GENERAL ORTHOPAEDICS

Is a staged reloading protocol effective to time the removal of circular frames?
A RETROSPECTIVE ANALYSIS

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Aims
The timing of when to remove a circular frame is crucial; early removal results in refracture or deformity, while late removal increases the patient morbidity and delay in return to work. This study was designed to assess the effectiveness of a staged reloading protocol. We report the incidence of mechanical failure following both single-stage and two stage reloading protocols and analyze the associated risk factors.

Methods
We identified consecutive patients from our departmental database. Both trauma and elective cases were included, of all ages, frame types, and pathologies who underwent circular frame treatment. Our protocol is either a single-stage or two-stage process implemented by defunctioning the frame, in order to progressively increase the weightbearing load through the bone, and promote full loading prior to frame removal. Before progression, through the process we monitor patients for any increase in pain and assess radiographs for deformity or refracture.

Results
There were 244 frames (230 patients) included in the analyses, of which 90 were Ilizarov type frames and 154 were hexapods. There were 149 frames which underwent single-stage reloading and 95 frames which underwent a two-stage reloading protocol. Mechanical failure occurred after frame removal in 13 frames (5%), which suffered refracture. There were no cases of change in alignment. There was no difference between refracture patients who underwent single-stage or two-stage reloading protocols (p = 0.772). In all, 14 patients had failure prevented through identification with the reloading protocol.

Conclusion
Our reloading protocol is a simple and effective way to confirm the timing of frame removal and minimize the rate of mechanical failure. Similar failure rates occurred between patients undergoing single-stage and two-stage reloading protocols. If the surgeon is confident with clinical and radiological assessment, it may be possible to progress directly to stage two and decrease frame time and patient morbidity.

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Introduction
Ilizarov methods were introduced to the western world in the early 1980s by the Lecco group. In the initial period, the Ilizarov technique was primarily used in salvage situations; however, the indications have broadened, and it is now the primary device for a number of complex and sometimes simple orthopaedic conditions.1,2

Circular frame surgery can cause pain, pin site infections, and morbidity in patients. Early frame removal can lead to refracture or change in alignment (plastic deformation), while unduly prolonging the time in frame increases the patient morbidity and complications.3

Radiological assessment of union with a circular frame in situ can be challenging...
due to multiple opaque metal parts obscuring the view. Complex fracture patterns also make radiological assessment difficult. Despite there being multiple techniques to determine fracture union, including imaging, mechanical testing, and serum markers, the most prevalent are the clinical assessment (pain or tenderness) of the fracture site and imaging (e.g. radiography, CT). Difficulty in weightbearing can be used to identify patients with delayed union or nonunion. However, in patients with a circular frame, pin site infection and the frame hardware can make the clinical and radiological assessment more difficult. CT is a commonly used imaging technique, but often does not provide the desired confidence to clinicians, and often over reports nonunion.

Nonunion or premature frame removal has a significant social and psychological impact on the patient, with huge financial implications for both the patient and society through healthcare costs and loss of earnings. Repeat procedures cause patient morbidity, and increased bed occupancy in hospitals.

Previous work by the Chertsey Group found that a staged reloading protocol was a safe, simple, and reliable technique to determine the time for removal of a circular frame. This was a study conducted on a small cohort of 36 tibial fracture patients using an Ilizarov type frame, and they reported no incidence of refracture, nonunion, or malunion at 12 months.

A staged reloading protocol is the preferred approach for frame removal in our unit. We designed this study to assess the effectiveness of a staged reloading protocol in all patients with a circular frame of any design and investigated the risk factors for mechanical failure.

The aims of this study are:

1. To assess the effectiveness of a staged reloading protocol and describe the incidence of mechanical failure of the bone following frame removal;
2. To analyze associated risk factors for mechanical failure; and
3. To describe the incidence of refracture and change in alignment in patients undergoing a single-stage and two-stage reloading protocol.

Mechanical failure is defined as either a refracture or radiological deformity of > 5° in either plane during the three-month follow-up period.

