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Evidence Table

**PICO:** For men and women in the military training environment, would use of orthotic devices in combat footwear be better than the use of traditional non-shock absorbing insoles at prevention of overuse injuries.

BSO = Biomechanical Shoe Orthoses; BMT = Basic Military Training; RCT = Randomized Controlled Trial; PWB = partial weight bearing; B = Back; LE = Lower Extremities

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| **Author, Name of Journal, Year** | **Title** | **Purpose and Design of Study** | **Number and Type of Subjects** | **Orthotic Intervention and Time Frame** | **Outcome Measures** | **Statistically Significant Results**  **(p<0.05)** | **Conclusion/**  **Recommendations** |
| Larsen K, Weidich F, Leboeuf-Yde C.  Journal of Manipulative and Physiological Therapeutics.  2002 | Can custom-made biomechanic shoe orthoses prevent problems in the back and lower extremities? A randomized, controlled intervention trial of 146 military conscripts. | To determine the effect of BSO on back and lower extremity injuries during BMT.  Prospective RCT | N = 146 military conscripts from Denmark (Experimental = 77, Control = 69)  Ages: 18 to 24 yo. | Custom made BSO   * Type = Semi-rigid * Made = Controlled pronation * Company = FormThotics   3 months | * Self-reported back/lower extremity problems * Specific problems of back, knees, lower extremity * # subjects with at least 1 day off due to B/LE pain * Total # of days off due to B/LE pain | Actual-use analysis:   * Reduced prevalence of back/LE injuries * Reduced prevalence of shin splints * Decreased number of off duty days | The authors do not believe the intervention is economically feasible (cost to prevent, $19 per pair). The use of orthotics did lower incidence of back/lower extremity injuries and decreased off duty days during training.  The authors did not take into account savings from potential healthcare visits. The outcome measure was a self-report questionnaire. |
| Baxter ML, Baycroft C, Baxter GD.  Military Medicine.  2011 | Lower Limb Injuries in Soldiers: Feasibility of Reduction Through Implementation of a Novel Orthotic Screening Protocol. | To access feasibility of screening protocol and effectiveness in reducing back and lower extremity injuries during BMT.  2-Arm Feasibility Study | N = 909 New Zealand Army personnel (Experimental = 102, Control = 807)  Experimental- new recruits, 47 issued orthoses  Control- active military personnel | Screening Protocol   * Rearfoot posture * Postural stability * Forefoot stability   Orthoses without Modification   * Company = FormThotics   Customized Orthoses  3 months | * Stress fracture: foot, shin, femur, lower back * Chronic pain or discomfort: hip, knee, lower back * Overuse injury in the ankle, knee, hip * Plantar fasciitis | Injury rates:   * Decreased incidence of stress fractures of foot, shin, and low back * Decreased incidence plantar fasciitis * Decreased incidence chronic pain or discomfort of hip, knee, and low back | The screening protocol and prescription of orthotics are effective in reducing lower extremity injury rates in the New Zealand military recruits during basic training.  The authors need to complete a study with an equivalent control group, more subjects are needed for intervention group, and information on type, fabrication, and company of orthoses should be reported. |
| Esterman A, Pilotto, L.  Military Medicine  2005 | Foot Shape and Its Effect on Functioning in Royal Australian Air Force Recruits. Part 2: Pilot, Randomized, Controlled Trial of Orthotics in Recruits with Flat Feet. | To determine the effect of BSO on pain, injury, foot health, and quality of life for recruits in BMT with flat feet.  RCT | N = 47 Royal Australian Air Force recruits diagnosed with flat feet (Experimental = 25, Control = 22) | Custom made BSO   * Type = flexible * Made = by orthotist * Company = Australian Orthotics Laboratory   8 weeks | Measured at baseline and week 8   * Lower limb pain * Training injury (>3 days of no training) * Foot pain and health (FHSQ) * Quality of life (WHOQOL) | None | Although there were no significant results, there was a trend to reduced pain and injury and increased foot health for recruits with flat feet that actually wore their orthoses.  The study would have benefited from a larger sample size, better fitting of orthoses, and wider definition of injury (needed to be off duty >3 days). |
