23 May 2025

Queensland Children's Hospital launches clinical study for temporal hollowing

Highlights

- **Osteopore and Queensland Children's Hospital (QCH) have launched a clinical trial for the treatment of temporal hollowing in 5 paediatric patients.**
- **Patient recruitment for the single-arm feasibility trial is anticipated by end of 2026, with patient follow-up expected to continue for 12 months post-surgery.**
- **The single-arm trial seeks to assess the feasibility of a 3D-printed, patient-specific polycaprolactone-tricalcium phosphate (PCL-TCP) onlay scaffold.**
- **Incorporated with bone marrow aspirate and platelet-rich fibrin (PRF), the PCL-TCP onlay scaffold seeks to restore frontotemporal contour in children.**

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 Children's Hospital (QCH) to treat temporal hollowing in children following cranial vault remodelling surgery for craniosynostosis.

A single-arm feasibility trial will be conducted in Australia, with the recruitment of up to 5 patients expected by end of 2026. Patient follow-up will continue for 12 months after surgery.

The trial will be led by Dr. Yun Phua, a Plastic and Reconstructive Surgeon based at QCH and Mater Hospital. Dr. Phua's subspecialty areas include craniofacial surgery and reconstructive microsurgery.

The study aims to assess the feasibility of using a 3D-printed, patient-specific polycaprolactone-tricalcium phosphate (PCL-TCP) onlay scaffold combined with bone marrow aspirate and platelet-rich fibrin (PRF), to restore the frontotemporal contour in children who have undergone cranial vault remodelling surgery.

Craniosynostosis is a congenital condition in which the bones of a child's skull fuse prematurely, potentially leading to abnormal head shape and neurological complications. Cranial vault remodelling is a common surgical procedure designed to correct this skull contour abnormality.

Temporal hollowing, a noticeable depression in the lateral forehead and temple area, can occur in up to 30-40% of patients following this surgery.

Currently, materials like hydroxyapatite and porous polyethylene are used for augmentation, but these are only considered when the patient is reaching maturity (10-12 years old). This procedure also requires a long bicoronal incision that stretches across the top of the skull from ear to ear.

The PCL-TCP onlay scaffold being assessed during this trial has the potential to support bone formation and growth as the child matures and may be implanted through a smaller incision.

The study has received clearance from the Human Research and Ethics Committee (HREC) at Children's Health Queensland and the Research Governance Office (RGO). The first patient recruited has been successfully recruited.

The study is supported by Maddox's Helping Hand Foundation (MHHF). Established in 2020, MHHF supports the Australian Centre for Complex Integrated Surgical Solutions (ACCISS). The Centre's mission is to help clinicians access new and emerging technologies that improve patient care, including 3D printing, computer-aided design (CAD), and virtual and augmented reality devices.

Commenting on the significance of the QCH study to children suffering from temporal hollowing, CEO Dr Yujing Lim, said:

"We are delighted to partner with Dr. Phua to advance unique regenerative solutions for children suffering from temporal hollowing.

"Children don't have good options for bone or tissue implants. Most of what is currently available on the market is permanent and does not grow with the patient.

"It is important for us to collaborate closely with clinicians to identify key areas of development to drive impact and patient benefit," said Dr Lim.

Commenting on the potential of the study to correct temporal hollowing, Dr. Yun Phua said:

"With a scaffold that can remodel with cranial growth, this trial has the potential to enable earlier correction of temporal hollowing in the paediatric age group, instead of waiting until adulthood.

"From what we know, this is the first study specifically looking at augmentation of the temporal region using a regenerative tissue scaffold in paediatric patients.

"We are very appreciative of the Maddox's Helping Hand Foundation's support for this clinical trial, and look forward to commencing the study," said Dr. Phua.

Commenting on the partnership with Dr Phua and Osteopore, MHHF Director Shelley Porter said:

"Our Team at the Maddox's Helping Hand Foundation are extremely pleased to be able to assist Dr Yun Phua in this upcoming clinical trial.

"Our main aim at MHHF is to assist surgeons in accessing new technologies to help provide better patient care and outcomes.

"We look forward to seeing the outcome of this trial, and the positive impact this treatment could have not only on the patient, but their family," said Ms Porter.

ENDS

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

For more information, please contact:

Dr Yujing Lim
Chief Executive Officer
Osteopore Limited
E: lim_yujing@osteopore.com

Isaac Stewart
Media & Investor Relations
Purple
E: istewart@purple.au

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.

Forward-Looking Statements

Some of the statements appearing in this announcement may be similar to forward-looking statements. You should be aware that such statements are only predictions and are subject to inherent risks and uncertainties. Those risks and uncertainties include factors and risks specific to the industries in which the Company operates and proposes to operate as well as general economic conditions, prevailing exchange rates and interest rates and conditions in the financial markets, among other things.

Actual events or results may differ materially from the events or results expressed or implied in any forward-looking statement. No forward-looking statement is a guarantee or representation as to future performance or any other future matters, which will be influenced by several factors and subject to various uncertainties and contingencies, many of which will be outside the Company's control. The Company does not undertake any obligation to update publicly or release any revisions to these forward-looking statements to reflect events or circumstances after today's date or to reflect the occurrence of unanticipated events.

No representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions or conclusions contained in this announcement. To the maximum extent permitted by law, neither of the Company's Directors, employees, advisors or agents, nor any other person, accepts any liability for any loss arising from the use of the information contained in this announcement.

You are cautioned not to place undue reliance on any forward-looking statement. The forward-looking statements in this announcement reflect views held only as at the date of this announcement. This announcement is not an offer, invitation or recommendation to subscribe for or purchase securities by the Company. Nor does this announcement constitute investment or financial product advice (nor tax, accounting or legal advice) and is not intended

to be used for the basis of making an investment decision. Investors should obtain their own advice before making any investment decision.