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ORIGINAL RESEARCH

Comparison of the quality of life in individuals with spinal cord injury wearing either reciprocating gait orthosis or hip knee ankle foot orthosis: a cross-sectional study

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ABSTRACT

Background: The quality of life (QoL) for patients with spinal cord injuries (SCI) is lower than that for healthy individuals. The main purpose of prescribing orthoses for these individuals is to improve their mobility and QoL. The hip knee ankle foot orthosis (HKAFO) has been the conventional choice for such patients, whilst the reciprocating gait orthosis (RGO) is a more contemporary option. Although the impact of these two types of orthoses on the biomechanics of walking has been previously evaluated in patients with SCI, there has been no specific comparison of their relative effects on QoL.

Objectives: This study aimed to evaluate the Sickness Impact Profile (SIP-68) QoL questionnaire's total score and its sub-scores in patients with SCIs wearing either RGOs or HKAFOs.

Methods: This study was performed on 22 participants (11 participants wearing RGOs and 11 wearing HKAFOs). QoL scores were evaluated in each group of patients using the total and sub-scores from the SIP-68 questionnaire.

Results: There were no significant differences in the total SIP-68 scores between the RGO and HKAFO groups ($p = .57$). However, emotional stability and emotional independence sub-scores were significantly lower for the RGO users than for the HKAFO users ($p = .03$ and $p = .01$), respectively.

Conclusions: Based upon this preliminary study, participants wearing RGOs or HKAFOs had similar QoL scores. However, those wearing RGOs may experience better emotional stability, communication, and emotional independence. This preliminary study does not provide definite conclusions since a large randomized control trial is required to compare the effects of these orthoses on the QoL scores in patients with SCIs.

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KEYWORDS
Reciprocating gait orthosis; hip knee ankle foot orthosis; quality of life; spinal cord injury

➤ IMPLICATIONS FOR REHABILITATION

- Our main aim in the current investigation was to shed light on the question that does the biomechanical superiority of the RGO to the HKAFO leads to better quality of life in SCI subjects who are using RGO. Regarding the fact that the primary goal of rehabilitation of people with SCI is to improve their quality of life, it seems that the more complicated newer orthosis (RGO) has no difference with the older type (HKAFO) in achieving the rehabilitation goals. More studies will in fact be necessary to find a definitive answer for this important question.
- According to the findings of our study, it seems to be more appropriate to prescribe RGO for male participants with higher body weight.

Introduction

Spinal cord injury (SCI) is defined as damage to the spinal cord, which leads to sensory, motor, and autonomic dysfunction in the area innervated below the level of damage [1]. SCIs are usually caused by trauma, disease, or congenital problems [2]. In 2008, the prevalence of this type of injury in Tehran was reported to be 4.4 per 10,000 individuals, and between 2003 and 2008, the incidence of SCI was 2.2 per 10,000 individuals [3]. The quality of life (QoL) in patients with SCIs is affected over the long term and is reported to represent a major secondary complication of SCIs [4–6].

One of the aims of the rehabilitation process, including orthotic prescriptions, is to improve the QoL for these patients [5,7]. The prescription of orthotics for SCI patients varies according to the severity and level of the spinal injury sustained [8,9]. Typically, for an injury of the T1–T12 vertebrae, the hip knee ankle foot orthosis (HKAFO) has historically been the orthotic of choice, while the reciprocating gait orthosis (RGO) is a more contemporary option (Figure 1) [10].

The RGO has been shown to be superior to the HKAFO in terms of static stability, walking speed, and energy consumption [11,12]. However, to the best of our knowledge, no previous study has compared the effects of these two types of orthotics on the QoL scores of patients with SCIs.

