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K. Malizos, M. Blauth, A. Danita, N. Capuano, R. Mezzoprete, N. Logoluso, L. Drago, C. L. Romanò

Fast-Resorbable, Antibiotic-Loaded Hydrogel Coating To Reduce Post-Surgical Infection After Internal Osteosynthesis. A Multi-Center, Randomized, Controlled, Prospective Trial.

Journal of Orthopaedics and Traumatology 2017; DOI 10.1007/s10195-017-0442-2

C. L. Romanò, K. Malizos, N. Capuano, R. Mezzoprete, M. D'Arienzo, C. Van Der Straeten, , S. Scarponi, L. Drago

Does an Antibiotic-Loaded Hydrogel Coating Reduce Early Post-Surgical Infection After Joint Arthroplasty?

Journal of Bone and Joint Infection 2016;1:34-41

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NOVAGENIT

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NOVAGENIT

DAC®

DEFENSIVE ANTIBACTERIAL COATING

CLINICAL RESULTS

RANDOMISED MULTICENTRE STUDIES

INVESTIGATING CENTRES

- Department of Reconstructive Surgery of Osteo-articular Infections C.R.I.O. Unit, I.R.C.C.S. Galeazzi Orthopaedic Institute, Milan, Italy
- Orthopaedic Surgery & Trauma, Medical School, University of Thessaly, Larissa, Greece
- Department for Trauma Surgery, Medical University, Innsbruck, Austria
- Department of Orthopaedics, San Luca Hospital, Vallo Della Lucania, Italy
- Department of Orthopaedics, San Camillo de Lellis Hospital, Rieti, Italy
- Orthopaedic Surgery & Trauma, University Clinic, Palermo, Italy
- Department of Orthopaedics, Medical University Ghent, Belgium

TRAUMATOLOGY CLINICAL STUDY

STUDY PROFILE

- Condition: Closed fresh fractures of long bones requiring the use of plates or intramedullary nails
- Intervention: Intraoperative application of DAC® + Antibacterial Agent
- Study design: Single blind - randomised - controlled - multicentre
- Endpoint Classification: safety and efficacy study
- Primary outcome measures:
  - clinical and laboratory evidence of safety
  - clinical and laboratory evidence of efficacy
- Level of evidence II

STUDY POPULATION

253 patients

- 126 treated group- internal osteosynthesis and DAC®
- 127 control group– internal osteosynthesis

Mean age (years): 58.6 ±17.6 (control) and 62.5±21.2 (treated)

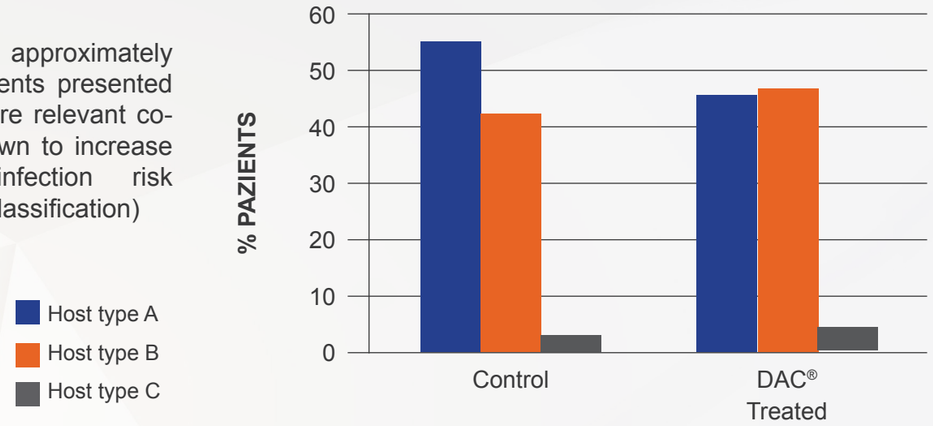
TYPE OF FIXATION	CONTROLS	%	TREATED	%
PLATE/SCREW	117	92.1	115	91.3
INTRAMEDULLARY NAIL	10	7.9	11	8.7

FRACTURE SITE

FRACTURE SITE	CONTROLS	%	TREATED	%
FEMUR	32	25.2	47	37.3
TIBIA/KNEE	11	8.7	16	12.7
ANKLE/FOOT	29	22.8	32	25.4
CLAVICLE	11	8.7	10	7.9
HUMERUS	8	6.3	6	4.8
FOREARM/WRIST	29	22.8	14	11.1
HAND	7	5.5	1	0.8

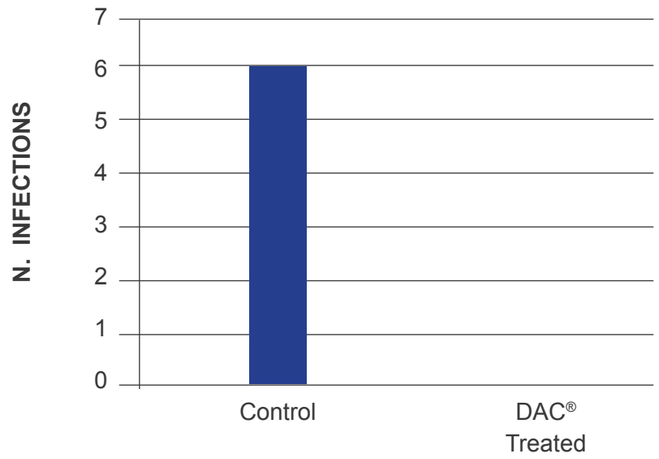
RISK PROFILE

In both groups approximately half of the patients presented with one or more relevant co-morbidities known to increase postsurgical infection risk (McPherson's classification)



