2 June 2026

Queensland Children's Hospital launches clinical study for paranasal augmentation in patients with unilateral cleft lip

Highlights

- **Osteopore and Queensland Children's Hospital (QCH) have launched and commenced a clinical trial for paranasal augmentation in 5 paediatric patients with unilateral (one-sided) cleft lip – which is the augmentation of the nose and surrounding upper jaw structure.**
- **Patient recruitment for the single-arm feasibility trial is anticipated by June 2027, with patient follow-up expected to continue for 12 months post-surgery.**
- **The first 3 patients have been recruited to the trial, with the first patient to be treated by July this year.**
- **Cleft lip and palate affects approximately 1 in 1,000 births globally[1], making it one of the most prevalent congenital conditions worldwide.**
- **The global cleft lip and palate repair market was valued at approximately USD 1.2b (~AUD 1.7b) in 2024 and is forecast to reach USD 1.9b (~AUD 2.7b) by 2033, growing at a CAGR of 5.5% [2].**

Australian-Singaporean regenerative medicine company **Osteopore Limited** (**ASX: OSX**; **Osteopore** or **the Company**) – a global leader in 3D-printed biomimetic and bioresorbable implants – is delighted to announce the launch of a clinical trial in partnership with Queensland

[1] DOI: 10.15761/OHNS.1000246

[2] https://www.verifiedmarketreports.com/product/cleft-lip-and-palate-repair-market/

Children's Hospital (QCH) to augment the appearance of the nose and surrounding upper jaw structure in children with one-sided cleft lip.

QCH will conduct a single-arm feasibility trial, with the recruitment of up to 5 patients expected by end of 2026. Patient follow-up will continue for 12 months after surgery. The first 3 patients have been recruited to the trial, with the first patient to be treated by July this year.

The trial will be led by Dr. Yun Phua, a Plastic and Reconstructive Surgeon based at QCH and Mater Hospital. This is the second paediatric study led by Dr. Phua – the first study was for the treatment of temporal hollowing, announced on 23 May 2025 [3].

The trial utilises Osteopore's medical-grade polycaprolactone-tricalciumphosphate (mPCL-TCP) scaffolds, manufactured using additive manufacturing (3D printing) to produce patient-specific implants precisely matched to each patient's anatomy.

The scaffolds are 3D printed from a bioresorbable composite (PCL-TCP) that gradually degrades as the body regenerates bone, mimicking the mechanical properties of trabecular bone throughout the healing process. Implants are designed using each patient's CT imaging data and manufactured under Osteopore's established Patient Specific Implant (PSI) workflow, already in clinical use at QCH.

The current standard of care for this condition — cancellous bone grafting harvested from the hip — is associated with poor long-term graft retention and unpredictable outcomes for nasal form.

Osteopore's scaffold is designed to replace this graft entirely, providing a structurally accurate, reproducible alternative that supports bone regeneration and nasal base support without adding surgical time. This represents a meaningful clinical advancement over existing practice.

[3] ASX announcement, "OSX partners QCH in trial for temporal hollowing in children", 23 May 2025.

Cleft lip and palate affects approximately 1 in 1,000 births globally[4], making it one of the most prevalent congenital conditions worldwide. Patients typically undergo multiple reconstructive procedures throughout childhood and adolescence.

The global cleft lip and palate repair market was valued at approximately USD 1.2b (~AUD 1.7b) in 2024 and is forecast to reach USD 1.9b (~AUD 2.7b) by 2033, growing at a CAGR of 5.5% [5]. Growth is being driven by rising surgical volumes, increasing awareness of treatment options, and the adoption of advanced biomaterials and surgical techniques.

This trial, conducted at one of Australia's leading children's hospitals, provides a strong clinical and commercial foundation for broader market adoption.

By delivering a more predictable and durable outcome, this technology has the potential to reduce revision surgeries, improve facial symmetry, and meaningfully enhance quality of life for patients — outcomes being measured using the validated Cleft-Q patient-reported outcome tool.

Commenting on the second study for children at QCH, CEO Dr Yujing Lim said:

"We are delighted to partner with Dr. Phua to advance yet another unique regenerative solution for children. Every child born with a cleft lip deserves the best possible outcome, and this trial reflects our commitment to making that a reality.

"This trial positions us at the forefront of a global market opportunity worth nearly USD 2 billion, and is precisely why we exist as a company — to engineer better outcomes for patients and create lasting value for our shareholders," said Dr Lim.

[4] DOI: 10.15761/OHNS.1000246

[5] https://www.verifiedmarketreports.com/product/cleft-lip-and-palate-repair-market/

Commenting on the study, Dr. Yun Phua said:

"As a plastic surgeon working with cleft patients, I see firsthand the profound impact facial asymmetry has on a child's confidence and quality of life. The techniques we currently rely on have served us well, but there are still cleft-related facial differences — such as nostril base shape — that remain difficult to correct.

"This trial gives us the opportunity to offer something truly personalised: an implant designed specifically for each child's anatomy that corrects the deformity and, over time, becomes their own tissue. I am excited to lead this work and hopeful it will set a new standard of care for cleft patients", said Dr. Phua

ENDS

This announcement has been authorised for release to the ASX by the Board of Osteopore Limited.

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About Osteopore Limited

Osteopore Ltd. is a global medical technology company founded in Singapore and listed in Australia that commercialises products designed to enable natural bone healing across multiple therapeutic areas. Osteopore's patented technology fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable material.

Osteopore's patent-protected scaffolds are manufactured using a proprietary manufacturing technique with a polymer that naturally dissolves over time to only allow natural and healthy bone tissue, significantly reducing the post-surgery complications commonly associated with permanent bone implants. Our 3D printing technology is unique to Osteopore.

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