Methods

This was a retrospective study undertaken at Hull Royal Infirmary, UK, a tertiary limb reconstruction referral centre. The study was registered and had institutional approval (no: 2017.137). Consecutive patients were identified from our department frame database, and electronic patient records were reviewed. Both trauma and elective cases were included of all ages, frame types, and pathologies who underwent circular frame treatment. Patients were excluded from the study if they were lost to follow-up, or if their treatment deviated from the reloading protocol, either by clinician or patient choice.

We consider dynamization to be a process which decreases the stiffness of the frame, to shift part of the load from the frame to the bone. This is performed by loosening the threaded rod nuts or struts of the frame then retightening the construct. This shifts some load from the frame to the bone, but there is no material shift in the frame. Dynamization may be done according to the clinical and radiological findings at any stage in the management of the patient, but is often practiced in early stages of the treatment.

We use the term reloading for the final stages of frame management. We defunction the frame to load the bone to test the integrity of the fracture or regenerate site, henceforth referred to as the fracture site. Stage one reloading provides full axial loading, with torsional and cantilever support from the threaded rods. Stage two reloading fully loads the bone in all axes. This improves
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The two stages (Figure 1) are described below, with a schematic description in Figure 2. Patients with a Hexapod frame can proceed to directly to stage two (Figure 1) or have their struts exchanged for threaded rods and proceed through stage one. Patients who proceed directly to stage two are considered to have had a single-stage reloading protocol. Patients who proceed through stage one and stage two are considered to have had a two-stage reloading protocol.

Most patients were allowed to fully weightbear throughout, although this was at the clinician’s discretion. If necessary, the reloading stage was reversed based on clinical and radiological assessment by the clinician. After frame removal, patients were seen at two weeks for clinical assessment, then for radiological and clinical assessment at six weeks.

**Stage one.** The nuts are loosened at one end of each of the threaded rods which span the fracture site. As the patient mobilizes, the loose nuts may move and fall off the threaded rod. To prevent this, an extra nut is tightened against the ultimate nut. The nuts are not completely removed as the patient is taught to stabilize the construct in the event of pain at the fracture site, or excessive irritation at the wire sites overnight when in bed. This stage provides full axial load bearing through the bone, but provides some support in torsion and cantilever loading. Preservation of the ultimate nuts also provides a ‘stopper’ to prevent catastrophic failure of the construct. Before the patient leaves the hospital, they are asked to walk for 20 minutes. If they report an increase in pain at the fracture site, this reloading step is reversed and the patient is reviewed again in four to six weeks. If there are no clinical concerns, they are reviewed in a further one to two weeks and progressed to stage two. No routine imaging is done in between stage one and stage two.

**Stage two.** Following successful completion of stage one, patients are progressed to stage two. In this stage, all rods across the fracture sites are removed, or all struts are loosened. This removes all support from the frame across the fracture site and allows full and normal loading in all three axes. Before the patient leaves the hospital, they are

| Variable                        | Two-stage protocol | Single-stage protocol | p-value * |
|--------------------------------|--------------------|-----------------------|-----------|
| Mean age, yrs (SD)             | 46 (16)            | 42 (18)               | 0.133     |
| Sex, n                         |                    |                       |           |
| Male                           | 64                 | 103                   | 0.084     |
| Female                         | 31                 | 46                    |           |
| Immunosuppressed               | 0                  | 1                     |           |
| Condition, n                   |                    |                       |           |
| Rickets                        | 0                  | 3                     |           |
| Osteogenesis imperfecta        | 1                  | 1                     |           |
| Asthma/COPD                    | 3                  | 10                    | 0.232     |
| Steroid use                    | 1                  | 3                     |           |
| Current/previous cancer history| 2                  | 2                     |           |
| Peripheral vascular disease    | 1                  | 1                     |           |
| Cardiovascular disease         | 5                  | 6                     | 0.651     |
| Diabetes                       | 6                  | 16                    | 0.241     |
| Smoking status                 | 42                 | 52                    | 0.183     |

*pChi-squared test.
COPD, chronic obstructive pulmonary disease; SD, standard deviation.
asked to walk for 20 minutes. If they report an increase in pain at the fracture site, this reloading step is reversed and the patient is reviewed again in four to six weeks. The patient should be warned to expect an increase in pin site pain and irritation during this stage, and may need to take some rods or struts home to stabilize the frame when sleeping. Patients are reviewed in a further one to
two weeks where radiological and clinical healing is confirmed prior to frame removal.

