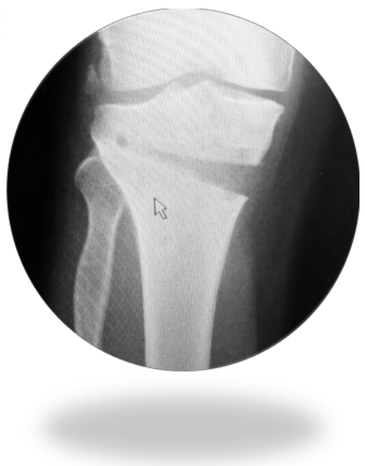
## Objectives

High tibial osteotomy for knee realignment is effective at relieving symptoms of knee osteoarthritis but the operation is surgically challenging (Fig 1a and 1b). A new personalised treatment with simpler surgery using pre-operatively planned measurements from computed tomography (CT) imaging and 3D-printed implants and instrumentation has been designed and is undergoing clinical trial. The aim of this study was to evaluate the early clinical results of a preliminary pilot study evaluating the safety of this new personalised treatment.



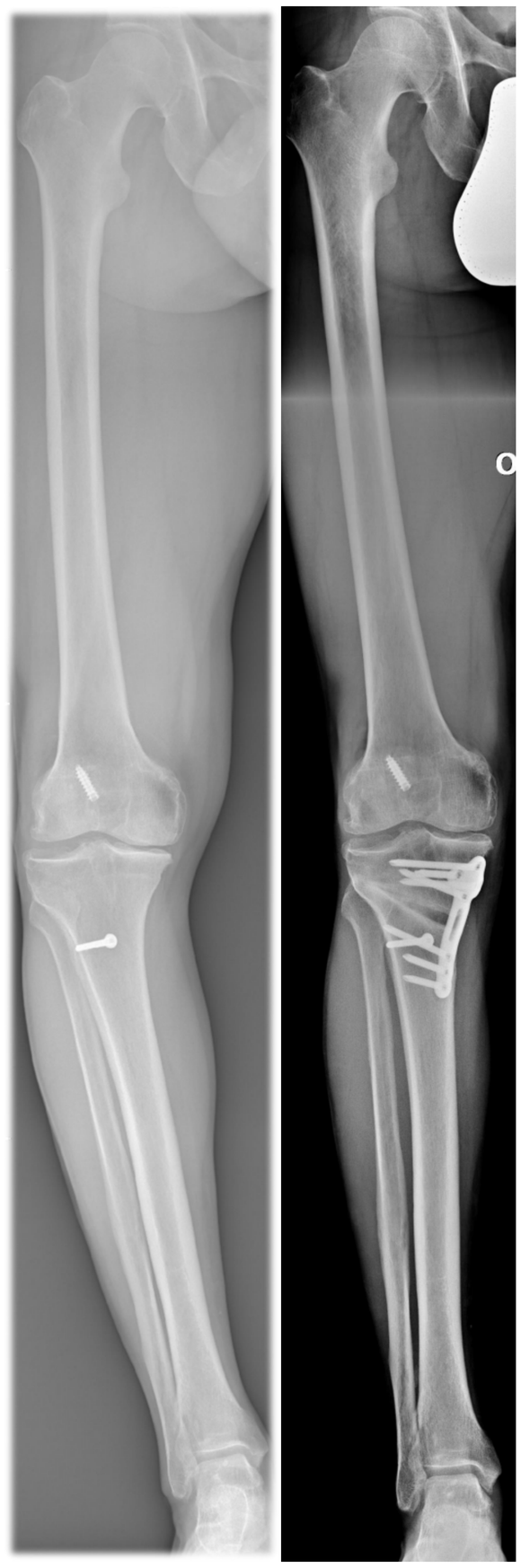
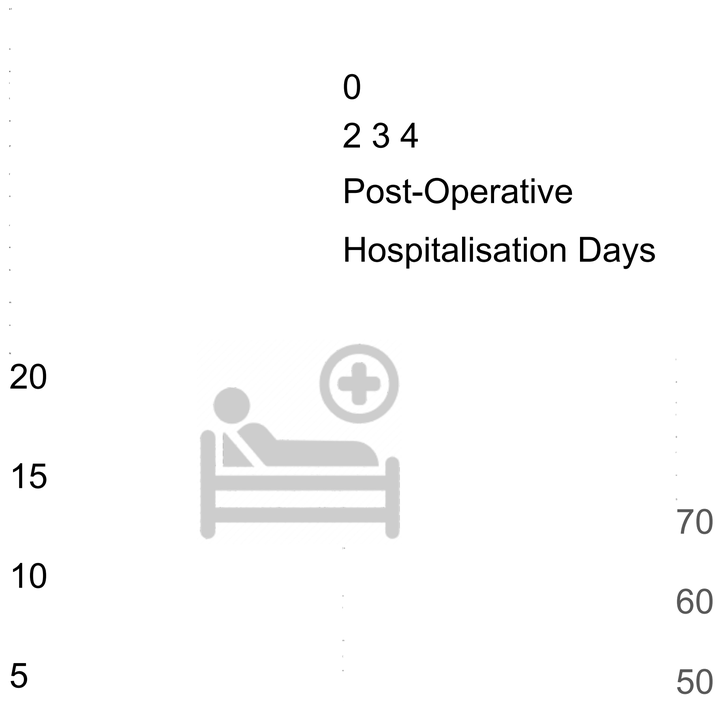
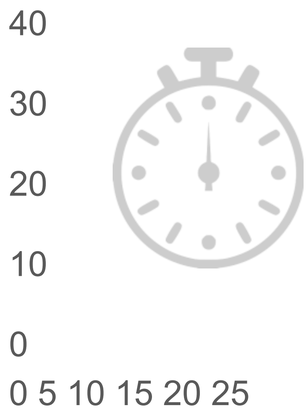


