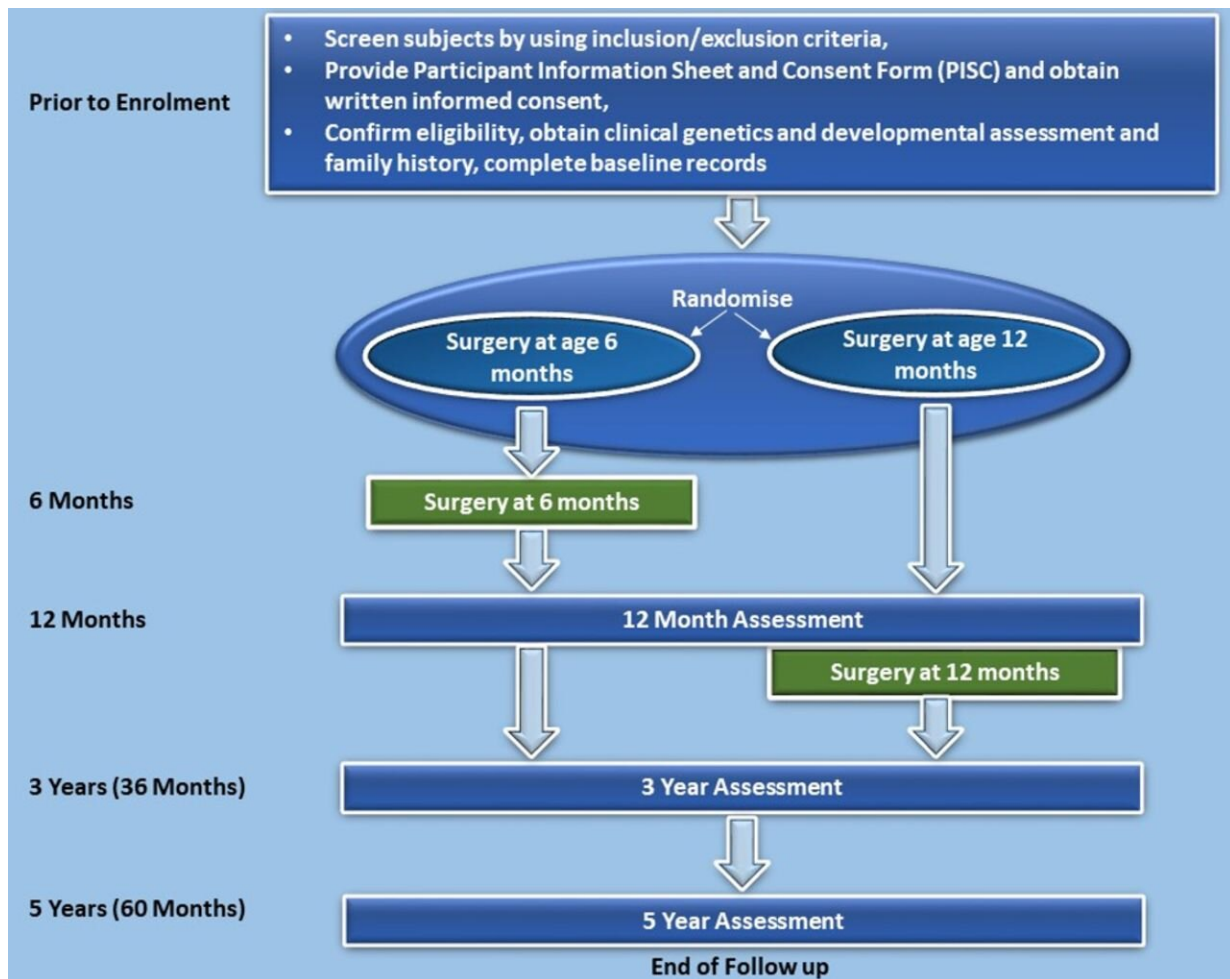


Earlier cleft palate surgery linked with better outcomes in children

August 30 2023, by Mike Addelman



Flow diagram of Timing Of Primary Surgery for cleft palate study design. Credit: *BMJ Open* (2019). DOI: 10.1136/bmjopen-2019-029780

Early surgery for isolated cleft palate repair is more likely to achieve a successful outcome, according to an international study of newborn babies from across Europe and South America.

The study was led by Professor William Shaw from The University of Manchester and Professor Carrol Gamble from the University of Liverpool, along with senior co-investigators from the Universities of Gothenburg, Copenhagen, São Paulo, and Edinburgh.

