Interim Report for BAOMS:

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
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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**

So far, the project has been a huge success in introducing maxillo-facial trainees, students, colleagues in other specialties and allied health professions to the role our specialty can play in clinical research. We have trained 21 clinicians in total (all required to complete NIHR Good Clinical Practice + local TORN Face training). The study was also highlighted in the induction programme for incoming foundation doctors/ED doctors to facilitate appropriate referrals for recruitment.

4) **Commencement of participant recruitment**

Unfortunately for various staffing and logistical reasons, the pandemic delayed our planned start date for recruitment. However, we are glad to report that recruitment commenced on the 13th November 2021 and at time of writing this report 7/200 patients have been recruited. 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**

The trial team gave two oral presentations at the BAOMS JTG Conference 2021 on 13-14/11/2021. The first detailed their work on capturing scar healing using objective visual analogue scales and subjective patient-reported outcomes. The second presentation discussed the logistics and lessons learned so far from a student- and trainee-led randomised controlled trial. Presentations were led by student and junior-doctor members of the team, supported by senior trainees. This was well received, and the trial team have subsequently received enquiries from other trainees interested in becoming involved in future projects or setting up their own trainee led projects.

The trial remains on budget, with projected costs unchanged at £4025. None of the grant money has been spent to date and all remains within the CuOMFS bank account. 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. Unfortunately, due to our delayed start date we have had to update our expected completion date for this project. Initially we had anticipated that we would complete recruitment by Spring 2021, however we have requested that the ISRCTN and NIHR portfolio extended our recruitment completion date to January 2022. Whilst our current expectation is that we will complete recruitment before this date, we felt that it was prudent to include a margin to account for any further unexpected delays we may face as the pandemic continues to unfold. 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