



**Helping your patients
embrace the journey,
not the back pain.**

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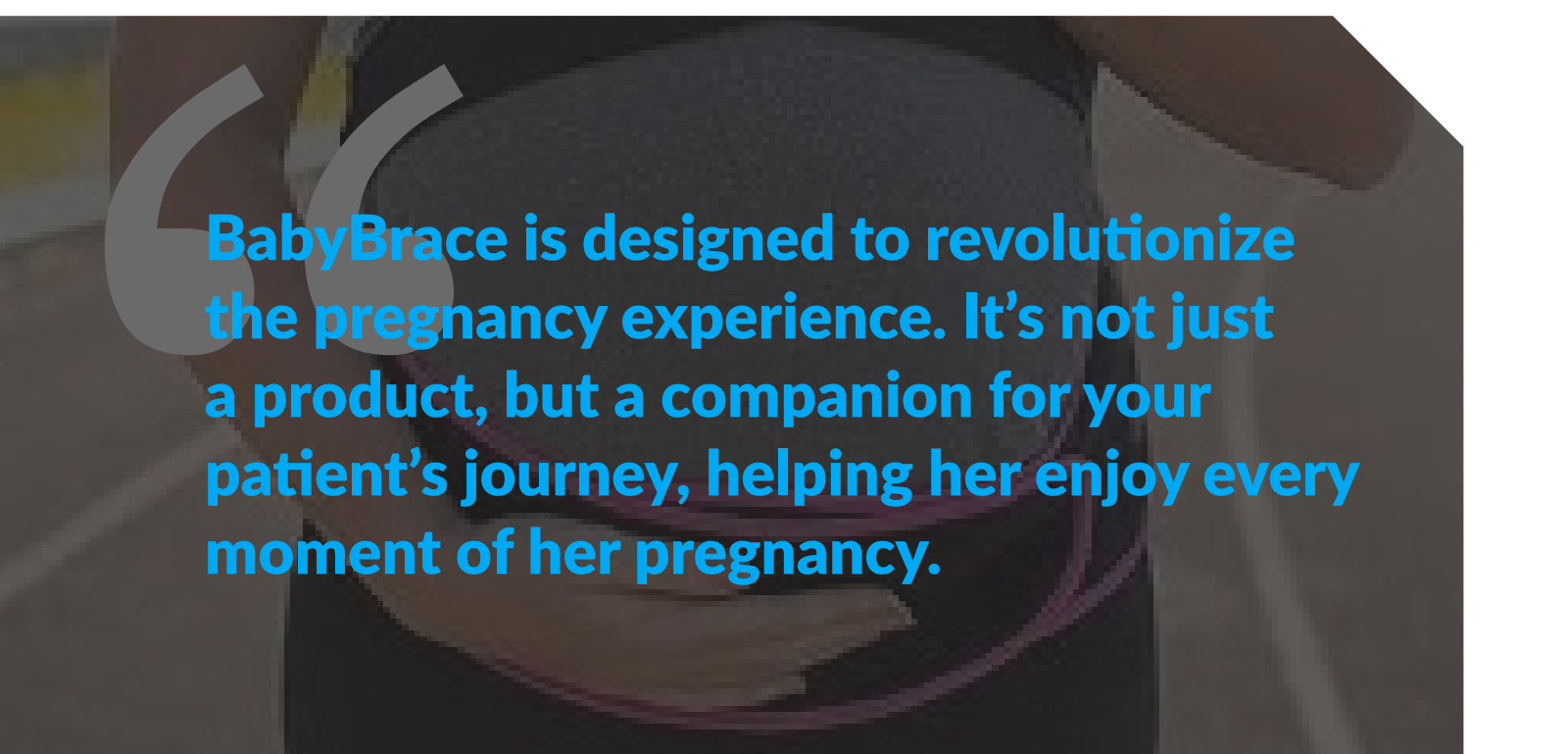


1910 Silver St.
Garland, TX 75042

(972) 494-3334
info@medicostx.com

Welcome to BabyBrace®!

Pregnancy is a magical journey your patients, filled with joy and anticipation. Unfortunately, it can also bring discomfort, specifically in the form of lower back pain. That's where BabyBrace® steps in.



BabyBrace is designed to revolutionize the pregnancy experience. It's not just a product, but a companion for your patient's journey, helping her enjoy every moment of her pregnancy.