**Statistical analysis.** Data were collected on demographics, comorbidities, treatment indications, and frame types. Digital radiographs were analyzed on a picture archiving and communication system (PACS). If data were missing, they were excluded for that variable. Data were analyzed on SPSS (version 28; IBM, USA). Patient characteristics were assessed for comparability between those undergoing single-stage and two-stage procedures. Data were assessed for normality, and for non-parametric data a chi-squared test was performed. A multivariate analysis with 95% confidence intervals were used to assess risk factors for refracture. A p-value < 0.05 was considered significant.

**Results**

We identified 282 patients who had undergone circular frame treatment during the study period. Of these, 230 patients (244 frames) underwent a reloading protocol and were included in the present analysis. Figure 3 shows the flow diagram of patients included in the study.

Of the 244 frames, 167 were male and 77 were female. The mean age was 44 years (42 to 46). Patient demographics and comorbidities are summarized in Table I. There were no significant differences between patients undergoing a single-stage and a two-stage reloading protocol. There were 149 and 95 patients who underwent a single-stage and two-stage protocol, respectively. The mean time until commencement of the reloading protocol was 201 days (standard deviation (SD) 7), and 180 days (SD 9) for single-stage and two-stage, respectively. Table II shows characteristics, including indications and bone segments of patients undergoing both single-stage and two-stage protocols. The tibial shaft was the most commonly injured bone segment. The elective indications included ankle fusions, knee arthrodesis following failed arthroplasty, limb lengthening, femoral osteomyelitis, infected tibial nail, tibial nonunion, and deformity corrections. A pin site or other infection was identified in 46 frames (19%) and secondary bone grafting was performed in 26 frames (11%).

During the reloading process, 14 frames had the protocol reversed; 11 in stage one and three in stage two of the reloading protocol. All of these patients were successful in their subsequent reloading and frame removal.

A total of 144 frames were removed in clinic, under Entonox, while 100 were removed in theatre. A total of 234 limb segments were allowed to fully weightbear immediately post-frame removal. However, at the surgeons’ discretion, three were non-weightbearing and seven were partial weightbearing for a period of up to six weeks, and ten patients were treated in a plaster cast.

Following frame removal, 13 out of 244 frames (5%) had mechanical failure. There were 13 patients who had a refracture. No patients had change in alignment (> 5°) without fracture. One patient sustained the refracture during a fall.

Multivariate logistic regression analysis was performed to identify factors associated with refracture during treatment (See Table III). Age (p = 0.006) was the only factor considered significant for refracture. Refracture was not associated with choice between single-stage or two-stage reloading (p = 0.772).

Further treatment options were discussed with all patients with mechanical failure, of which six had further surgery, one refused further surgery, and six were treated conservatively.

**Discussion**

We have demonstrated that a staged reloading protocol for circular frame removal has a low rate of mechanical failure with 5% risk of refracture and no cases of significant deformation at three months. This was using a method similar to that described by the Chertsey Group,

who reported no incidence of nonunion or refracture at 12-months follow-up. However, their study was only in 36 patients. We demonstrated a low failure rate in 244 frames, confirming the effectiveness of this protocol in all frame types and reloading protocols, for all indications.

Determination of bony union can be challenging, particularly in circular frames where external devices obscure the fracture site. Successful bony union leads to normal weightbearing and the return to functional activities. This can be clinically used to confirm bony union.

The radiographic union score for tibia (RUST) score was developed to determine bony union in the tibia, according to the assessment of the callus and fracture line visibility of each cortex. The score can vary from a minimum of four (no healing) to a maximum of 12
for specialist equipment, and personnel can limit their utility. Furthermore, serological markers have been studied to help predict fracture union. 23 CTX, TRACP 5b, TGF B1, and total n-terminal propeptide of type I collagen have shown promising results, 29, 31 but are non-specific and have not translated into clinical use. 32

Age was the only factor significantly associated with refracture (Table III). Therefore, more caution should be taken when commencing reloading in older patients. However, numbers were small for the multivariate analysis, as demonstrated by the wide confidence intervals, and therefore a larger study would be needed to better quantify associations.

