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Prospective Case Study for Evaluation of Clinical Efficacy and Patient Satisfaction of a Novel Adjustable Wrist Splint for Simple Distal Radius Fracture

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Abstract

Background: Distal radius fractures are one of the most common fractures. Plaster casting remains the common treatment of choice for simple distal radius +/- ulna fractures. Casting has been noted by patients to be heavy, itchy, cumbersome, restrictive of work and leisure activity, and presents a hygiene risk. To alleviate the difficulties noted with casting, an evaluation of a novel adjustable wrist orthosis in the non-operative management of distal radius fractures was performed.

Methods: All patients presenting to the participating clinic and who met the inclusion criteria were invited to participate in the study. The Zero-Cast™ device was applied by a trained healthcare professional. All patients were followed-up at 1, 2, and 4-6 weeks. Participants completed the Patient Questionnaire and the Patient Rated Wrist Evaluation (PRWE) at their final clinic visit. X-rays examinations were undertaken. The healthcare professionals who applied the orthosis also completed the Healthcare professional questionnaire. Complications from the treatment were recorded.

Results: This trial took place at a single clinic; 5 clinicians participated in the trial. 32 patients were included in this study. Radiologically all fracture were stable with no loss of position. There were no reported complications. Patients provided an overall rating for orthosis comfort scoring of 2.2 out of 10 (10 being least comfortable). Most patients felt the orthosis was convenient for hygiene scored 2.7. On ease of activity to daily living the orthosis was scored at an average of 2.7. An overall average PRWE score of 2.5 (scoring 1=best – 10=worst). Clinician feedback was generally positive. Average time taken to apply the orthosis was 5.2 mins.

Discussion: This study was limited by the lack of a 'control' group and by the limited number of patients in the cohort. This study was performed as a new-technology, early evaluation of patient experience and the outcomes were found to be positive. This study should encourage other investigators to design studies that will further test the potential benefits offered by new treatment devices.

Conclusion: We recommend using this new device for simple and stable fracture however more research is warranted prior to its utilisation in complex distal radius fractures.

Keywords: Distal radius fracture • Adjustable wrist orthosis • PRWE • Patient satisfaction

Introduction

Distal radius fractures are one of the most common fractures occurring in the human body [1-3]. Distal radius fractures accounts for 2.5% of ER presentation [4]. 23% of all sports fractures in one study were noted as occurring in the distal part of the radius [5]. A simple distal radius fracture is defined as a distal radius +/- ulna fracture that does not require fracture reduction (eg. buckle fracture, minimally displaced green-stick fracture, minimally displaced distal radius fracture). Simple distal radius fractures account for the majority of all distal radius fractures [5]. These fractures are shown to be structurally stable ie. they hold their position with minimal support [5-7]. The treatment aim for the typical simple fracture pattern is pain relief and early restoration of function. The use of removable, Velcro™-closure wrist splints for simple distal radius +/- ulna fractures has been reported in recent literature [6]. Some of the studies have concluded that removable wrist splints have advantages over plaster cast for the treatment of simple distal radius +/- ulna, highlighting ease of use, lack of plaster complication and early rehabilitation [6].

Several studies have indicated that pain is worse during the early stages of healing in removable wrist splint devices when compared to plaster cast treatment [5,7]. It can be inferred that pain may be a likely consequence of the inability of removable splints to provide adequate fracture stabilisation. In addition, concern with poor patient compliance has been another factor of concern to clinicians [7]. Despite over 160 years of use [8], plaster casting remains the common treatment of choice for simple distal radius +/- ulna fractures. Casting has been noted by patients to be heavy, itchy, cumbersome, restrictive of work and leisure activity, and presents a hygiene risk [5,9]. To alleviate the difficulties noted with casting, an evaluation of a novel adjustable wrist splint in the non-operative management of distal radius fractures was proposed.

Null hypothesis

The Zero-Cast™ wrist splint is efficacious in the management of simple distal radius +/-ulna fractures.

Materials and Methods

A prospective case study was designed to evaluate the clinical efficacy of

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Zero-Cast Wx™ (Zero-Cast Limited, Auckland New Zealand), an adjustable wrist orthosis, in the management of distal radius fractures (Figure 1).

Inclusion criteria

- Extra-articular distal radius fractures (classified according to the AO classification of distal forearm fractures as 23-A2, 23-A3 or 23-C1)
- Patients with distal radius fractures that would routinely be treated non-operatively in a below elbow cast.