A REAL PROBLEM

Approximately 50 -80 percent of women experience lower back pain during pregnancy due to changes in the body's center of gravity, increased belly weight, and hormonal changes that may cause ligaments to become lax. These changes are normal but can cause significant discomfort and stress on the lower back.

A REAL SOLUTION

BabyBrace is an FDA-approved medical device specifically designed to address these changes, providing your patient with much-needed relief. It works by normalizing her center of gravity, adjusting to her body's changes during pregnancy, and offering modularity for postnatal use.

ADAPTS WITH PREGNANCY

What makes BabyBrace truly special is its custom fit. Each brace is tailored specifically to your patient, ensuring maximum comfort throughout her pregnancy. As her body changes, BabyBrace adapts with her, with easily adjustable arms that can be placed in multiple positions to ensure ongoing comfort and support.

How BabyBrace® Works.



Now your patients can enjoy their pregnancies with less pain and more comfort.

As a provider, you know how during the pregnancy journey, a woman's body undergoes many changes. One of these is the increase in belly weight that subtly shifts her body's center of gravity forward. As a result, her body instinctively adapts by amplifying the curve in her lower spine and tilting her pelvis forward.

Here's where the magic of BabyBrace® comes in. Expertly designed to mold seamlessly to her unique form, BabyBrace provides a gentle lift and support that repositions her body's center of gravity to its natural, comfortable alignment. This thoughtful design significantly reduces stress on your patient's spine and supporting muscles, bringing her much-needed relief from back pain.



Video



Learn More

BabyBrace® was specifically designed by a board certified spine surgeon to combat lower back pain during pregnancy. This FDA-approved, custom-fitted brace is designed to adapt with your patient, providing her with unmatched comfort and support. Watch our video and discover how BabyBrace can transform her pregnancy journey.

**Baby
Brace**



How to make BabyBrace® part of your patients' lives.

BabyBrace® isn't just a medical device, it's a partner that adjusts with your patients as they journey through pregnancy. BabyBrace is covered by most insurance. Insurance requires the following information:



Physician Prescription

BabyBrace is available by prescription only. We have included a prescription form in this booklet for your convenience.



Medical Necessity Chart Notes

Medical chart notes must include documentation that supports why the brace is being ordered. See "Document Guidelines" on the next page for additional information.



Patient Demographics & Insurance Info

Medicos will contact you if any information is missing and file the claim with your patient's insurance company.

We'll Reach Out

Once we have received verification from your patient's insurance company, someone from Medicos will contact her to set up a appointment for her BabyBrace fitting. If applicable, we'll also review any out-of-pocket costs with her at that time.

Fax or email prescriptions, chart notes, patient demographics and insurance information to:



(972) 487-9663



info@medicostx.com

Documentation Guidelines

Supporting documentation must include subjective and objective, beneficiary specific information used for diagnosing, treating, or managing the condition for which BabyBrace® is ordered.



Chart notes should be submitted with the order to support the need for BabyBrace. Chart notes must indicate a face-to-face encounter with the beneficiary within six months prior to prescribing the item. A test is not necessary, but if one is performed, it must be included in the medical records.

Medical records must document that the spinal orthosis was ordered for one of the following indications.

- To reduce pain by restricting mobility of the trunk
- To support weak spinal muscles and/or a deformed spine
- To facilitate healing following an injury to the spine or related soft tissues
- To facilitate healing by following a surgical procedure on the spine or relates soft tissue.

Example: Patient Jane Doe was seen today for _____. She complained of back pain and that it is negatively affecting her daily activities. I have prescribed an LSO to reduce pain by restricting the mobility of the trunk and to support weakened spinal muscles.

Maternity support garments and off-the-shelf slings attempt to provide support for the abdomen during pregnancy. However, these products do not meet the definition of spinal orthosis and therefore are not approved by Medicare or commercial insurances.

Who is Medicos?

Welcome to Medicos, where we dedicate our time and expertise to helping individuals find relief from pain, improve mobility, and accelerate recovery. Our mission is simple: to enhance the quality of life for patients.

With a rich history spanning over four decades, we've remained steadfast in our commitment to delivering cutting-edge medical equipment. We collaborate with industry-leading manufacturers celebrated for their innovation, exceptional performance, and uncompromising quality.

