Interim Report for BAOMS 23 November 2022

Trial Of Resorbable versus Non-Resorbable sutures for traumatic lacerations of the face (TORN Face)

CUH Trial Ref:	A095791
IRAS Project ID:	289842
ISRCTN ID:	ISRCTN55795740
NIHR Portfolio ID:	48907
Chief Investigator:	Mr Shadi Basyuni
CI Address:	Department of Oral and Maxillo-Facial Surgery, Cambridge University Hospital NHS Foundation Trust, Cambridge, CB2 0QQ
Co-investigators	Mr Vijay Santhanam, Mr Gareth Nugent, Mr Ian Jenkyn, Mr Ashley Ferro, Mr Henry Bennett, Dr Clarissa Hjalmarsson, Dr Jonathan Chu

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TORN Face is a single centre, single-blinded randomised controlled trial with 2 treatment arms: resorbable (Vicryl Rapide) versus non-resorbable (Ethilon) sutures for traumatic lacerations of the face.

The primary objective of this trial is to compare the long-term cosmetic outcome of using resorbable versus non-resorbable sutures. The primary outcome measures will be difference in visual analogue scale (VAS) cosmesis at six months post-wound closure. Secondary outcomes include patient reported outcomes, complication rates and a cost-benefit analysis.

We are very grateful to BAOMS endowments committee for financially supporting this study. Since receiving the grant award from BAOMS we have made the following progress:

1) **Ethical approval for the study**

   Ethical approval was granted by the Central Cambridge Research Ethics Committee on 24th May 2021 (REC reference 21/EE/0097)

2) **Registration of trial with ISRCTN and NIHR**

   The trial has been prospectively registered with the ISRCTN registry (ISRCTN55795740) and has also been registered as an NIHR portfolio study (CPMS ID: 48907)

3) Training for recruiters

The project has continued to be a success in introducing maxilla-facial trainees, students, colleagues and allied health care professions to the role of Oral and Maxillofacial Surgery in clinical research. In addition to the 21 clinicians who were previously trained in preparation for the trial, we have now trained a further 6 Dental Core Trainees (DCTs) to recruit and 2 DCTs have joined the trial team to help with patient follow-up.

4) Continuation of participant recruitment

Recruitment has continued to progress well, particularly with a return to pre-pandemic levels of patient presentations with oral and maxillofacial trauma. At the time of writing, we are glad to report that 145/200 patients have been recruited, 109 patients have completed their 3-month follow-up, and 75 their 6-month follow-up. Recruitment has been delayed somewhat by transition of the Dental Core Trainee team September 2022 (and therefore the need for additional training), and through the introduction of the Head and Neck Assessment Hub (HANAH), a new initiative designed to optimise patient flow and quality of care for Oral and Maxillofacial Surgery patients presenting to the Emergency Department. To date there have been no adverse events (AE), no adverse reactions (AR), no serious adverse events (SAE), no serious adverse reactions (SAR) and no suspected unexpected serious adverse reactions (SUSAR).

5) Publicity and National Presentations

In addition to two previous oral presentations at the BAOMS JTG Conference 2021, the trial team has also presented a poster at the BAOMS Annual Scientific Meeting on 22-24 June 2022. This poster provided an update on trial recruitment at the time of the Meeting and provided insight into particular challenges faced during the process as the first trainee-led Randomised Control Trial in the UK. This poster was led by student and junior doctor members of the team, with support by senior trainees.

The trial remains on budget, with projected costs unchanged at £4025. The trial team continue to meet regularly to check in with the trial's current progress, discuss key upcoming phases of the trial, and to proactively identify potential obstacles to trial progression. In light of delays with recruitment, as a consequence of DCT transition in September and logistical delays through the establishment of the Head and Neck Assessment Hub, we have requested that the ISRCTN and NIHR portfolio extend our recruitment completion date to September 2023. We are currently at 72.5% recruitment and thus anticipate comfortably completing recruitment by this extended date. We are grateful for the continued support from BAOMS and your patience with regards to the delay from our initial timescales.

The team look forward to continuing their work on the trial over the coming months, outcome measures will be completed 6 months after our last patient is recruited. The team will then commence the data analysis phase and we look forward to presenting BAOMS and BJOMS with our results in the near future.

We will of course keep BAOMS up to date with any progress from our side. *If you have any questions, please do not hesitate to contact the trial's chief investigator, Mr Shadi Basyuni, at shadi.basyuni@nhs.net.*

Shadi Basyuni