PR 0407-02 en EU/US

CHAPTERS

3. White Wound Drainage

Information sheet for surgeons

White coloured wound exudate

The science behind CERAMENT™

CERAMENT™ is an osteoconductive bone graft substitute that consists of hydroxyapatite (HA) particles, calcium sulfate (CaS) [1] crystals and a liquid component.

By combining CaS and HA an optimal balance is achieved between implant resorption rate and bone ingrowth rate [2]. After CERAMENT™ has been injected into a bone void, tissue fluids fill microporous channels in the material, and both passive dissolution and active resorption of the CaS begins, leaving behind a HA scaffold for colonization by osteoblasts and formation of new bone [3-5]. The HA is gradually incorporated into the newly formed bone trabeculae with time [6-8].

Why does white coloured wound exudate occur?

In deep voids, CaS is resorbed from the site of injection by the cancellous bone vascular network and surrounding soft tissue. In some cases where the void is not in contact with cancellous bone, for example if there is sclerotic bone present, or if CERAMENT™ is in close proximity to the surface of the skin, there is a small risk that dissolved CaS can lead to a collection of fluid (seroma) [9] or serous wound exudate [4].

This exudate is white in color because of the CaS in it, and is known to occur with bone graft substitutes containing CaS [4, 9-12] (“white drainage”). It is sterile [9-13] and in most cases resolves within two-three weeks without further therapy [9].

What should I do if my patient experiences white coloured wound exudate?

The white color of the wound exudate can also be an indication of a (recurrent) infection and so there may be an impulse to schedule immediate revision surgery.

Since this "white drainage" has generally been reported to be not infected and resolves without treatment, the following diagnostic tests can be carried out before the decision to perform surgery is taken:

- Clinical observations: temperature, heart rate and blood pressure
- CRP and white blood cell count
- If a seroma is present, aspiration of the fluid and determination of the white blood cell count and microbiology (stained smear (Gram) for bacteria and culture)

Test results:

If all or most of the above parameters are negative, an infection is very unlikely and conservative treatment with standard wound care [9] should be considered. The patient should be followed up closely and the above tests may be repeated. In most cases the wound exudate should resolve within two-three weeks.

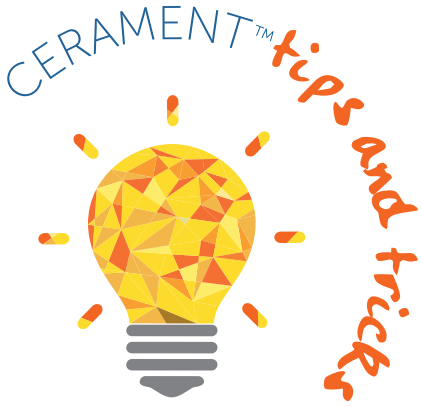
If the above parameters indicate an infection (raised temperature, tachycardia, elevated white blood cell count and CRP, a high number of white blood cells in the aspirate or bacteria visible in the gram stain) revision surgery should be considered.

Possible risk factors for wound exudate [2]:

- Contact with bone of poor quality [4]
- Volume of bone graft substitute implanted >20mls
- Bone with thin subcutaneous covering
- Very heavy bleeding at the site of the implantation

From the literature it is known that:

- Seroma / wound ooze is sterile [3-7]
- Wound exudate generally resolves on its own without further therapy within 2 weeks [3]
- Wound healing is not influenced [3]



- Ensure good contact with cancellous bone:
- If CERAMENT™ is not in contact with cancellous bone, eg if there is sclerotic bone present, or if CERAMENT™ is in close proximity to the surface of the skin, there is a small chance that dissolved CaS can lead to a collection of fluid (seroma) [9] or serous wound exudate [4]
- Wait three minutes after mixing till you start to inject CERAMENT™|BONE VOID FILLER ('Spaghetti-test')
- Control bleeding during surgery
  - Extensive bleeding might result in intermixing of blood with the CERAMENT™ paste
- Consider using a tourniquet if applicable
- Follow normal surgical practice and if applicable use a drain with contact to the hardened CERAMENT™
  - The drain may draw white coloured fluid some hours after surgery, which does not endanger or jeopardise the success of surgery
- Close soft tissue and skin in layers