Therefore, the primary purpose of this study was to compare the SIP-68 QoL questionnaire's total score and its sub-scores in

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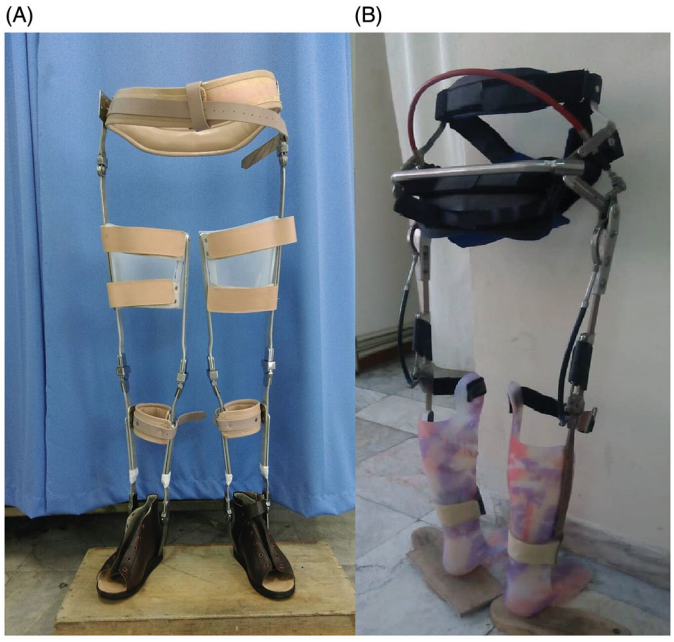

Figure 1. (A) HKAFO: This type of orthosis encompasses the hip, knee, and ankle joints to control selected motions. (B) RGO: This type of orthosis, in addition to providing control to the selected motions of the hip, knee, and ankle joints, helps SCI patients develop a reciprocating gait pattern. If the patient flexes her/his right hip, then the device helps in the extension of the left hip which results in a reciprocating gait pattern. RGO: reciprocating gait orthosis, HKAFO: hip knee ankle foot orthosis, SCI: spinal cord injury.

patients with SCIs wearing either RGOs or HKAFOs. The researchers hypothesized that these scores would show improvement for patients wearing RGOs in comparison to patients wearing HKAFOs. The secondary purpose of the current study was to evaluate the relationships among the patient's age, weight, gender, injury level, and injury duration relative to the QoL questionnaire score and its sub-scores.

Methods

Participants

This was an observational cross-sectional QoL study of individuals who had SCIs at the thoracic level and wore either HKAFOs (Figure 1(A)) or RGOs (Figure 1(B)). Patients with complete thoracic SCIs who used an orthosis for at least 2 h each day in the 6 months prior to the study start date were eligible for inclusion in this study [13,14]. The exclusion criteria included other associated disabilities such as limb amputations, brain traumas, and failure to achieve Grade A status on the American Spinal Injury Association (ASIA) Impairment Scale. A database created by the National Red Crescent Society was used to recruit the participants. All potential participants were contacted by telephone, and the aims and procedures of the study were explained to each of them. Individuals who met the participation criteria and agreed to sign an informed consent form were considered eligible participants. The eligible participants were sent the Sickness Impact Profile (SIP-68) questionnaire and consent form by mail along with a pre-paid envelope so that the completed questionnaire and the signed consent form could be returned.

Since the database identified only 13 RGO users, they were contacted first. Eleven participants volunteered and met the study criteria. HKAFO users were then contacted and matched to those wearing RGOs by age (±5 years), sex, and weight (±10 kg). In order to include 11 matched volunteers and patients wearing HKAFOs, 80 records were examined. Those who satisfied the matching and inclusion criteria were contacted. After contacting 20 individuals, a sample of 11 volunteers for the HKAFO group was obtained. Demographic data such as age (years), gender (male, female), weight (kg), average daily duration of wearing an orthosis in the prior 6 months (hours), time since receiving the orthosis (months), and the type of orthosis were recorded for each participant.

Table 1. Comparison of the injury level and daily use time in reciprocating gait orthosis (RGO) and/or hip knee ankle foot orthosis (HKAFO) users.

	RGO		HKAFO		
Characteristics	Mean	SD	Mean	SD	*p*-value
Injury duration (month)	28.27	12.94	28.36	13.11	.59
Daily use time (hours)	2.34	1.15	2.09	0.53	.98
Age	39.54	13.28	38.72	13.63	.88
Weight	65.90	16.66	65	17.46	.90

RGO: reciprocating gait orthosis (RGO) group ($n = 11$); HKAFO: hip knee ankle foot orthosis (HKAFO) group ($n = 11$). The mean difference was considered significant at $p = .05$.