Putting Patients and Their Providers First

At Medicos, we celebrate uniqueness. We know each patient has distinct needs, and that's why our team includes licensed orthotists and

certified brace fitters. They work diligently to ensure patients receive a device that not only addresses their requirements but also fits their bodies perfectly.

Our wealth of experience and deep expertise reassure patients of our understanding of their medical conditions and the hurdles they may encounter on their journeys back to wellness. Remember, at Medicos, we do more than supply medical equipment—we empower lives.

Your trusted partner.

Medicos holds a distinguished position as a respected and accredited provider of top-of-the-range medical equipment and devices. Our reputation for excellence has earned us the trust of both patients and healthcare providers.

We accept most private insurance plans and Medicare, making our services accessible to a wide range of patients.

Navigating through medical paperwork, documentation, and billing can be daunting and time-consuming. We get it.

That's why we have a team of billing specialists well-versed in insurance policy guidelines and requirements, ready to help you through the process.

At Medicos, we don't just provide medical solutions; we build relationships based on trust, care, and a shared goal of enhancing lives. We're here to support you and your patients every step of the way.

Like to Learn More?

Call or Email Us!



(972) 494-3334



info@medicostx.com

Contact us to receive a clinical study of the effectiveness of BabyBrace.[®]



MEDICOS

BABY BRACE PRESCRIPTION/ORDER FORM

Phone: 972.494.3334 Toll Free: 800.441.0030 Fax: 972.487.9663 Email: orders@medicostx.com

PATIENT INFORMATION

Complete patient information below or attach patient demographic sheet that includes insurance information.

Patient Name: _____ DOB: _____ Order Date: _____

Waist Circumference (Inches): _____ Current Gestational Age: _____ Weeks: _____ Days: _____ Height: _____ Weight: _____

PRESCRIBER INFORMATION

Physician/Prescriber Name: _____ NPI#: _____

Address: _____ City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ Email: _____

****Please include chart notes (with supporting indication of medical necessity), demographics, and patient demographics**
Fax to 972.487.9663 or Email to: orders@medicostx.com**

ORDER INFORMATION

Item prescribed: Lumbar Sacral Orthosis, Custom Fitted or OTS

HCPCS Code: L0631/L0648 Quantity Dispensed: 1

Indicate the patient's primary ICD-10 Diagnosis Code which requires the use of an LSO: _____

PRIMARY DIAGNOSIS

SECONDARY DIAGNOSIS

Low Back Pain

M54.50 low back pain, unspecified

Pain in Thoracic Spine

M54.6

Traumatic Symphysis Pubis Diastasis

O71.6

Radiculopathy

M54.10 unspecified side

M54.14 thoracic region

M54.15 thoracolumbar region

M54.16 lumbar region

Round Ligament Pain Affecting Ante Partum

O26.891 first trimester

O26.892 second trimester

O26.893 third trimester

O26.899 unspecified trimester

MEDICAL NECESSITY DISCLAIMER: By my signature below, I am prescribing the brace listed above. The items listed above are requested based on the patient's diagnosis. This item will or is reasonably expected to assist the patient in achieving and maintaining maximum functional capacity in performing daily activities.

Physician Signature: _____ Date: _____

(Signature Stamps NOT Accepted)

An Investigational Study of BabyBrace® on Whole Body
Center of Gravity and Contact Force Distributions
- A Clinical Investigation -

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Erin Shucosky, RN
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Scoliosis and Spine Center
University of Maryland St. Joseph Medical Center
Baltimore, Maryland



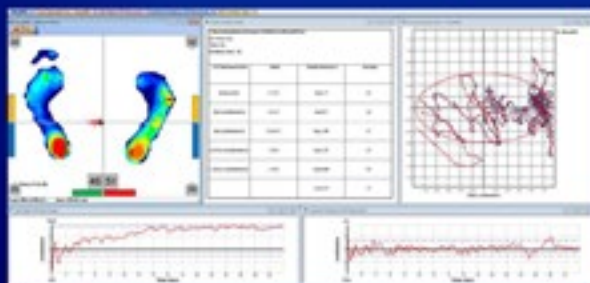
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Study Objectives

Objectives:

1. Quantify changes in whole center of body mass with a surrogate pregnancy vest and gestational orthoses.
2. Determine circumferential force distributions between the orthoses and patients body, with specific emphasis on the anterior lift afforded by the braces.