| Milgrom C, Finestone A, Lubovsky O, Zin D, Lahad A.  Spine (Phila Pa 1976).  2005 | A controlled randomized study of the effect of training with orthoses on the incidence of weight bearing induced back pain among infantry recruits. | To examine the effect of various BSO on weight bearing induced back pain during BMT.  RCT | N = 404 eligible Israeli infantry recruits (Group 1 = 129, Group 2 = 126, Group 3 = 126)  Mean Age = 18.8 years | Group 1  Custom made BSO:   * Type = semi-rigid * Made = subtalar neutral position, cam mill * Company = ProLab Orthotics   Group 2  Custom made BSO:   * Type = soft * Made = subtalar neutral, PWB in foam box * Company = Eshed Advanced Orthopedics Ltd.   Group 3  Shoe inserts:   * Type = non-supportive * Made = prefabricated * Company = Eshed Advanced Orthopedics Ltd.   14 weeks | Every 2 weeks   * Subjective back pain * Objective back pain (vertebral or paraspinal tenderness, forward flexion restrictions, and sciatica) * Completion of training | * More soft BSO recruits finished training | The use of soft or semi-rigid BSO did not reduce the rates of weight bearing induced back pain in recruits completing basic training. The soft BSO had the best comfort and compliance of the groups.  The use of military packs in this population might decrease the generalization of these results to the civilian population. A study comparing the soft custom BSO to no BSO, with a larger sample, might be beneficial (per protocol analysis, soft 9.3% and placebo 18.9%). |
| Franklyn-Miller A, Wilson C, Bilzon J, McCrory P.  Am J Sports Med.  2011 | Foot orthoses in the prevention of injury in initial military training. | To determine the effect of BSO fabricated by the D3D system on injury rates during BMT.  RCT | N = 400 Britannia Royal Naval College cadets identified as medium to high risk (Experimental = 200, age: 24.75, mass: 77.2 kg, M:F 68:32; Control = 200, age: 24.9, 79.2 kg, M:F 62:38) | Pressure Plate Protocol:   * Barefoot * Walking trials * Running trials * Low, medium, or high risk   Custom made BSO:   * Type = soft/foam * Made = modular injected-molded * Company = D3D   7 weeks | * Lower limb overuse (>2 more days out of PT)- anterior knee pain, iliotibial band syndrome, patellofemoral pain syndrome, medial tibial stress syndrome, chronic exertional compartment syndrome, Achilles tendinopathy, or plantar fasciitis * Other adverse events (blisters) | Intention-to-Treat analysis:   * Reduction in lower extremity injuries * Lower number of injuries per training hour | The use of pressure plate analysis and D3D orthoses reduce lower extremity injuries in the BRNC population during the initial training phase.  This type of intervention could be harder to implement due to cost of equipment and orthoses ($73). The results might not be able to be generalized to infantry populations due to different training. |
| Ekenman I, Milgrom C, Finestone A, Begin M, Olin C, Arndt T, Burr D.  Am J Sports Med.  2002 | The Role of Biomechanical Shoe Orthoses in Tibial Stress Fracture Prevention. | To examine tibial strains and strain rates during walking and running with various orthoses and footwear.  Randomized Controlled Laboratory Study | N = 9 physically fit special forces Swedish Police officers  Age: range 26 to 40  Weight: range 67 to 96 kg | 1st custom made BSO:   * Type = semi-rigid * Made = subtalar neutral casts * Company = Langer Biomechanics Group   2nd custom made BSO:   * Type = soft * Made = subtalar neutral casts * Company = Eshed Advanced Orthopedics Ltd.   