The study found that surgery on medically fit infants across 23 specialized [cleft](#) centers at 6 months of age reduced the risk of velopharyngeal insufficiency (VPI) at five years in comparison with cleft repair at 12 months.

Published in the *New England Journal of Medicine* today (30 August), the study could have major implications on current treatment pathways.

VPI happens when the [soft palate](#) does not close tightly between the mouth and the nose during speech, causing air to escape from the nose during speech and difficulties in producing specific speech sounds.

Conducted over nearly 20 years, the TOPS trial is the culmination of the life work Professor Bill Shaw and Gunvor Semb from The University of Manchester, who are now both retired.

Of the babies randomly allocated to receive their surgery at six months, 235 out of 281 (84%) stayed in the study until their age 5-year assessments and provided video and audio recordings of their speech assessments. In the group randomly allocated to receive their surgery at 12 months it was 226 out of 277 (82%).

The results of the international trial found:

- Randomization to primary surgery for cleft palate repair at age 6 months compared to age 12 months was associated with better speech outcome at 5 years of age. At five years, insufficient velopharyngeal function was observed in 21 (9%) and 34 (15%) of infants randomized to the 6- and 12-month age groups, respectively.
- There were three serious adverse events in the 6-month group and one in the 12-month group. All were resolved at follow up.
- Other safety events were uncommon and similar between groups. Rates of secondary surgery were similar between groups, but reasons varied. More infants in the 6-month group required a secondary surgery for VPI, while more infants in the 12-month group required secondary surgery for fistula.
- At one year, hearing and middle ear function were poorer in the group awaiting surgery. These differences, however, were not apparent at ages 3 and 5.
- Though there were no notable differences between groups for growth at one year, dentofacial development outcomes at five years were poorer for the group randomized to surgery at 6 months. However, the difference between the two groups was not thought to be clinically meaningful.

Isolated cleft palate is a condition where the roof of the mouth is not closed properly, leaving a gap or hole and affects one to 25 newborns per 10,000 births worldwide.

Depending on the type and severity of the defect, cleft palate may result in communication difficulties arising from speech development and hearing loss, feeding problems, issues with dental development and facial growth, and psychological difficulties.

Professor Gamble, who led trial design and analysis, from the Institute of Population Health at the University of Liverpool said, "TOPs is a

great example of the Team Science approach to research required to successfully deliver this complex and challenging trial. The analysis of the speech recordings required 41 speech and language therapists from participating sites to travel to the UK to assess the speech recordings at one-, three- and five-year assessment time points. This resulted in a rich and complex data for analysis.

"This study shows us that overall the outcomes for children are better if they undergo corrective surgery earlier.

"If medically fit babies with a nonsyndromic isolated [cleft palate](#) have surgery at six months it limits the disruption it can cause to future key developments particularly linked to speech and hearing.

"These important findings will allow clinicians to make informed decisions about infant patient treatment and reduce the amount of further medical care they may need."

Professor Tanya Walsh, from The University of Manchester who now co-leads the research with Professor Kevin Munro said, "There has been limited evidence from high quality randomized controlled trials on the optimal age to undergo cleft repair [surgery](#) to achieve better outcomes

"Surgery is carried out between 6 and 14 months in the many specialist cleft centers in Europe and the U.S. The results of this important trial will greatly support parental and clinical and decision- making."

She added, "This research was led by our Manchester colleague Prof Bill Shaw, who has since sadly retired through ill health. Bill dedicated much of his life to cleft research.

"We are all immensely proud of Bill's passion for and dedication to cleft research, which has been nothing short of inspiring. His kindness,

empathy, and genuine interest in others will be long remembered by his colleagues and friends."

Orthodontist Dr. Ross E. Long, a long-time cleft research collaborator and friend of Bill Shaw said, "A hundred years of research has not been able to answer such basic questions in cleft care, like: 'what works best?'"

"This study is a fitting tribute of Bill Shaw's efforts to answer that question, and the support he received from colleagues around the world, and especially at The University of Manchester.

"Such an effort would never have been possible without his vision and commitment to quality research.

"He is truly a friend to all of us who strive to improve the lives of the patients we treat. Our memory of him and what he has accomplished to identify best practices in cleft care, will surely guide our thinking for years to come."

More information: William Shaw et al, Timing Of Primary Surgery for cleft palate, *New England Journal of Medicine* (2023).

Provided by University of Manchester

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