

SOLARIO Study Published in The New England Journal of Medicine

BONESUPPORT™, a leading company in orthobiologics for the treatment of bone injuries, today announces that the SOLARIO study has been published in The New England Journal of Medicine (NEJM), one of the world's most prestigious peer-reviewed medical journals. The study demonstrates that systemic antibiotic treatment in orthopedic infections can be reduced from weeks to days without compromising outcomes when local antibiotic therapy is used. The findings support a potential paradigm shift in orthopedic infection management.

SOLARIO is the first large, randomized, controlled study to robustly evaluate whether local antibiotic therapy allows safe and effective reduction in systemic antibiotic treatment in orthopedic infections. In the current trial, a short course (≤ 7 days) of systemic antibiotics was noninferior to a long course (≥ 4 weeks) with regard to definite treatment failure at 12 months in patients who had undergone surgical management of bone and joint infection that included local antibiotics. The study included both bioabsorbable and Polymethylmethacrylate Bone Cement, (PMMA), medical device-drug combinations incorporating antibiotics as ancillary medicinal substances. CERAMENT® G was the most used product in the study, administered in 280 patients (56%), followed by CERAMENT® V, which was used in 146 patients (29%). In comparison, PMMA-based antibiotic carriers were used in 60 patients (12%), while preformed PMMA spacers or beads were used in 11 patients (2%), predominantly in patients with Prosthetic Joint Infections.

Professor Martin McNally of the Oxford Bone Infection Unit, who originally designed the trial, said: "The SOLARIO findings demonstrate that duration of systemic antibiotic treatment can be dramatically reduced without compromising outcomes when effective local antibiotic therapy is used. Long courses of antibiotics have been preferred in orthopaedics for many years without good evidence that they benefit patients. The SOLARIO trial challenges the reliance on long systemic therapy, showing that good local therapy with very limited empiric systemic antibiotics is a safe alternative. It provides a better patient experience, with few adverse events and contributes to improved antibiotic stewardship. It will be a game changer for many patients around the world."

The median duration of postoperative systemic antibiotic therapy was 6 days in the short-duration group and 42 days in the long-duration group. With this duration reduction, while significantly lowering the adverse effects associated with prolonged antibiotic therapy as demonstrated by the SOLARIO study, CERAMENT G and CERAMENT V continue to offer effective solutions in the surgical management of bone infections. The results from the study are poised to dramatically reshape clinical practices in managing bone infections and underscore the critical role local antibiotic eluting bone substitutes play in reducing systemic antibiotic use, a major victory for antimicrobial stewardship, patient safety, and well-being.

More on the SOLARIO study:

The SOLARIO study was a multi-centre, randomized controlled open-label non-inferiority trial involving 500 patients that investigated whether the duration of systemic antibiotic therapy could be reduced to less than seven days when combined with the use of surgical treatment with local antibiotics. SOLARIO was designed and coordinated from the Oxford Bone Infection Unit, United Kingdom and patients were recruited from 25 centres across 5 European countries.

475 subjects were assessed in the primary analysis. Definite treatment failure occurred in 34 of 241 patients (14.1%) in the long-duration group and in 26 of 234 patients (11.1%) in the short-duration group.

There was no difference in infection recurrence between the short arm and the long arm, highlighting the efficacy of local antibiotics in controlling infection while allowing systemic antibiotics to be stopped within seven days post-surgery resulting in substantially fewer adverse events.

Symptoms potentially related to antibiotic treatment were reported at the 6-week follow-up visit by 45.2% of the patients in the long-duration group and 17.2% of those in the short-duration group. Such symptoms were reported at the visit between 3 and 6 months by 20.4% and 8.5%, respectively.

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About BONESUPPORT™

BONESUPPORT (Nasdaq Stockholm: BONEX) develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient's own bone and have the capability of eluting drugs. BONESUPPORT's bone graft substitutes are based on the patented technology platform **CERAMENT**. The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver. The company is based in Lund, Sweden, and the net sales amounted to 1,175 msek in 2025. Please visit www.bonesupport.com for more information.

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Attachments

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