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Methods

IRB Study Approval

1. *All procedures described and conducted for the current investigation were first reviewed approved by the Western Institutional Review Board (WIRB) and University of Maryland St. Joseph Medical Center IRB prior to commencement of study procedures.*
2. *Written informed consent for participation in this project and data publication was obtained from each participant prior to taking part in the experiment.*



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Methods

Participant Demographics

Inclusion Criteria:

- 1) Study Participants: n=25
- 2) Age: 21 – 38 Female.
- 3) Body Mass Index (BMI): 20 – 32.
- 4) Physical ability to wear a 25 to 30 pound vest for at least 40 minutes in a standing position.

Exclusion Criteria:

- 1) Previous spinal surgery or history of back pain requiring conservative care.
- 2) History of lower extremity problems: vascular, motor, neurogenic or unknown cause.
- 3) History of vertigo or disequilibrium related issues.
- 4) Pregnancy.
- 5) Subject has current chemical/alcohol dependency or significant psychosocial disturbance.
- 6) Subject is currently enrolled in another investigational study.



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Methods

Surrogate Pregnancy Vest – Empathy™ Belly

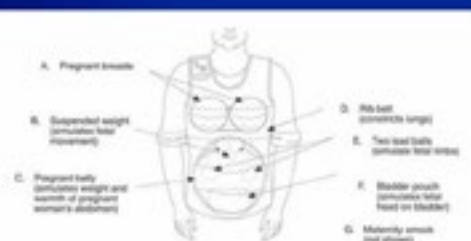


Figure 1. Name and location of Empathy™ Belly components.

Component	Quantity	Weight breakdown			
		Small		Large	
		Weight in lb (kg)	Component weight in lb (kg)	Weight in lb (kg)	Component weight in lb (kg)
A. Pregnant breasts	2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
B. Suspended weight	1	2 (0.9)	2 (0.9)	2 (0.9)	2 (0.9)
C. Pregnant belly (water)	1	8 (3.6)	8 (3.6)	11 (5.0)	11 (5.0)
D. Rib belt	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
E. Two-lead balls	2	7 (3.2)	14 (6.4)	7 (3.2)	14 (6.4)
F. Bladder pouch	1	6 (2.7)	6 (2.7)	6 (2.7)	6 (2.7)
G. Maternity smock	1	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total Empathy Belly weight		30 lb (13.6 kg)		33 lb (15 kg)	



(Image adapted from The Empathy Belly™ Instructor Training Manual P.3 Published by Birthways, Inc. 1996.)



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Methods

Gestational Braces and Supports



BabyBrace™
(VHM Bracing, LLC
Tampa, Florida)

NEOTech Care™
Maternity Belt
(Model NTCT 005)

SOFT FORM®
Maternity Support
Belt

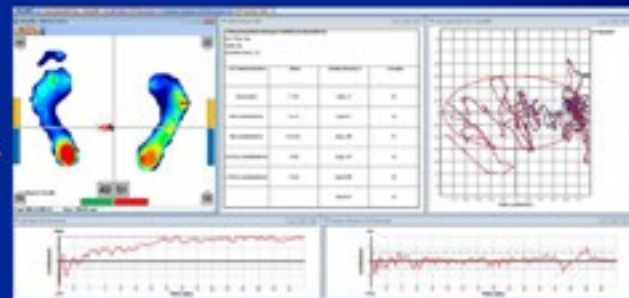
Babo Care®
Maternity Belt

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Methods

Experimental Endpoints

1. Visual Analog Scale (completed for baseline and each brace evaluated)
2. Center of Gravity (CoG) Calculation – A/P Shift from Baseline (0,0)



