Comparing Maximum Tolerable Pressure

BCI spinal orthoses are the easiest and most consistent to use among 10 braces tested

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Spinal orthoses stabilize and relieve the lumbar spine using three mechanisms of action:

- They physically restrict movement and motion of the lumbar spine and help the wearer to achieve proper posture.\(^1,2\)

- By splinting the lower trunk (lumbar spine and pelvis), spinal orthoses reduce the activity of the paraspinal musculature.\(^2,3\)

- By increasing the intra-abdominal pressure, they push on the diaphragm and pelvic floor, resulting in a reduction of spinal load with widening of the dorsal intervertebral disc space, facet joints, and intervertebral foramina.\(^2,4,5\)

To achieve these effects, clinicians often recommend that patients tighten spinal orthoses to their subjective maximal tolerable pressure. Patients who suffer from reduced muscle strength and osteoarthritis of the finger joints, may have limited ability to tighten an orthosis and reach maximum tightness. Thus, the easier a spinal orthosis can be tightened to the maximal pressure, the easier it is for the patient to use and the greater the possible clinical effects. Therefore, a study was conducted by Syprosoft Engineering, Irvine, CA, to investigate the pull force required to tighten 10 commonly available spinal orthoses to the maximal tolerable pressure.

**Methods**

Ten spinal orthoses, five fitting the descriptor of L0631 (Passport [BCI], Horizon [Aspen], Miami [Össur], M-Spine 584 [M Brace], Sleeq [Quinn Medical], and five fitting the descriptor of L0637 (Protégé [BCI], Horizon [Aspen], Miami [Össur], M-Spine 574 [M Brace], Sleeq [Quinn Medical]) were repeatedly tightened to subjective tolerance by five healthy volunteers. Tightness-to-tolerance (T3) is defined as the maximum tightness that the user can comfortably tolerate while using the brace. To get to T3 the user has to apply force on the pull handles. The force required to reach T3 was measured using a Dillon Force Gauge, Model GS. Applied force data was collected three times each day for three days from each volunteer to ensure any natural variations can be properly averaged out. The force measurements were averaged for each subject and brace.

**Results**

The average pull force required to reach T3 differed between subjects and braces.

None of the volunteers were able to reach T3 with the two M-Spine braces tested. Thus, no data can be presented for the M-Braces. Out of the other eight spinal orthoses, the BCI Passport and Protégé demonstrated the lowest pull force required to reach T3 (Fig. 1).

![Figure 1: Pull force required to reach tightness to tolerance (T3).](image-url)
The data for the two BCI braces showed not only the lowest pull force necessary to reach T3, but also that the pull force required to reach T3 was the most consistent in each brace and across subjects. Each subject needed about the same pull force to tighten the Passport or Protégé, respectively, to tolerance. This consistency was not seen in the other braces tested. The order of subjects from lowest to highest pull force required to reach T3 varies considerably between orthoses.

Discussion

The pull force required to tighten the BCI Passport and Protégé to individual tolerance is the lowest across all subjects. Moreover, based on the consistency of the pull force measurements, the pull mechanism of the BCI orthoses appears to be the most consistent and predictable. Assuming that the tolerable abdominal pressure is more or less constant in each individual and the translation of pull force into abdominal pressure is consistent in every brace, the pull force curves of all braces across subjects should be largely parallel. As this is not the case, it can be concluded that the BCI Passport and Protégé are the easiest and most reliable spinal orthoses to use for the patients, ensuring the lowest and most consistent pull force to reach maximum stabilization and relief of the lumbar spine.