DAC® EFFECTIVENESS EVIDENCE

Six surgical site infections were reported in the control group (4.7%), compared to none in the treated group (P=0.02) at 18 months follow-up



75% OF CONTROL GROUP HOST TYPE C DEVELOPED SURGICAL SITE INFECTION

CONCLUSIONS

About 50% of the enrolled patients presenting one or more co-morbidities. The results are very encouraging with 4.7% of the control group presenting with infection, versus 0% in the treated group (P<0.02).

PROSTHESIS CLINICAL STUDY

STUDY PROFILE

- Condition: Total hip or knee joint replacement
- Intervention: Intraoperative application DAC® + Antibacterial Agent
- Study design: Single blind - randomized - controlled - multicenter
- Endpoint classification: safety and efficacy study
- Primary outcome measures:
  - clinical and laboratory evidence of safety
  - clinical and laboratory evidence of efficacy
- Level of evidence II

STUDY POPULATION

373 patients

- 189 treated group – prosthesis and DAC®
- 184 control group - prosthesis

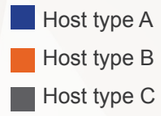
Mean age (years): 71 ± 10.6 (control)

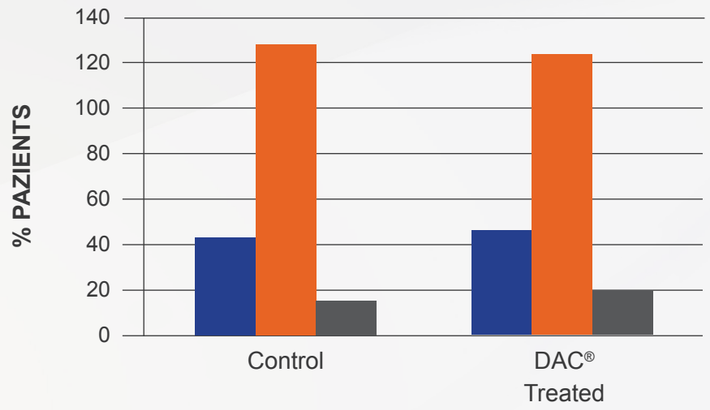
Mean age (years) 69 ± 12.6 (treated)

		CONTROLS	%	TREATED	%
JOINT	HIP	141	76.6	153	80.9
	KNEE	43	23.4	36	19.0
TYPE OF SURGERY	PRIMARY	132	71.7	135	71.8
	REVISION	52	28.3	54	28.2

RISK PROFILE

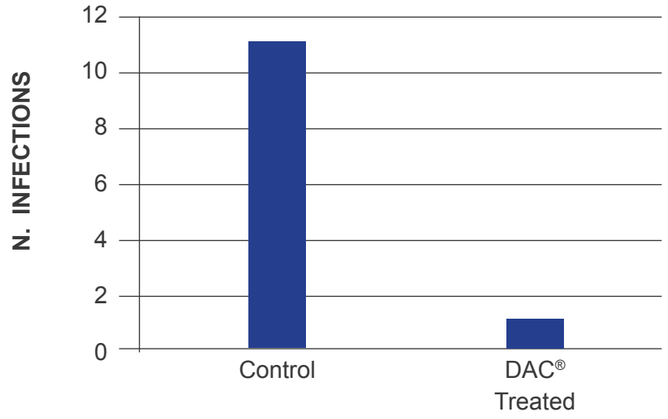
In both groups 76% of the patients presented with one or more relevant co-morbidity known to increase postsurgical infection risk (McPherson's classification)





DAC® EFFECTIVENESS EVIDENCE

11 surgical site infections were reported in the control group (6%), compared to only one (0.6%) in the treated group (P=0.003) at 14.5 months follow-up



TREATED PATIENT					
HOST TYPE	RELEVANT CO-MORBIDITIES	PRE-OPERATIVE DIAGNOSIS	ONSET OF INFECTION (MONTHS FROM SURGERY)	CULTURAL EXAMINATION	TREATMENT
B	DIABETES; BMI > 40	HIP OSTEOARTHRITIS	< 1	NEGATIVE CULTURES	NO FURTHER INFECTION RECURRENCE

13.5% (7/52) OF CONTROL GROUP SECOND STAGE REVISION DEVELOPED SURGICAL SITE INFECTION VS 0% (0/54) IN THE TREATED GROUP.

3% (4/132) OF CONTROL GROUP PRIMARY SURGERY DEVELOPED SSI VS 0% (0/135) IN THE TREATED GROUP.

CONCLUSIONS

The patient population presents an incidence of high risk factors. Results showed 6% infection in the control group, versus 0.5% occurrence of infection in the treated group (P<0.003).