References and further reading

1. Nilsson M, Zheng MH, Tägil M. The composite of hydroxyapatite and calcium sulphate: a review of preclinical evaluation and clinical applications. Expert Rev Med Devices 10(5), 675-684, 2013.
2 CERAMENT™ G| Product Data Sheet, Bonesupport AB PR-0283-02EN
3 Nilsson M, Wang JS, Wielanek L, Tanner KE, Lindgren L. Biodegradation and biocompatability of a calcium sulphate-hydroxyapatite bone substitute. J Bone Joint Surg [Br] 2004; 86-B: 120 – 125
4 Beuerlein MJ, McKee MD. Calcium sulfates: what is the evidence? J Orthop Trauma. 2010; 24 Suppl. 1: S46-51
5 Papadia D, CERAMENT™ white paper: displaced intra-articular calcaneal fractures treated with open reduction internal fixation (ORIF) combined with an injectable and bone remodelling bone substitute (CERAMENT™): A preliminary report, PR 0293-01 EN
6 Hatten HP, Voor MJ. Bone healing using a bi-phasic ceramic bone substitute demonstrated in human vertebroplasty and with histology in a rabbit cancellous bone defect model. Interven Neuro 2012, 18: 105-113
7 Wang JE et al. Biomechanics and bone integration on injectable calcium sulphate and hydroxyapatite in large bone defect in rat. Abstract, 52nd Annual Meeting Am Ortho Res Soc, Chicago, March 2006, 18-22.
8 Abramo A, Geijer M, Kopylov P, Tagil M: Osteotomy of distal radius fracture malunion using a fast remodeling bone substitute consisting of calcium sulphate and calcium phosphate. J Biomed Mater Res 92B:281-286, 2010
9 Ferguson JY, Dudareva M, Riley ND, Stubbs D, Atkins BL, McNally MA. The use of a biodegradable antibiotic-loaded calcium sulphate carrier containing tobramycin for the treatment of chronic osteomyelitis: a series of 195 cases. Bone Joint J. 2014; 96-B: 829-36
10 Kelly CM, Wilkins RM, Gitelis S, Hartjen C, Watson JT, Kim PT. The use of a surgical grade calcium sulphate as a bone graft substitute. Results of a multicenter trial. Clin Orthop Relat Res. 2001; 382: 42–50
11 Borrelli J, Prickett WD, Ricci WM. Treatment of nonunions and osseous defects with bone graft and calcium sulphate. Clin Orthop Relat Res. 2003; 411: 245–254
12 McKee MD, Wild LM, Schemitsch EH, Waddell JP. The use of an antibiotic impregnated, osteoconductive, bioabsorbable bone substitute in the treatment of infected long bone defects: early results of a prospective trial. J Orthop Trauma. 2002; 16: 622–627
13 McKee MD, Li-Bland EA, Wild LM, Schemitsch EH. A prospective, randomized clinical trial comparing an antibiotic-impregnated bioabsorbable bone substitute with standard antibiotic-impregnated cement beads in the treatment of chronic osteomyelitis and infected nonunion. J Orthop Trauma. 2010; 24: 483-490

Information sheet for nurses

My patient has developed white coloured wound drainage after surgery with a bone graft substitute called CERAMENT™

The science behind CERAMENT™

CERAMENT™ is an osteoconductive bone graft substitute that consists of hydroxyapatite (HA) particles, calcium sulfate (CaS) [1] crystals and a liquid component.

By combining CaS and HA an optimal balance is achieved between implant resorption rate and bone ingrowth rate [2]. After CERAMENT™ has been injected into a bone void, tissue fluids fill microporous channels in the material, and both passive dissolution and active resorption of the CaS begins, leaving behind a HA scaffold for colonization by osteoblasts and formation of new bone [3-5]. The HA is gradually incorporated into the newly formed bone trabeculae with time [6-8].