Exclusion criteria

- Patients unable to provide informed consent
- Patients who cannot complete the study protocol
- Patients who require surgical treatment
- Patients with previous fractures/deformity of the distal radius/ulna or carpusPatients with skin rashes or skin sensitivity
- Open fractures
- Multi trauma

All patients presenting to the participating clinic (Whitecross A&M) and who met the inclusion criteria were provided with a Patient Information Sheet and invited to participate in the study. Patients who agreed to participate were required to sign a consent form. The Zero-Cast™ device was applied by a trained healthcare professional in accordance with the instructions for use that accompanied the device. An information sheet, outlining how to care for the Zero- Cast™ splint was provided to each participant. Where necessary, the method of analgesia was chosen according to best clinical practice.

All patients were followed-up at one week, two weeks and six weeks for clinical evaluation. The study participants completed a Patient Questionnaire and a Patient Rated Wrist Evaluation (PRWE) at their final clinic visit (Table 1). X-rays examinations were undertaken at each of the first three visits to determine maintenance of fracture reduction. Any required adjustments to the splint were documented and any loss of position was recorded. Complications arising from the treatment, including skin-pressure areas, rashes and/or ulcerations were recorded.

Healthcare professional applying the orthosis were asked to complete the Healthcare Professional Questionnaire. Time to apply and adjust was recorded.

Novel adjustable wrist splint

The Zero-Cast Wx™ device manufacturer claims that their adjustable twin-plate design maintains fracture reduction by applying three-point loading as described by Charnley [10]. The twin plates (dorsal and volar) of Zero-Cast™ are contoured to the patient's distal radius anatomy. They are manufactured in high-density plastic and lined with closed-cell, memory-foam to prevent pressure and skin issues. The plates are configured in an adjustable way to allow the 3-point fixation at the fracture site (2-4 cm from the joint line) [11]. The device uniquely allows limited movement at wrist the joint with the wrist

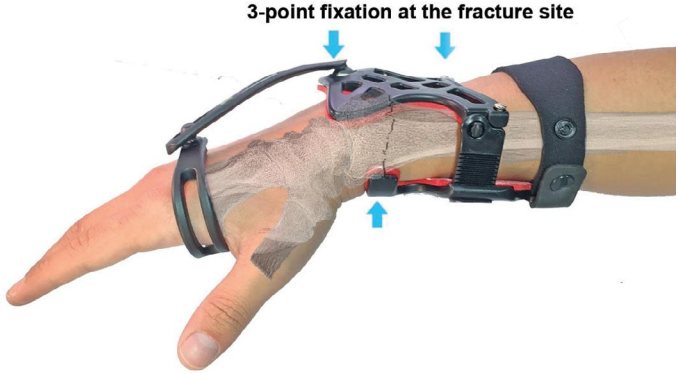

Figure 1. Zero-Cast Wx- A novel adjustable wrist orthosis developed by Zero-Cast Ltd.

Table 1. Study participant.

No. of Participant	32
Male	14
Female	18
Child	25
Adult	7

stabilizer component, which holds the wrist at the desired orientation while providing small movement at the wrist joint helping to reduce joint stiffness.

The device has secure locking mechanisms that are tamperproof; however clinicians can adjust the device at any time throughout treatment. This allows a single Zero-Cast Wx™ device to complete the full fracture treatment period using one device compared to 2-3 plaster/fibre casts used during a typical conventional treatment.

The device has an open design, allowing for clear visualization of the limb and easy adjustment. The device claims to be waterproof, permitting patients to bathe and shower while wearing the device. The device is significantly lighter in weight to a plaster cast and coupled with its low profile, may minimize the morbidity associated with traditional casting, particularly for patients in the elderly age group.

Results

This trial took place at a single urgent care clinic; 5 clinicians participated in the trial. 32 patients were included in this study: 14 males and 18 females. The youngest participant was 4 years old and the oldest was 79 years old. 25 children and 7 adults. Two patients (one child and one adult) did not tolerate the orthosis for more than 3 days and were not included in the results. The child requested a change to plaster claiming that he wanted his friends to decorate and sign his cast. The adult patient reported subsequent additional issues with the plaster cast that required several cast changes during treatment. Radiologically all fracture were stable, with no change of position during the treatment. There was no reported complication among the study cohort.

Clinician feedback was generally positive. They reported an average time taken to apply the orthosis at 5.2 mins. 4 applications took more than 10 mins whereas 7 took less than 3 minutes. Clinicians who undertook pre-application training were noted to significantly decrease their application times. The majority of device applications and adjustments were performed in the consultation room rather than in a designated plaster room. Clinician rated Ease of Orthosis Application as a '2' on easy to hard scale of 10 (with 10 being the hardest). Ease of adjustability was assessed by the clinician at 2.3 out of 10 (10 being the hardest). The clinician rated how each patient tolerated the device-application with the score of 1.8 out of 10 (10 being worst tolerated). No issues of patient tampering with their orthosis were identified (Table 2).