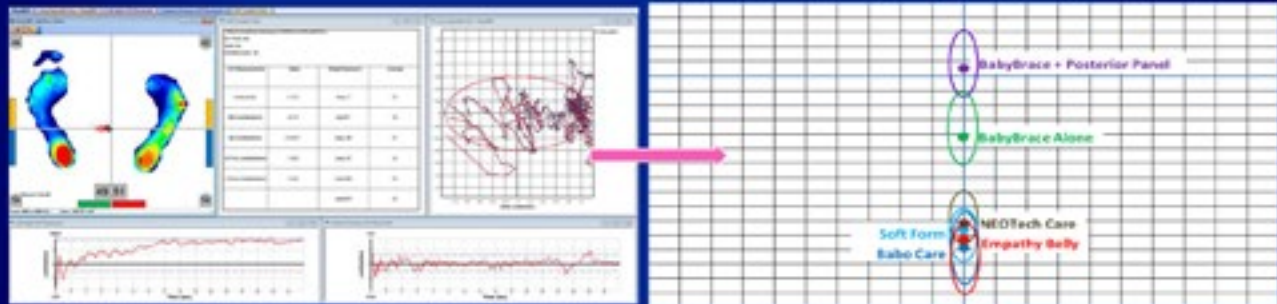
(MobileMat™ High Resolution Platform, Tekscan, Inc.
South Boston, MA)

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Methods

Experimental Endpoints

1. Visual Analog Scale (completed for baseline and each brace evaluated)
2. Center of Gravity (CoG) Calculation – A/P Shift from Baseline (0,0)
- 30 second evaluation time interval per brace



(MobileMat™ High Resolution Platform, Tekscan, Inc. South Boston, MA)



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Methods

Experimental Endpoints

3. Circumferential Force Distributions (Newtons) – 6 Sensor Locations



(FlexiForce™ Force Measurement Sensors, Tekscan, Inc. South Boston, MA)



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Methods

Experimental Endpoints

3. Circumferential Force Distributions (Newtons) – 6 Sensor Locations



(FlexiForce™ Force Measurement Sensors, Tekscan, Inc. South Boston, MA)



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Results

Demographics



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Results

Visual Analog Score (VAS)



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Results

Anterior Force (Newtons)



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Results

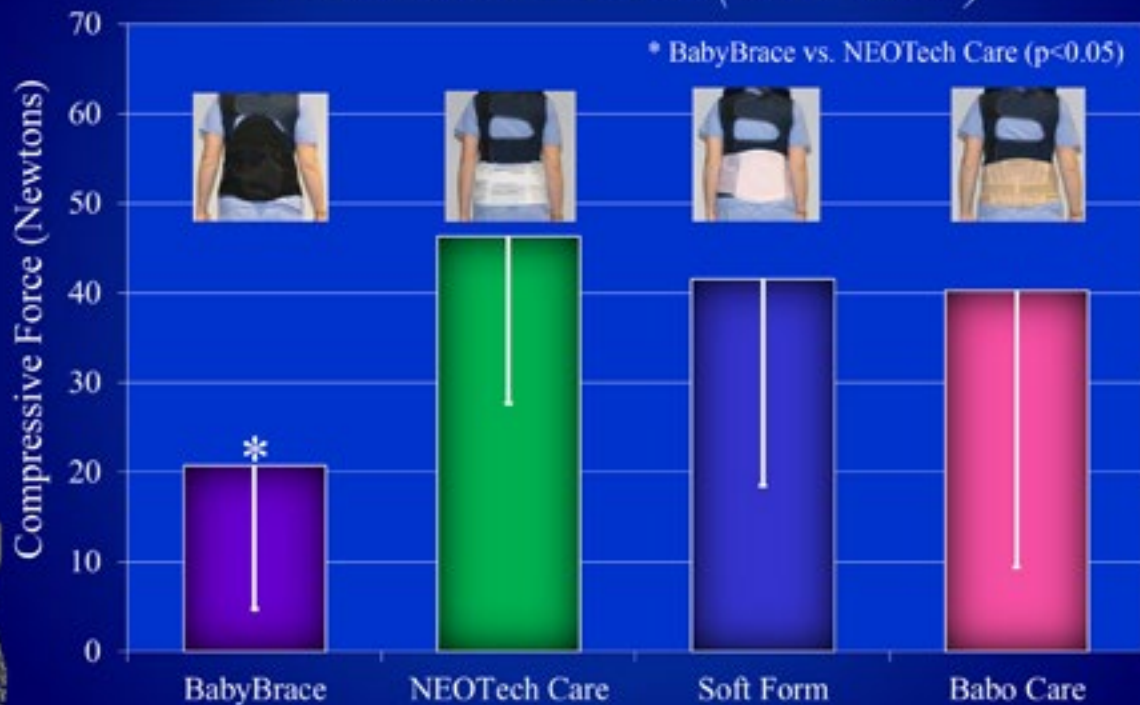
Lateral Force (Newtons)