Tools

The Persian version of the SIP-68 questionnaire was used to evaluate the subjective QoL of each participant. The reliability and validity of the original version of this questionnaire were 0.91 and 0.92, respectively [15,16]. A version of the SIP-68 was previously translated into Persian and then revalidated; the validity and reliability for the Persian SIP-68 were reported to be 0.75 and 0.90, respectively [17]. This questionnaire was self-explanatory and designed to quantify the participant's QoL in six areas: physical independence (17 questions), mobility control (12 questions), range of motion (11 questions), social behaviour (12 questions), emotional stability (6 questions), and communication and emotional independence (10 questions). Therefore, the questionnaire included a total of 68 questions, and all the questions were answered by a simple "yes" or "no". A "yes" response was quantified as a score of 1, while a "no" response was quantified as 0. An overall rating score of 68 represented the worst possible QoL, whilst an overall score of 0 represented the best possible QoL.

Statistical analysis

All statistical analyses were performed using SPSS for windows version 14.0 (SPSS Inc., Chicago, IL, USA). Data were evaluated for normality using the Kolmogorov–Smirnov (KS) test and an independent *t*-test was then used to compare the mean scores of dependent variables for the HKAFO and RGO study groups. Correlational analyses were also used to examine the relationship between the two groups (RGO and HKAFO) in terms of age, weight, injury time, injury level, and subjective QoL scores. Data are shown as means (±SD), and statistical significance was accepted at $p < .05$.

Results

A total of 22 participants (6 females and 16 males) between the ages of 22 and 64 years (mean age: 39.13 ± 13.14) and weighing 40–94 kg (mean weight: 64.95 ± 16.68) were enrolled. The demographic characteristics of the participants are provided in Table 1.

The total score and sub-scores from the SIP-68 questionnaire were compared, and emotional stability ($p = .037$) and communication and emotional independence ($p = .011$) sub-scores were significantly different between the RGO and HKAFO groups (Table 1). The total scores from the QoL questionnaire were not

Table 2. Total and sub-scale scores for reciprocating gait orthosis (RGO) and/or hip knee ankle foot orthosis (HKAFO) users.

	RGO		HKAFO		
Subscale	Mean	SD	Mean	SD	*p*-value
Physical independence	10.64	2.24	10.00	3.06	.585
Movement control	8.00	1.34	8.36	1.62	.574
Communication and emotional independence	1.00	1.09	2.82	1.83	.011*
Social behaviours	5.09	1.97	5.55	1.86	.585
Emotional stability	1.36	1.43	2.73	1.42	.037*
Range of motion	6.09	1.70	4.45	2.01	.053
Total score	32.18	6.35	33.91	7.88	.578

RGO: reciprocating gait orthosis (RGO) group ($n = 11$); HKAFO: hip knee ankle foot orthosis (HKAFO) group ($n = 11$). *The mean difference was considered significant at $p = .05$.

statistically different between the RGO and HKAFO groups ($p = .578$; Table 2).

Further analysis showed that there was no significant correlation between the total questionnaire score and participants' ages ($p = .468$), although this relationship was significant within the RGO and HKAFO groups when considered separately ($p = .041$ and $p = .009$, respectively). The total questionnaire scores decreased in older participants in the RGO group, with opposite results for the HKAFO group (Figure 2, Table 3).

When considering all the participants together, there was no significant relationship between the participant's weight and their total SIP-68 score ($p = .166$), although this relationship was significant in the RGO group with the total SIP-68 score being lower in heavier participants ($p = .022$; Table 3).

Analysis also revealed that there was no significant relationship between the level of injury and the total SIP-68 score ($p = .206$). However, there was a significant correlation between the total SIP-68 score and lesion duration when considering the entire dataset and the RGO group alone ($p = .041$ and $p = .009$, respectively); the QoL score was shown to increase as lesion duration increased (Table 3).

Discussion

This was an observational cross-sectional study of the QoL scores of 22 participants who had sustained SCIs at the thoracic level and wore either RGOs or HKAFOs. This is the first study to compare RGOs and HKAFOs in terms of QoL scores with a rehabilitation goal in SCI patients.