**Fig 2a** **Fig 2b** **Methods**

The single-centre prospective clinical trial is ongoing (IRCCS Istituto Ortopedico Rizzoli; IRB-0013355; ClinicalTrials.gov NCT04574570), with recruitment completed and all patients having received the novel custom surgical treatment. To preserve the completeness of the trial reporting, only surgical aspects were evaluated in the present study. Specifically, the length of the implanted osteosynthesis screws was considered, being determined pre-operatively eliminating intraoperative measurements, and examined post-operatively (n=7) using CT image processing (ScanIP, Synopsys) and surface distance mapping (Fig 2a and 2b). The surgical time, patient discharge date and ease of wound closure were recorded for all patients (n=22).

**Fig 1a** **Fig 1b**



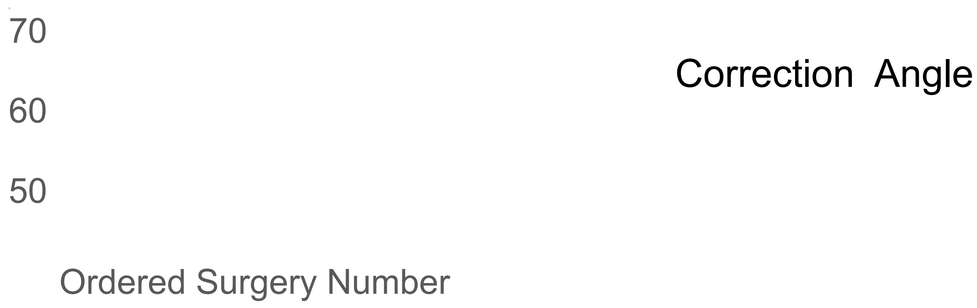




**Fig 3** **Fig 4** **Results**

Over the study period the average surgical time (skin incision to suture) reduced from 54 to 31 minutes (range: 17-62, n=22) (Fig 4). It was noted that wound closure was easier than the conventional surgery due to the lower profile of the implant. Over seventy percent of patients were discharged day 2 post-op (Fig 3). The position, orientation and length of all screws matched the pre-operative configuration to within approximately 1mm.

## Conclusions

The early trial results are promising from a clinical perspective. It was evident that surgical time was saved because no intraoperative screw length measurements were required, and the use of custom instrumentation significantly reduced the surgical inventory. The reduced invasiveness and ease of surgery may contribute to faster patient recovery compared to conventional techniques. The full trial results will be

reported later this year.

**Contact: ali@toka.org.uk**