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Results

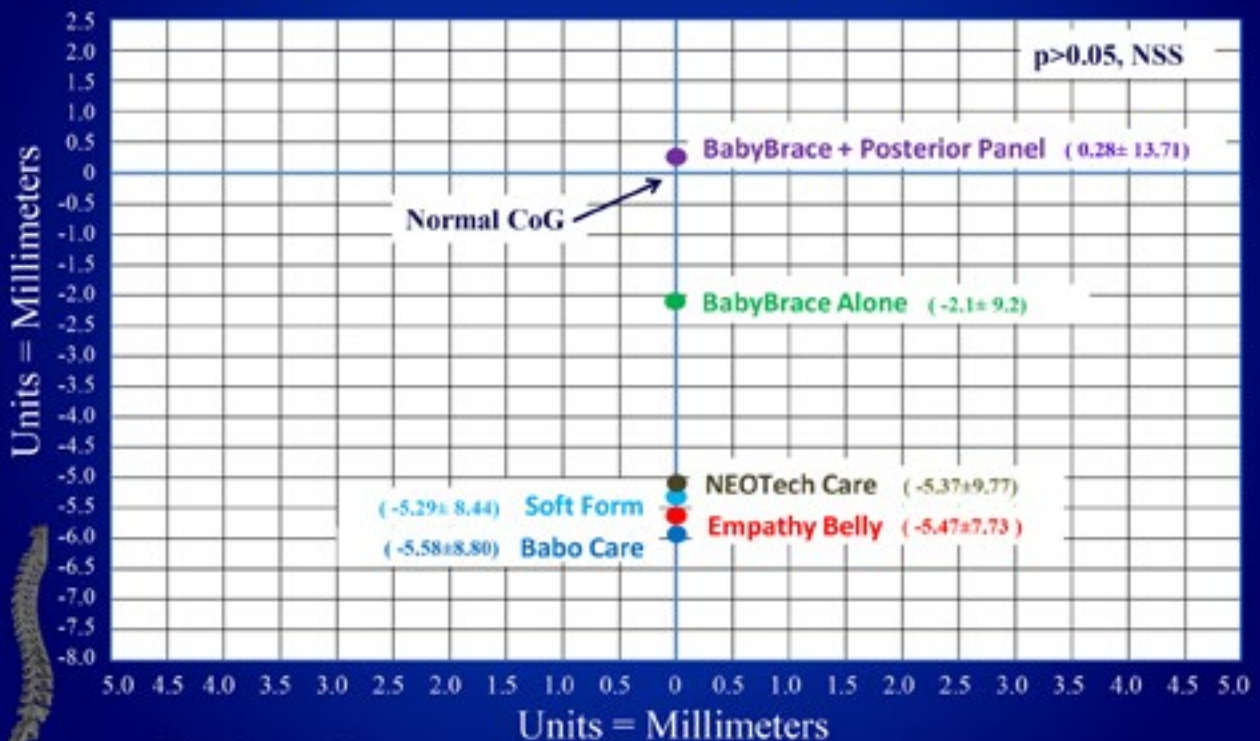
Posterior Force (Newtons)