The average time each patient spent in their orthosis was 26.9 days. Patients provided an overall rating for orthosis comfort, scoring an average of 2.2 out of 10 (10 being the least comfortable). Most patients felt the orthosis was convenient for hygiene (washing/showering/toileting/feeding) scoring 2.7. For Ease of Activity of Daily Living (put on clothing/open and close buttons and perform other activities of daily living) the orthosis was scored at average of 2.7 with score of 10 being the hardest.

The PRWE score consist of a validated series of questions for wrist injury evaluations. PRWE scoring has three sections; Pain, Function and Usual Activity. Patient score the set of questions in each section on a scale of 1-10. Lower scores are better. Average of the scores per section is calculated and the overall average is calculated. Average score for the Pain section was 2.9. The Function section of questions recorded an average score of 2.3. Scoring for the Usual Activity section was 2.5. This gave an overall average PRWE score of 2.5 (Table 3).

Discussion

The orthotic device under investigation has unique adjustable twin-plate

Table 2. Clinician feedback.

Application time	3.2 mins
Ease of application	2.0/10
Ease of adjustment	2.3/10
Tolerated by patient	1.8/10

Table 3. PRWE.

Pain	2.9
Function	2.3
Usual activity	2.5
Activity of daily living	2.5

Table 4. Patient feedback.

Average Time in Zero-Cast Wx	26.9
Comfort	3.1/10
Convenient/hygiene	2.7/10
Activity of daily living	2.7/10

construction to provide 3-point stability at the fracture-site, while permitting small motion of the supported wrist joint. All other treatments, including plaster, immobilise most of the hand, wrist and forearm in addition to the fracture site. Morbidity from plaster and fibre cast treatment is well documented [9,12,13]. The patient healing experience with plaster casting has been reported as unpleasant and at times this can lead to additional clinic visits. Treatment with plaster/fiberglass casting can be challenging for many patients, adversely impacting their normal daily living activities including routine hygiene. For some, including children and older patients, plaster removal can be particularly traumatic [12,14]. Zero-Cast Wx™ claimed patient related benefits of being waterproof, lightweight and tamperproof, have encouraged us to investigate this device on our patient population.

In this study, we only included patients who presented with a stable fracture configuration. This is the group of patients routinely treated in an urgent care setting. Our radiographic evaluations confirmed no patients experienced loss of position and this was expected from our review of previous studies [5,14-16].

We found overall patient experience with the device to be excellent. We noted the ability of patients to wash and shower while wearing the device was an important determinant for the positive patient experience. Being lightweight and less restrictive were added factor that played roles in eliciting positive patient feedback (Table 4).

We found the Zero-Cast Wx™ device quick to apply with a 3-step application process. This is aided by the open-design that makes application predictable and permits easy visualisation of anatomical landmarks throughout fitting. Adjustments to the device were easy for the clinician to undertake (if device required tightening or loosening due to swelling). At the end of treatment, removal was a quick process that took around 30 seconds on average. We found that the ability to apply in the consultation room, ease of device-application and short learning curve were noteworthy to the clinician, while management noted increased patient throughput in the clinic.

Permitting movement of the wrist joint offers a series of theoretical advantages and is an interesting concept. Leaving the wrist joint mobile and supported did not affect the stability of fracture healing. We noted no adverse effect on stability or fracture healing in the study. We believe the limited wrist joint motion that is permitted during treatment with this device may result in a reduced requirement for rehabilitation in adults. We note that the study had limited adult patients to validate this assumption. Further study is recommended to test the rehabilitation requirement in the patient treated with this device.

Clinicians in this study did not utilise the Velcro™ closure splints such as the Futuro™ Splint in the treatment of the wrist injury due to their concerns with how easily patients can remove and tamper with such devices during treatment. We had previously noted several incidences of tampering with plaster and fiberglass casting at our clinic. Zero-Cast Wx™ has a tamperproof system that was found effective to maintain fitting throughout the prescribed treatment period. We further noted that reports of the fitted device being less itchy, permitting restricted movement, and allowing submersion in water, may have helped contribute to patients, being less tempted to tamper with their device.

This study was limited by the lack of a 'control' group and by the limited number of patients in the cohort. The breadth of ages was wide and this provided both advantages and some disadvantages. This study was performed as a new-technology, early evaluation of patient experience and the outcomes were found to be very positive. This study should encourage other investigators to design studies that will further test the potential benefits offered by such interesting new treatment devices.

Conclusion

A novel adjustable wrist orthosis (Zero-Cast Wx) was investigated for the treatment of simple distal radius fractures. Patients rated the new device as more comfortable, less limiting and hygienic. We found the new device was quick and easy to fit in the clinic room setting. We recommend using this new device for simple and stable fracture however more research is warranted prior to its utilisation in complex distal radius fractures.

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