compress the graft material and shape it to the defect being filled.

For the six immediate extraction socket graft cases, coronal socket occlusion was achieved using a combination of a native collagen membrane derived from porcine pericardium – Jason membrane (Botiss biomaterials, GmBH), and horizontal mattress sutures using 5.0 PTFE sutures, (Implacore Sp, Poland and Hu-Friedy, USA). For, the combined immediate socket and radicular cyst case, primary closure of both the socket and flap were achieved by periosteal release and suturing using Vicryl Rapide 4.0 interrupted sutures, (Ethicon, J&J MedTech, USA). No post operative antibiotic regime was given for any of the seven cases.

For the six purely immediate socket grafting cases, patients were reviewed at one week with suture removal. All six cases had uneventful healing and at 12 weeks post grafting, the sites were accessed via crestal full thickness mucoperiosteal flaps and the bone evaluated. All six cases showed the clinical appearance of full socket healing and so core samples were obtained from the grafted regions using trephine drills of appropriate diameter for the surgical site osteotomy and subsequent implant placement. (Devemed, GmBH, or General Medical, UK). For these six cases, the trephine internal diameters were either 2 or 3mm. For the combined immediate socket and radicular cyst graft case, the case was reviewed at 2 weeks with suture removal. Uneventful healing was followed by sectional CBCT scan evaluation at 32 weeks, with return at 33 weeks post-grafting for site access via crestal full thickness mucoperiosteal flap and core harvesting from the lower first molar site using a 5mm internal diameter trephine, (Devemed, GmBH). A Southern Max dental implant (Southern Implants, SA) was placed into the trephined site, a healing abutment placed, and the flap closed transmucosal via PTFE 4.0 interrupted sutures, (Hu-Friedy, USA).

Socket grafting has been demonstrated to aid in the preservation of the crestal bone and is especially important when implant placement at the site is part of the treatment plan.[37] It is not uncommon that implant placement will be delayed following extraction and following extraction during site healing without support the crestal bone will resorb and may complicate implant placement at the later date.[38] Various graft materials are available and in use for socket grafting procedures. Those include allografts, xenografts and synthetic materials, each with their pro and con to their usage. The benefits of synthetic materials is lower cost compared to allografts and xenografts, plus avoidance of immunological reactions that have been reported with those other materials.[39,40]

Whereas beta tricalcium phosphate graft material has demonstrated to be well tolerated immunologically causing no negative reactions in patient usage.[41] Calcium sulphate has also demonstrated a lack of immunological reaction as a graft material.[42] Usage of the two materials allows preservation of the space being grafted to allow host conversion to new bone and vascularization of the grafted site. The site can be re-entered for implant placement at 12-weeks post graft placement and full conversion of the graft material occurs in 6-12 months depending on volume of the graft material.[43] Socket preservation utilizing a synthetic graft material consisting of beta-tricalcium phosphate and calcium sulphate is well tolerated by the immune system and preserves the volume of missing bone while the host converts the graft to new bone.[44-45]

Conclusion

The histological analysis of the 7 cases presented demonstrates a consistent finding of new bone at 12-weeks when core samples were procured from the grafted sites. Additionally, minimal particles of graft material was noted histologically, supporting

conversion of the EthOss graft material to host bone and vascularization of the graft to support that conversion process to vital bone. The material was well tolerated and at the 12-week re-entry overlaying soft tissue demonstrated a lack of inflammation and healthy keratinized gingiva.

Conflict of interest:

Dr. Fairbairn is an owner and developer with EthOss, the other authors have no conflicts of interest with regards this article or products mentioned.

Acknowledgement section:

All listed authors contributed to the article and no other individuals contributed that are not listed

Funding:

No funding was received for this article or its research.

Author contributions:

Dominic O'Hooley – Treated patient, gathered information, reviewed draft
Peter Fairbain - Treated patient
Stuart Kilner - Treated patient
Robert Horowitz - Treated patient
Gregori Kurtzman – Wrote draft, incorporated edits into draft for final version, managed submission.

Summary box:

What is known on the topic:

- The article reviews 7 cases performed in 7 different patients where bone grafting was performed in anticipation of implant placement.
- Those were allowed to heal and organize, then at implant placement core samples were taken and histologically analyzed to determine conversion to host bone and the absence of residual graft material.

The submitted study adds:

- The results demonstrated that the graft material consisting of β Tricalcium Phosphate and Calcium Sulphate converts to healthy host bone and should be considered as a choice of graft material in these clinical situations.

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