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A COMPARATIVE STUDY OF THREE BIOABSORBABLE ANTIBIOTIC CARRIERS IN CHRONIC OSTEOMYELITIS: 313 PATIENTS WITH MINIMUM 1 YEAR FOLLOW-UP

M. McNally¹, J. Ferguson, J. Kendall, M. Dudareva, M. Scarborough, D. Stubbs

¹The Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospital, Oxford, United Kingdom

Aim

To evaluate the clinical outcome of a collagen fleece with gentamicin (Septocoll[®] E, Biomet), calcium sulphate with tobramycin pellets (Osteoset[®] T, Wright Medical) and CERAMENT[™]|G as bone defect fillers after excision of chronic osteomyelitis.

Methods

- 313 cases were followed up for 1-2 years:
 - Septocoll[®] E n=74
 - Osteoset[®] T n=166
 - CERAMENT[™]|G n=73
- All three carriers were reviewed prospectively.
- All three carriers were used for dead space filling after resection of C-M Stage III and IV chronic osteomyelitis.
- Apart from the carrier used, there was no other protocol change.
- Data was collected on patient age, comorbidities, operation details, microbiology, postoperative complications and need for plastic surgery or external fixation. All operations were performed by two surgeons. All patients had similar systemic antibiotic therapy and rehabilitation.
- Primary outcomes were recurrence rate, fracture rate and wound leakage rate (wound leaking for longer than 2 weeks).

Results

All three groups had similar mean age and range, microbiological cultures, need for free muscle flaps or local flaps, proportion of femur, tibia and upper limb bones and use of external fixation.

There were small differences in the proportion of C-M Class B hosts and anatomic type III cases between the groups, with the CERAMENT[™]|G group having significantly more Class B hosts compared to the Osteoset[®] T group (see Table 1).

	Septocoll® E	Osteoset® T	CERAMENT™ G
Mean Age (range)	48.2 (19-80)	45.6 (16-82)	52.0 (21-84)
% Polymicrobial infection	21.4	16.8	20.3
% Staph aureus	33.5	31.9	31.6
% needing free/local flaps	24.3	24.7	23.3
% needing external fixation	21.6	27.1	23.2
C-M Host Class B %	74.3	65.7*	83.3*
C-M Type III %	82.5	79.4	87.8

Table 1: Patient data for all three groups. *indicates a significant difference.

All patients were followed up for at least one year. Mean follow-up was 1.75 years for Septocoll® E, 1.96 years for Osteoset® T and 1.78 years for CERAMENT™|G.

The primary outcome results are shown below ('Collagen' refers to Septocoll® E, and 'Calcium Sulphate' to Osteoset® T):

Outcome of Treatment

	C-M Stage III & IV		Min 1 yr F/U
	Collagen	Calcium Sulphate	Cerament™ G
Number	74	166	73
Total wound leakage % (>14 days)	17.6	20.5	9.6*
Fracture rate %	2.7	3.6	1.4*
Recurrence rate %	6.6	8.4	4.1*

CERAMENT™|G had significantly fewer prolonged wound leaks, a lower fracture rate and a lower recurrence rate

Conclusions

Septocoll® E and Osteoset® T had similar rates of fracture, infection recurrence and wound leakage. In comparison to Osteoset® T:

- At 1-2 years after surgery, CERAMENT™|G had half the rate of:
 - prolonged wound leaks
 - fracture rate
 - recurrence rate

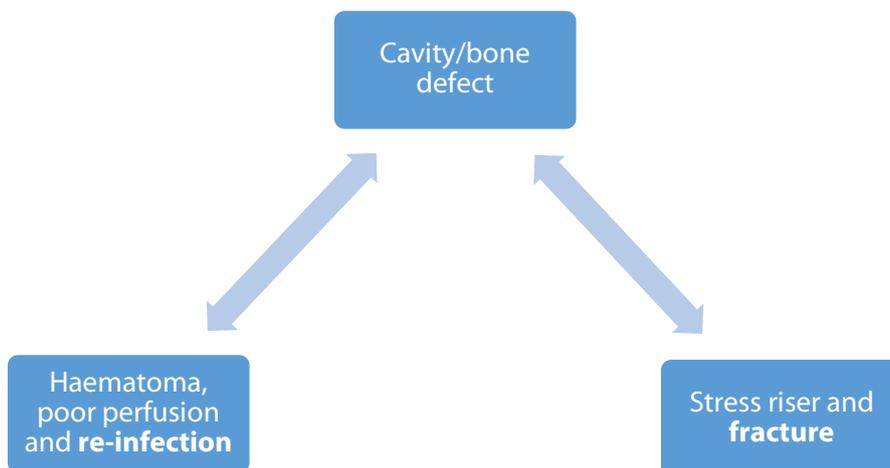
This was despite a higher percentage of compromised C-M Class B hosts in this group, which would predict a higher risk of failure.