Our analysis showed that total QoL scores were not significantly different between the HKAFO and RGO users and thus the study hypothesis was refuted. This form of comparison was unique to this study and it was therefore not possible to compare this specific result with that of previous studies. On the other hand, several studies have shown that RGOs show greater improvement in the kinetic and kinematic aspects of walking than HKAFOs [12,18,19]. However, the results of the present study may imply that these improvements in kinetics and kinematics are not significant enough to yield a major functional difference and are therefore unable to affect the QoL scores.

The SIP-68 questionnaire has six sub-scales, which were used herein to examine relative QoL scores in RGO and HKAFO users. Among these sub-scales, only the scores for emotional stability and communication and emotional independence were shown to be statistically significant when compared between the RGO and HKAFO groups, with lower scores for those sub-scales in patients wearing RGOs than those wearing HKAFOs. As previously stated, it was not possible to compare our current results with those of previous studies. However, the researchers can conclude that the RGO, which is more modern and costs nearly seven times as much as the HKAFO, may provide more perceived satisfaction.

Further analysis showed that there was a relationship between the participant's age and the total SIP-68 score (QoL). It was shown that the QoL scores may improve as the participants' age increases. This result is consistent with a previous report by Jain et al. [20]. The researchers believe that this result was due to the mobility afforded by the RGOs, which occurred at a level that was only acceptable by older participants, yet did not meet the expectations of younger participants.

Our analysis of the relationship between the participant's weight and the total SIP-68 QoL score revealed that the mean total QoL score was related to weight only in RGO users, with participants with a higher weight presenting with better QoL scores when using RGOs. Since the weight of RGOs is one of the major drawbacks for this type of device, it is possible that the ratio of the orthosis weight to the participant's body weight leads to problems for participants with a lower weight. In line with this concept, it is reasonable to consider that participants who were heavier were able to bear the RGO's weight in a more convenient manner. The researchers recommend that future studies target this concept in more detail to ascertain whether recommending RGOs to patients with lower body weights should be avoided unless an alternative lighter type of orthosis is developed.

Our analysis of the relationship between the injury level and the total SIP-68 QoL score suggested that lesion levels had no relationship to total QoL scores. Similarly, Change et al. reported that injury levels had no direct effect on QoL scores [21]. Other studies have revealed that injury levels had indirect effects on QoL scores through their impact on activity levels and participation [22,23]. From our present data, the researchers believe that lesion levels have no direct effects on the total QoL scores, since the common features of all injury levels include the loss of physical mobility and independence. Neither of the orthoses led to an improvement in terms of independence at any injury level.

Our analysis also presented a relationship between lesion duration and the total QoL scores for the RGO group alone as well as when all participants were combined. Thus, for participants wearing the RGO orthosis, the longer the lesion duration, the lower the QoL score. This finding differed with the results of a study performed by Lude et al. [24]. The researchers of our study postulate that as time passes from when the injury occurred, the participant's hope of recovery using the RGO orthosis would decrease, and thus longer lesion durations may result in lower QoL scores.

Regarding our evaluation of participant eligibility, it is noteworthy that among the contacted SCI participants who wore the RGOs, none was excluded from the study because they used their orthoses for ≥ 2 h per day. Conversely, of the 20 HKAFO users who were contacted, 8 were excluded from the study because they were using their orthosis for <2 h per day. This was particularly noteworthy since this equates to 40% of the total number of HKAFO participants contacted. This indicates that many patients with SCIs who are prescribed HKAFOs do not wear their orthoses for an adequate amount of time. Future studies should specifically examine the underlying reasons for this reduction in HKAFO use time with the resulting information applied to choosing and prescribing this type of orthosis.