Running shoes:   * Nike Air Max   Military boots:   * Israeli army infantry boots | In Vivo Strain Measurements   * Peak to peak maximum tension strain rates * Peak to peak max compression strain rates * Maximum tension strain rate * Maximum compression strain rate | * Higher peak to peak strains during walking in boots compared to running shoes * Reduced peak to peak strains during walking with soft BSO and semi-rigid BSO in boots compared to boots alone * Reduced tension and compression strain rates during walking with soft BSO in boots compared to boots alone * Increased peak to peak strain during running with semi-rigid BSO in boots compared to boots alone | Both types of BSO may reduce tibial stress fractures secondary to diminished peak to peak strain rates during walking with military boots. The soft custom seems to provide the same benefits during walking with boots without the potential adverse affects of semi-rigid during running.  The authors performed this study of trained, healthy individuals which might not yield the same results as untrained persons. The sample size was also small and some of the gauges malfunctioned during the procedures. |
| Finestone A, Novack V, Farfel A, Berg A, Amir H, Milgrom C.  Foot Ankle Int.  2004 | A prospective study of the effect of foot orthoses composition and fabrication on comfort and the incidence of overuse injuries. | To determine the effect of different kinds of BSO on incidence of overuse injuries and comfort during BMT.  Prospective RCT | Part 1:  N = 451 male Israeli recruits (Group 1 = 227, Group 2 = 224)  Mean age = 18.74  Part 2  N = 423 male Israeli recruits (Group 3 = 215, Group 4 = 208)  Mean age = 18.91 | Group 1  Custom made BSO:   * Type = soft * Made = subtalar neutral casts, foam impression * Company = Tafnit Orthopaedics   Group 2  Prefabricated Orthoses:   * Type = soft * Made = prefabricated * Company = Tafnit Orthopaedics   Group 3  Custom made BSO:   * Type = semi-rigid * Made = subtalar neutral, cam milling machine * Company = ComfortFit   Group 4  Prefabricated Orthoses:   * Type = semi-rigid * Made = prefabricated * Company = ComfortFit   14 weeks | * Acceptance rates * Comfort scores * Incidence of stress fractures, ankle sprains, or foot problems | * Lower amount of recruits finished training in the soft prefabricated group * Lower comfort scores in the soft prefabricated group * Of the recruits that completed training with assigned orthoses, soft orthoses had overall higher comfort scores | There were no differences between injury incidences for the various types of orthoses. Therefore the use of soft custom orthoses should be used due to increased comfort and acceptance and decreased cost of fabrication compared to semi-rigid.  The study had no true control group from which to compare incidence rates to and information about injury surveillance was not provided. |
| Finestone A, Giladi M, Elad H, Salmon A, Mendelson S, Eldad A, Milgrom C.  Clinical Orthopaedics and Related Research.  1999 | Prevention of stress fractures using custom biomechanical shoe orthoses. | To examine the effects of different types of custom BSO on the incidence of stress fractures during BMT.  RCT | N = 404 Israeli infantry recruits (Group 1 = 132, Group 2 = 128, Group 3 = 126, Group 4 = 18)  Age range: 17.7 to 27.3 | Group 1  Custom made BSO:   * Type = semi-rigid * Made = subtalar neutral casting, orthotist * Company = ProLab Orthotics   Group 2  Custom made BSO:   * Type = soft * Made = subtalar neutral casting, PWB foam box * Company = Eshed Advanced Orthopedics Ltd   Group 3  Shoe inserts:   * Type = non-supportive * Made = prefabricated * Company = Eshed Advanced Orthopedics Ltd.   Group 4  Decided not to wear BSO after randomization  14 weeks | Every 2 weeks   * Incidence of stress fractures * Comfort | * Lower rates of stress fractures in combined BSO groups to no BSO groups * Soft BSO more comfortable than semi-rigid and insoles * Semi-rigid more comfortable than insoles | The use of BSO in the Israeli Army reduces the incidence of stress fractures during initial training. The soft BSO provided the recruits with enhanced comfort without diminishing the preventative quality of the orthoses (soft 10.7% incidence versus semi-rigid 15.7%).  Authors did not look at other lower extremity injuries and there was a high dropout rate. |