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Results

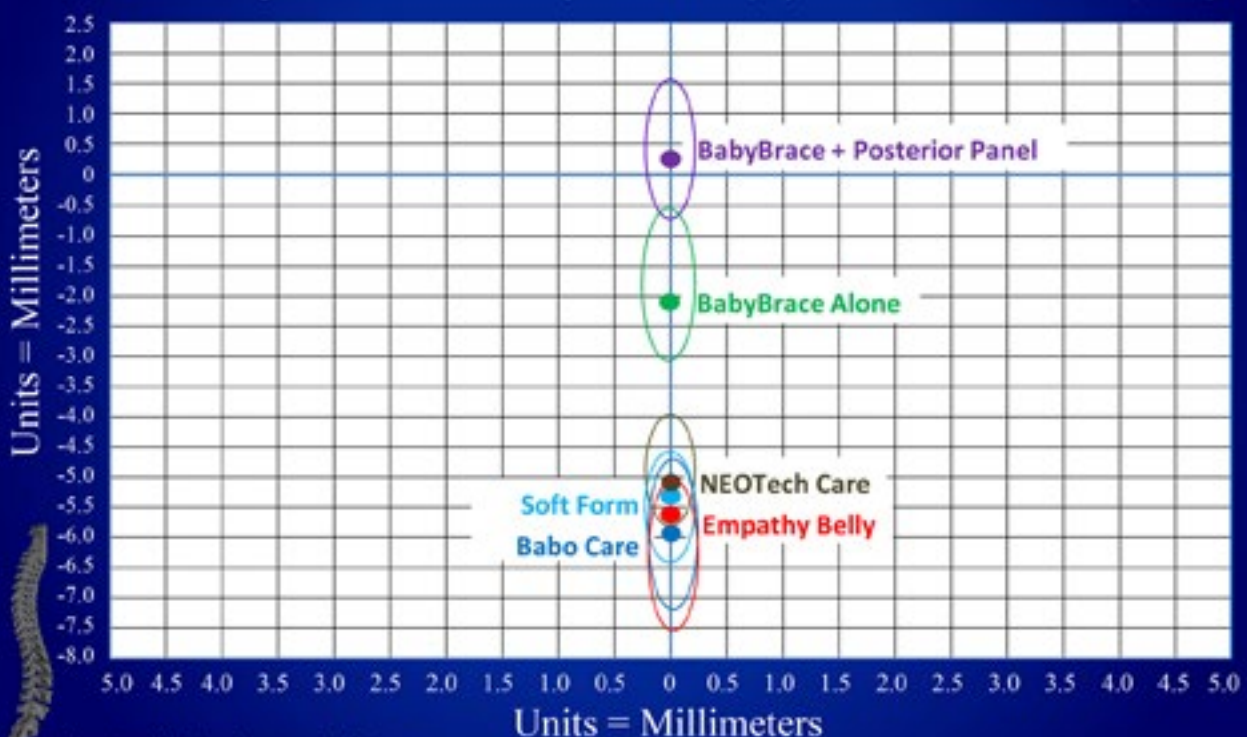
Mean Shift in Center of Gravity from Baseline (0,0)



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Results

Mean Shift in Center of Gravity from Baseline (0,0)



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Summary Points

1. VAS: Significantly elevated with Empathy Belly versus baseline ($p < 0.05$). No differences between braces ($p > 0.05$).

2. Circumferential Force:

Anterior: BabyBrace significantly improves anterior lift versus all other braces ($p < 0.05$).

Lateral: BabyBrace and NEOTech Care significantly improve compression versus all other braces ($p < 0.05$).

Posterior: BabyBrace significantly reduces compression versus NEOTech Care ($p < 0.05$).



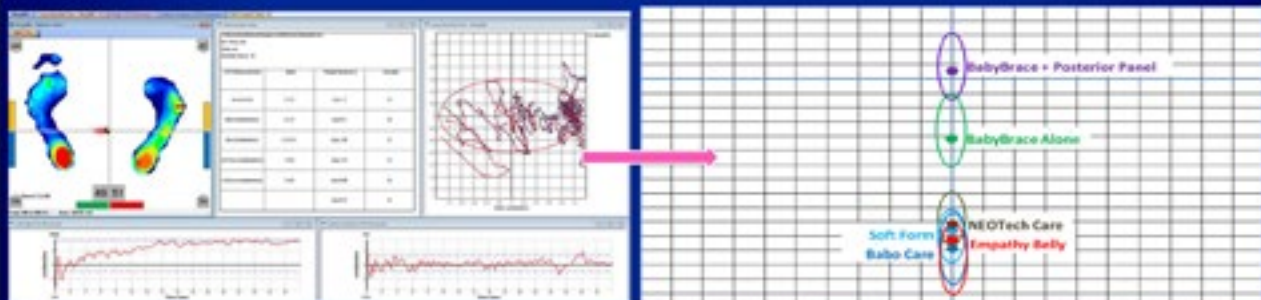
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Summary Points

3. Center of Gravity:

- No significant differences between braces ($p > 0.05$).

- Babybrace appears to restore CoG to the near normal condition, with and without posterior panel. Significance precluded by high standard deviations.



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Your custom-fitted BabyBrace® is available at:



Location

1910 Silver St.
Garland, TX 75042

Contact Us

(972) 494-3334
info@medicostx.com

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