In the present study, 14 patients (6%) had the reloading process reversed, 11 patients in stage 1 and three patients in stage two. None of these patients suffered refracture or a change in alignment > 5° with subsequent reloading and frame removal. The authors believe that the reloading protocol has prevented mechanical failure in this group of patients. Fracture union can be confirmed clinically when a patient is able to fully weightbear without pain or subsequent deformity. Weightbearing after tibial fracture and external fixation has been correlated with fracture stiffness. 7 However, there are individual and cultural differences in perception and tolerance of pain among patients. 11, 32 Ideally, pain scores should be used to quantify pain assessment during the reloading protocol.

We have demonstrated no increase in refracture rates between patients undergoing single-stage and two-stage reloading protocols (p = 0.772, chi-squared test). Although this was a retrospective study, our patient groups were well matched (see Table I). It may therefore be possible, if the surgeon is confident with clinical and radiological assessment, for the patient to progress directly to stage two and undergo single-stage reloading. This could precipitate faster patient recovery, satisfaction and return to work, as well as lowering healthcare costs.

A reloading protocol increases the time in frame by two to four weeks, with a subsequent increase in pin site infections, joint stiffness, disuse atrophy and psychological stress. However, there are significant advantages of a staged reloading protocol for frame removal. In patients who were symptomatic on reloading, we simply retightened the construct to support the bone. Had we progressed directly to frame removal, the mechanical failure rate would have been significantly increased.

The mean time to commence a single-stage protocol was three weeks more than that of a two-stage protocol at 180 and 201 days, respectively. This three-week delay could have mitigated any increased risk of refracture caused by a single-stage reloading protocol. The majority of our patients who followed the single-stage protocol had hexapod frames, and the majority of those who followed the two-stage protocol had ilizarov frames. Despite the differences in the mechanical properties of hexapod

### Table III. Multivariate analysis for refracture.

| Refracture experienced | p-value* | Odds ratio | 95% CI |
|------------------------|----------|------------|--------|
| Age, yrs               | 0.006    | 1.07       | 1.02 to 1.17 |
| Sex                    | 0.165    | 0.33       | 0.07 to 0.58  |
| Smoker                 | 0.392    | 0.58       | 0.17 to 2.00  |
| Infection during treatment | 0.478 | 0.61       | 0.35 to 2.40  |
| Other comorbidities    | 0.855    | 1.13       | 0.30 to 4.30  |
| Type of frame          | 0.163    | 6.33       | 0.47 to 84.0  |

*Multivariate analysis.
and Ilizarov frames, the failure ratio (9:4) is comparable to the number of frames in each group (154:90) of hexapod to Ilizarov frames. Furthermore, multivariate analysis showed no association between type of frame and refracture (p = 0.163). Ideally, to explore the effect of single-stage versus two-stage reloading, the type of frame should be standardized across patient groups. This is a retrospective study and based on a small number of patients, and therefore we cannot make any firm conclusions. Further research is needed to identify bone healing accurately to eliminate the risk of refracture.

This study is not without limitations. We have assumed no issues with the construct of the circular frames and the compliance of patients could not be confirmed in all patients. The relationship of the protocol to pin site infection and fracture subtype were not explored. This protocol is not suitable for non-weightbearing bone segments. The decision to proceed to reloading was decided by the senior surgeons in the team. Surgeon experience may have had an impact on the rate of mechanical failure, and in deciding whether a patient should undergo a single-stage or two-stage reloading protocol.

In conclusion, the staged reloading protocol is a safe, simple, inexpensive, and clinically effective method to determine the timing of circular frame removal. A staged reloading protocol can reduce the risk of mechanical failure. There are similar rates of mechanical failure following single-stage and two-stage reloading protocols. If the surgeon is confident with clinical and radiological assessment, it may be possible for patients to progress directly to stage two and undergo single-stage reloading.

**Take home message**
- A staged reloading protocol can reduce the risk of mechanical failure.
- There are similar rates of mechanical failure following single-stage and two-stage reloading protocols.
- If the surgeon is confident with clinical and radiological assessment, it may be possible for patients to progress directly to stage two and undergo single-stage reloading.

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