Limitations

The main limitation of this study was the small sample size. This was due to the limited number of SCI patients who were

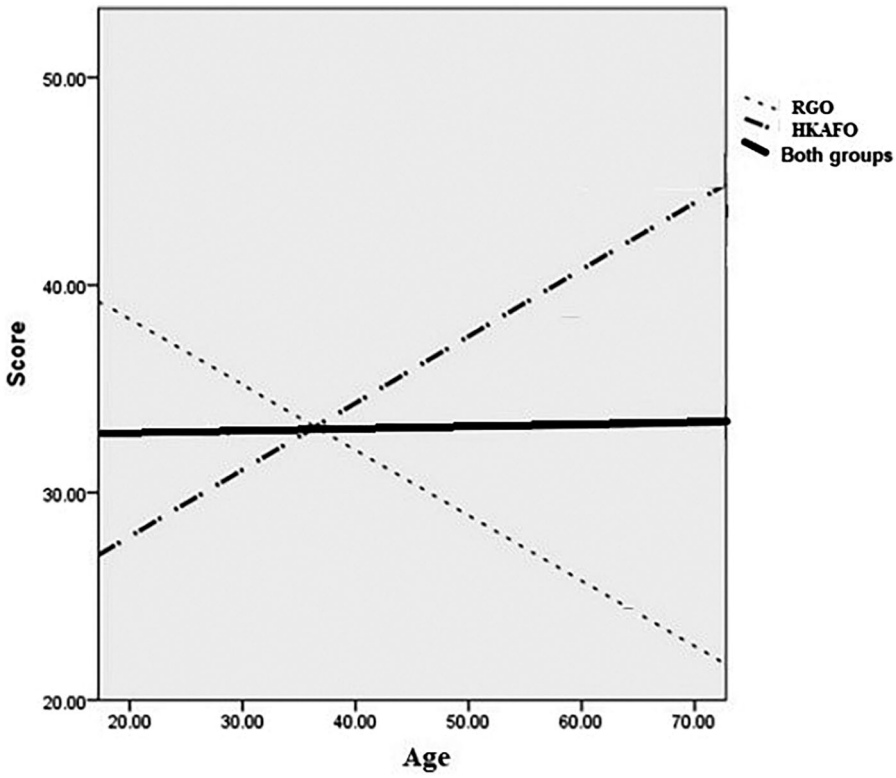

Figure 2. Scatter plots correlating age and the total quality of life (QoL) scores in the reciprocating gait orthosis (RGO) group, the hip knee ankle foot orthosis (HKAFO) group, and both groups combined.

Table 3. Correlations comparing the total score and age, weight, injury level, and injury time.

	Age (*p*-value)	Weight (*p*-value)	Injury level (*p*-value)	Injury duration (*p*-value)
RGO/HKAFO	.468	.166	.206	.041*
RGO	.014*	.022*	.096	.009*
HKAFO	.038*	.387	.575	.344

RGO: reciprocating gait orthosis (RGO) group ($n = 11$); HKAFO: hip knee ankle foot orthosis (HKAFO) group ($n = 11$); RGO/HKAFO: RGO and HKAFO groups combined ($n = 22$). *The mean difference was considered significant at $p = .05$.

prescribed RGOs. Consequently, the findings of this study should be considered with caution. However, despite the small number of participants, only patients with SCIs categorized as having Grade A on the ASIA Impairment Scale were included with the number of participants in the HKAFO group being matched to the number of participants in the RGO group. Therefore, the present study cohort can be considered as relatively homogenous. It is also noteworthy to mention that similar sample size issues are evident in previous studies investigating the efficacy of orthotic management in the QoL scores of SCI patients [25,26].

Conclusions

In conclusion, the results of this preliminary study suggest that individuals wearing RGOs and HKAFOs have a similar QoL score, although emotional stability and communication and emotional independence scores improved in individuals wearing RGOs. On the other hand, RGOs may yield the best results for participants with greater body weight and at the beginning of the rehabilitation programme. The current preliminary study does not provide definite conclusions and further randomized control trials are required to compare the effectiveness of these orthoses on the QoL scores of patients with SCIs.

Data archiving

The datasets generated during the current study are available in the Figshare repository, http://dx.doi.org/10.6084/m9.figshare.7531478.

Authors' contribution

All authors have materially participated in the research and/or article preparation. All authors have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, and (3) final approval of the version to be published. All authors agreed to be accountable for all aspects of this research in ensuring that questions related to the accuracy or integrity of any part of this research are appropriately investigated and resolved.

Ethical statement

The Ethics Committee of the Iran University of Medical Sciences (IUMS) in which the study was conducted approved the research protocol [93/D/105/4944]. The researchers certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Disclosure statement

The authors declare no conflicts of interest.

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