The authors conclude that these results are because CERAMENT™|G:

- Dissolves more slowly than Septocoll® E and Osteoset® T and this may lead to **better bone formation**
- Offers higher levels of antibiotic in the defect
- Has a controlled antibiotic release profile

Comments

Two of the key aspects for success during surgical treatment of osteomyelitis are débridement and dead space management. Where a cavity or bone defect exists, this can lead to re-infection and/or fracture:



Despite the use of surgical débridement and long-term antibiotic therapy, the recurrence rate of chronic osteomyelitis in adults is 30%¹

The reported fracture rates following the treatment of osteomyelitis with bone graft substitutes has been between 4.6% - 8%²⁻⁵

Martin McNally has outlined four key factors for ideal dead space management and good clinical results:

- no haematoma (i.e. the void/cavity is completely filled)
- structural stability
- bacteriocidal activity
- bone remodelling

CERAMENT™|G meets most of these criteria for dead space management, because it is:

- injectable and flowable, and so can completely fill a dead space
- provides a high level of gentamicin (150 – 64 times above the MIC has been reported in the first 48 hours⁶) for a prolonged period of time⁷, and this elution is consistent
- it remodels into new bone

Septocoll® E and Osteoset® T deliver antibiotics but have a rapid dissolution which may result in a persistent dead space with higher re-infection and fractures rates compared to CERAMENT™|G.

This highlights the importance of bone remodelling for clinical outcomes, which sets CERAMENT™ apart from other bone graft substitutes.

References

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⁵Gitelis S et al. Use of a calcium sulfate-based bone graft substitute for benign bone lesions. Orthopedics 24:162-166, 2001

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⁷Report S009/2012, Data on file, BONESUPPORT AB

Appendix 1: Abstract of McNally et al paper, EBJS 2015.



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A COMPARATIVE STUDY OF THREE BIOABSORBABLE ANTIBIOTIC CARRIERS IN CHRONIC OSTEOMYELITIS: 313 PATIENTS WITH MINIMUM 1 YEAR FOLLOW-UP

M. McNally, J. Ferguson, J. Kendall, M. Dudareva, M. Scarborough, D. Stubbs

¹The Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals, Oxford, United Kingdom
E-mail: martin.mcnally@ouh.nhs.uk

Keywords: Osteomyelitis, Local Antibiotics, Outcomes, Absorbable

Aim

To evaluate the clinical outcome of three different local antibiotic delivery materials, used as bone defect fillers after excision of chronic osteomyelitis.

Methods

We reviewed all patients receiving Collagen Fleece with Gentamicin (Septocoll E)(n=74), Calcium Sulphate with Tobramycin pellets (Osteoset T)(n=166) or Calcium Sulphate/Hydroxyapatite biocomposite with Gentamicin (Cerament G)(n=73) for dead space filling after resection of C-M Stage III and IV chronic osteomyelitis. Data was collected on patient comorbidities, operation details, microbiology, postop complications and need for plastic surgery or external fixation. All operations were performed by two surgeons. All patients had similar systemic antibiotic therapy and rehabilitation.

Primary outcomes were recurrence rate, fracture rate and wound leakage rate.

Results

All three groups had very similar mean age and range, microbiological cultures, need for free muscle flaps or local flaps, proportion of femur, tibia and upper limb bones and use of external fixation. There were small differences in the proportion of C-M Class B hosts and anatomic Type IV cases, between the groups. All patients were followed up for at least one year. Mean follow-up was 1.75 years for Septocoll E, 1.96 years for Osteoset T and 1.78 years for Cerament G.

After surgery, there were fewer prolonged wound leaks with Cerament G (leakage persisting for more than 2 weeks). Fracture rates and infection recurrence were twice as common with Osteoset T compared with Cerament G at between one and two years after operation (see Table).

Conclusions

The use of a biocomposite material delivering local aminoglycoside was associated with lower recurrence rates and few wound problems, compared with collagen or calcium sulphate alone. This may reflect the higher levels of antibiotic in the defect and controlled release profile. The improved recurrence rate was despite a higher percentage of compromised Class B hosts.

	Septocoll E	Osteoset T	Cerament G
Number	74	166	73
Mean Age (range)	48.2(19-80)	45.6(16-82)	52.0(21-84)
C-M Type III %	82.5	79.4	87.8
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