ActivAided Orthotics Presents:
Low profile corrective lumbar system for Spondylolisthesis

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Executive Summary

The objective of this project is to offer solutions to the various reasons why current conservative treatment methods for spondylolisthesis fail. The sleek, low profile design and comfort of the ActivAided brace solves the issue with patient noncompliance. The incorporation of stiffness, compression, and tension offer the appropriate amount of support while training the patient's muscles corrective habits, leaving the patient in better conditioning than prior to the injury. Additionally, the brace can be worn during many types of physical activity, encouraging the acquisition of proper technique and safe motions.

Clinical Need

Spondylolisthesis is the slippage of one lumbar vertebra in relation to another, most often accompanied with fractures of pars interarticularis. Young athletes are particularly susceptible to developing spondylolisthesis since it is often caused by imposing excessive forces on the spine as in chronic overuse, improper training technique, or training through fatigue. Current surgical or conservative treatments are inadequate. **Spinal fusion surgery** restricts spinal flexibility and leads to adjacent segment degeneration. **Traditional Braces** that must be worn for up to 12 months are uncomfortable and inhibits daily activities. This leads to patient noncompliance and therefore ineffective treatment. Most importantly, patients rarely are able to return to their previous level of activity.

Conceptual Design

Primary areas of focus:

- Pain relief – modular pockets for therapy inserts
- Posture support –tensile and compressive regions
- Core muscle strengthening – localized pressure and adjustable tensile components
- Patient compliance – integrate into low-profile wearable design with minimal motion restriction

Novelty

Treatment Approach: *Pain is the problem, not motion*

Inhibit specific harmful motion to realign and heal spinal, not total immobilization
Remedy pain with heat/ice packs and additional lumbar support
Promote core muscle strengthening to prevent future injury and stabilize spine

Integrated Design: *Holistic back therapeutic*

Orthosis includes corrective elements on torso and abdomen
Innovative belt design allows for secure placement, but ease in removal
Variable heat/ice and support packs allow for customizable pain relief therapy

Focus on Compliance: *You'll want to wear it!*

Minimally restrictive of motion for unencumbered mobility
Low-profile and form-fitting for wear under daily clothes
Flexible and durable for wear during exercise
Machine washable for ease in cleaning

Initial Prototype

Evaluated proof of concept and design feasibility
Tested on subjects during experimentation and identified objectives for second prototype:

- Upgrade materials
- Include additional pockets for pain relief
- Incorporate tensile resistance on abdomen
- Improve postural support comfort and effectiveness
- Enhance aesthetics and quality of construction

Experimentation

Hypothesis: The device promotes improved posture and does not limit the mobility of the wearer

Protocol: Assess physical motion and flexibility to compare null state, Boston brace, and ActivAided prototype during a series of tasks:

Mobility:

- Shuttle run – run 20ft shuttles, 2 repetitions (timed)
- Stair climb – walk up and down one flight of stairs (timed)
- Get-up-and-go – Stand, walk 10ft, turn, walk back, sit (timed)

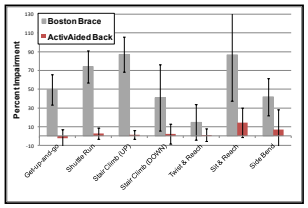
Range of Motion:


Side bend


Sit and reach


Twist and reach

Results: Boston brace and ActiveAided Back tests were normalized with respect to null, and percent impairment was compared. From the results, it is apparent that the traditional Boston Brace treatment causes a higher percent impairment when it comes to all of the movements tested. The greatest impairments for the Boston Brace were the stair climb and the sit and reach, which increased time up a flight of stairs and decreased the number of inches reached forward by almost 90%. More importantly than proving that the Boston Brace is an undesirable option, is the fact that The ActivAided prototype minimally impaired movements tested. Most movements were only impaired by ~2% or less. The only motions more greatly impaired were the sit & reach and the side bend. This is most likely due to the front and back stiff plates and the tight fitting design. Preliminary testing gives a good indication towards compliance, however further testing is necessary to prove the posture correcting, muscle strengthening, and pain relief abilities of the ActivAided Back.



Final Prototype

ActivAided BACK

A. Rigid plate on dorsal lumbar-sacral joint
Inhibits hyperextension of lower back

B. Internal pockets
Removable heat/ice pack for pain relief
Lumbar support with inflatable pack

C. Elastic compressive belt
Connects upper orthosis to spandex shorts
Velcro closure for easy adjustment and removal
Provides stiff abdominal stimulation and compression

D. Elastic butterfly shoulder support
Localized tension between scapula for thoracic posture control
Prevents hunching from over-correction of lumbar hyperextension

E. Compressive abdominal strap
Secures orthotic placement
Increases postural awareness and support

F. Compressive spandex shorts
Anchors upper orthosis to ensure optimal corrective placement

G. Integrated shirt design
Low-profile and wearable for maximum patient compliance

FDA Regulation

Physical Medicine Devices classification (as defined in **21 CFR Parts 862-892)**

- 890.3490 TruncalOrthosis
- Class I device
- Exempt from 510(k) or PMA
- Does not require FDA clearance before US marketing
- ActivAided Back will be registered with generic category and classification name before distribution using FDA's Unified Registration and Listing System

Product Costs

Estimated costs of materials and manufacturing for the ActivAided Back are provided in Table 1. Raw materials prices based on bulk materials available in the United States and labor in China. This estimate of $30.08 per unit is an overestimate of actual costs incurred.

Part	Item	lengths (yards)	bulk cost ($/yard)	cost/unit
Shirt and Shorts	60" spandex	1.00	14.00	$14.00
Posture Support	2" knitted elastic	2.33	0.23	$0.54
Chest Compression	4" knitted elastic	0.83	0.89	$0.74
Compressive Belt	4" Woven elastic	1.00	1.75	$1.75
Pocket Lining	60" sport mesh	0.14	7.50	$1.07
Back Plate Lining	60" denim	0.17	7.00	$1.17
Belt Fastener	4" velcro loop	0.17	0.59	$0.10
Belt Fastener	4" velcro hook	0.06	0.59	$0.03
Back Plate	InstaMorph	6 oz.	.78/oz.	$4.68
	labor (China)	6 hrs	1/hr	$6.00
			Total	$30.08

Table 1: Material prices and cost per unit

Market Description

The Opportunity:

- Back pain is experienced by 80% of people[1]
- Treatment and loss of productivity accounts for $100 billion, annually[2]
- Leading cause of mobility loss or limited activity in patients under 45[3]
- Pharmaceutical treatment projected to reach $23 billion by 2018[4]
- Prevelance of spondylolisthesis is 13% of athletes and 6% of the general population [5,6]

The Strategy:

- Target consumer directly to avoid insurance reimbursement complications
- Predicted sales at $150-$200 based on alternative treatments and competitor products

Future Work

- Patent approval and funding acquisition
- Refine technological design
  - Determine optimal material properties for effectiveness and cost-efficiency
  - Upgrade and specify final materials
- Conduct long-term testing on spondylolisthesis patients for definitive proof of concept
- Create LLC to develop and commercially market ActivAided Orthotics
  - Differentiate products for various markets – sports, post op, silver

References

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[4] http://www.chiroeco.com/chiropractic/news/7641/34/us-back-pain-market-approaches-$23-billion-in-2018---anticipated-long-actingabuse-resistant-opioids-drive-value
[5] F. Rossi MD, S. Dragoni MD. The prevalence of spondylolysis and spondylolisthesis in symptomatic elite athletes: radiographic findings. *Radiography* 2001 ;7(1):37-42.
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