Why does white coloured wound exudate occur?

In deep voids, CaS is resorbed from the site of injection by the cancellous bone vascular network and surrounding soft tissue.

In some cases where the void is not in contact with cancellous bone, for example if there is sclerotic bone present, or if CERAMENT™ is in close proximity to the surface of the skin, there is a small risk that dissolved CaS can lead to a collection of fluid (seroma) [9] or serous wound exudate [4].

This exudate is white in color because of the CaS in it, and is known to occur with bone graft substitutes containing CaS [4, 9-12] (“white drainage”). It is sterile [9-13] and in most cases resolves within two-three weeks without further therapy [9].

What should I do if my patient experiences white coloured wound exudate?

Contact the surgeon who performed the surgery or his team they will decide the actions to take – other surgeons may not use bone graft substitutes and may repeat surgery when it is not needed.

The white color of the wound exudate can also be an indication of a (recurrent) infection and so there may be an impulse to immediately schedule revision surgery. "White drainage" has generally been reported to be not infected and resolves without treatment.

The surgeon may request some of the following diagnostic tests be carried out before the decision to perform surgery is taken:

- Clinical observations: temperature, heart rate and blood pressure
- CRP and white blood cell count
- If a seroma is present, aspiration of the fluid and determination of the white blood cell count and microbiology (stained smear (Gram) for bacteria and culture)

Test results:

Negative test results

- Infection is very unlikely and conservative treatment with standard wound care should be considered [9].
- The patient should be followed up closely and the above tests may be repeated.
- In most cases the wound exudate should resolve within two-three weeks.

Positive test results

- This can indicate an infection
- Raised temperature, tachycardia, elevated white blood cell count and CRP, a high number of white blood cells in the aspirate or bacteria visible in the gram stain
- Revision surgery may be considered.

Possible risk factors for wound exudate [2]:

- Contact with bone of poor quality [4]
- Volume of bone graft substitute implanted >20mls
- Bone with thin subcutaneous covering
- Very heavy bleeding at the site of the implantation

From the literature it is known that:

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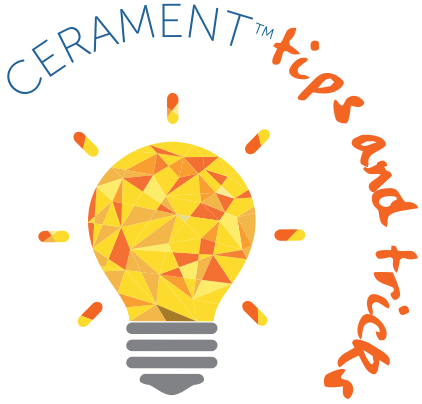

- Only call the surgeon who performed the surgery – or a member of his team experienced in using bone graft substitute
- Perform clinical observations
  - Temperature
  - Heart rate
  - Respirations

References and further reading

1. Nilsson M, Zheng MH, Tägil M. The composite of hydroxyapatite and calcium sulphate: a review of preclinical evaluation and clinical applications. Expert Rev Med Devices 10(5), 675-684, 2013.
2. CERAMENT™|G Product Data Sheet, BONESUPPORT AB PR-0283-02EN
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CERAMENT™|BONE VOID FILLER

Implantation Card

Patient name :

Date of implantation :

Surgeon :

Telephone :

Email :

This patient has bone graft substitute CERAMENT™|BONE VOID FILLER implanted

If you have any concerns about the skin and soft tissues related to this surgery, please contact the surgeon named on this card.

BONESUPPORT™

To learn more about BONESUPPORT
please email us at info@bonesupport.com

BONESUPPORT AB
Scheelevägen 19
SE-223 70 Lund
Sweden

T: +46 46 286 53 70
F: +46 46 286 53 71

www.bonesupport.com

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