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Suitability of the noninvasive halo for cervical spine injuries: a retrospective analysis of outcomes

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Abstract

BACKGROUND CONTEXT: Conventional halos (CHs) have been used since 1959 and have long been regarded as the standard for external stabilization of the injured cervical spine. Unfortunately, there use is associated with several significant complications including infection, pin loosening, dysphasia, dural and skull penetration, and pressure ulcers. Recently, a pinless noninvasive halo (NIH) (Seattle Systems/Trulife, Poulsbo, WA) was introduced with the goal of providing cervical spine stabilization and control approaching that of the CH in a less invasive fashion. The design of this orthosis could prove useful if it is found to produce the same outcomes with fewer complications than the CH.

PURPOSE: To review outcomes of patients fitted with the NIH to determine its suitability for treating cervical spine injuries.

STUDY DESIGN: Retrospective case series.

PATIENT SAMPLE: Consisted of 19 patients fitted with NIHs as inpatients and followed as outpatients at a university-based level-1 trauma center.

OUTCOME MEASURES: Data on fracture alignment and healing as assessed by imaging, neurological status, treatment complications, and patient demographics were collected.

METHODS: A retrospective chart review of patients treated for cervical trauma at a university-based level-1 trauma center by attending surgeons was performed. Subjects were identified for the study by reviewing inpatient fitting records of the Department of Orthotics and Prosthetics. Data regarding patient demographics, tobacco use, classification of injury, surgical treatment, total time in NIH, complications, fracture alignment, and neurological status were collected.

RESULTS: Average time spent in the NIH was 79 days, all fractures successfully healed in acceptable alignment, and no neurologic deterioration was noted. Complications were limited to one case of occipital ulceration, two cases of noncompliance, (loosening straps), and one case of recurrent subluxation that was later resolved.

CONCLUSIONS: This study offers preliminary data to support a larger scale, randomized trial with long-term follow-up to compare the clinical efficacy of the NIH to that of CHs in patients with cervical spine trauma. Biomechanical studies of the stability of the cervical spine in the NIH, currently underway, will help to assess the suitability of the NIH as an alternative to CHs. The complications encountered do not preclude further investigation of this device and patient tolerance of this treatment has been satisfactory.

Keywords: Halo; Noninvasive halo; Cervical-thoracic orthosis; Cervical spine trauma

Introduction

Nickel and Perry developed the original halo system in 1959 for the treatment of patients with cervical instabilities or paralysis as the result of poliomyelitis based on the work of Bloom during WWII [1,2]. The intended use was to provide cervical immobilization to carry out occipital-cervical fusions [2,3] and consisted of a stainless steel ring and a full-length

FDA device/drug status: approved for this indication (Halo); does not require FDA approval (Noninvasive Halo).

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body cast [4]. Thompson [5] and Freeman [6] extended its use to the treatment of fractures of the cervical spine.

The conventional halo (CH) system is considered the most rigid form of external stabilization of the cervical spine. Its ability to restrict cervical spine motion has been the subject of numerous studies [7–11]. Studies using X-ray have demonstrated that the CH can limit motion by 96% in normal human subjects [7]. In normal human subjects and cadavers with or without cervical instability, the halo has limited flexion and extension from 1.0° to 3.4° and it appears to immobilize the spine against axial rotation to a greater degree [7,8]. Lind et al. [9] and Anderson et al. [10] have indicated that the CH system fails to immobilize the unstable cervical spine as much as was originally believed. Using X-ray, they found that intersegmental motion at the level of the injury averaged 7.0–8.1° and linear translation averaged 1.7 mm. CH use also has the potential to create a snaking effect in the cervical spine [10]. Alternative orthoses such as the Minerva brace (USMC, Pasadena, CA) may decrease this effect [11].

Successful and failed treatment outcomes with the CH system have been reported in the literature. Vieweg and Schultheil reviewed 35 studies published from 1962 to 1999 involving 682 patients with cervical spine injuries to determine treatment outcomes after application of a CH [12]. They found that bony upper cervical spine injuries treated with CHs had healing rates between 85% and 96%. Reports of injuries involving multiple levels with or without primarily ligamentous injury showed less favorable results.

Complications associated with the use of the CH and its associated pin fixation are well documented and include pin and ring loosening in 36% to 60% of patients, pin infection in 20% of applications [13,14], and possible skull and dural penetration due to falls. Other complications with CH use can include dysphagia and pressure ulcers in 4% to 11% of patients [14]. Facial scarring at the site of pin insertion, especially following infection, also detracts from CH use. An orthosis that could provide sufficient stabilization without these risks would be a substantial improvement. We hypothesize that the NIH provides stabilization adequate to promote fracture healing and prevent additional neurologic damage to the patient.

The concept of a noninvasive halo (NIH) is not a novel idea. It was originally proposed by Wilson et al. to combat the issue of failed immobilization of the cervical spine in other nonhalo orthoses and decrease complications caused by prolonged use of a mandibular immobilizing component common to other cervical-thoracic orthoses [15].

More recently, a pinless halo design (Seattle Systems/Trulife, Poulsbo, WA) was introduced with the goal of providing cervical spine stabilization and control approaching that of the CH in a less invasive fashion (Fig. 1). The original design was intended for a pediatric population, but has since been modified to include the adult population. Mueller and Mueller examined the effectiveness of the NIH on an adult population and published the first case series of three adult patients with nondisplaced or minimally displaced cervical fractures [16]. Results documented the efficacy of the use of the NIH during acute hospital stay. Unfortunately, there was no long-term follow-up due to the subjects' return to out-of-state residences.

The authors are unaware of any other case series assessing the efficacy of the NIH.

EVIDENCE & METHODS

Context

Conventional halo treatment for cervical fractures / subluxations affords excellent stability; but complications due to design and invasiveness are commonly encountered.

Contribution

This retrospective chart review aimed to assess the usefulness of a new non-invasive halo for select cases of cervical fracture. The authors have reported acceptable outcomes; but concepts used for inclusion such as surgeon preference, intuitions regarding risk of neurological injury, and stable and anatomic alignment are quite subjective.

Implications

This report raises many questions. How should new technologies be used clinically when insufficient basic science (in this case, biomechanical) data is available? When is it appropriate to begin an RCT (in this case, against traditional halo) when preliminary data suggests a new treatment may be competitive? Can a 20 patient case-series statistically imply even minimum safety assurance (confidence interval for catastrophic failure is only 0 to 15%). While much more research is needed here, readers should consider with respect the known risks and benefits of gold-standard care compared to the many unknowns of introducing novel treatments for pathologies portending real and present dangers.

—The Editors

Methods

The thoracic component of the NIH consists of a padded carbon composite anterior-only chest plate with two