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The Risks and Benefits of Running Barefoot or in Minimalist Shoes: A Systematic Review

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THE RISKS AND BENEFITS OF RUNNING BAREFOOT OR IN MINIMALIST SHOES: A SYSTEMATIC REVIEW

by

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A thesis submitted in partial fulfillment of the requirements
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ABSTRACT

The popularity of running barefoot or in minimalist shoes has notably increased in the last decade due to claims of injury prevention, enhanced running efficiency, and improved performance when compared to running in shoes (shod). A systematic review of the literature was performed using the Downs and Black checklist to assess the methodological quality of studies proposing risks or benefits between running barefoot, shod, or in minimalist shoes. The databases Ovid MEDLINE, SPORTDiscus, and CINAHL were searched using keywords or "Booleans" including: "Barefoot", "Running" and "Minimalist," exclusively. All included articles were obtained from peer reviewed journals in the English language with a link to full text and no limit for year of publication. The final selection was made based on inclusion of at least one of the following outcome variables: pain, injury rate, running economy, joint forces, running velocity, electromyography, muscle performance, or edema. Significant results were gathered from identified articles and compared using "Levels of Evidence" by Furlan et al.

Twenty-three publications were identified and rated for quality assessment in September 2013. Out of 27 possible points on the Downs and Black checklist, all articles scored between 13 and 19 points with a mean of 17.4. Evidence from the articles ranged from very limited to moderate. Moderate evidence suggested overall less maximum vertical ground reaction forces, less extension moment and power absorption at the knee, less foot and ankle dorsiflexion at ground contact, less ground contact time, shorter stride length, increased stride frequency (cadence), as well as increased knee flexion at ground contact in barefoot running compared to shod. The low scores from the quality assessment using the Downs and Black checklist indicates that improved methodological quality is necessary to provide strong evidence comparing the

risks and benefits of running barefoot, shod, and in minimalist shoes. The literature between shod, minimalist, and barefoot running is inconclusive. There is limited evidence showing differences in kinematics, kinetics, electromyography, and economy results in minimalist shoes. Thus, an alternative and suitable method to effectively replicate barefoot running has not yet been determined.

DEDICATION

For those who have experienced running-related injuries while training hard to achieve their highest performance possible,

And especially, for my friends Hosam Bassiouni, Jon Alford, and Michael Wood who each continue to strive for their very best in running and other forms of exercise despite their struggle overcoming previous injuries.

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LIST OF ABBREVIATIONS

The following table describes the significance of different abbreviations used throughout the thesis. The page on which each one is first used is given.

Abbreviation	Meaning	Page
BHS	Barefoot Heelstrike	9
BTS	Barefoot Toestrike	9
EMG	Electromyography	7
FFS	Forefoot Strike	3
GMP	Gross Metabolic Power (W/kg)	19
GRF	Ground Reaction Force (N)	13
HR	Heart Rate (Beats/Minute)	10
MFS	Midfoot Strike	3
MRI	Magnetic Resonance Imaging	11
RER	Respiratory Exchange Ratio	10
RFS	Rearfoot Strike	3
ROM	Range of Motion	10
RPE	Rate of Perceived Exertion (0-10)	10
SHS	Shod Heelstrike	9
VO_2	Oxygen Consumption (mL O_2/kg/min)	10

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INTRODUCTION

Over the last decade, the popularity of running has grown considerably in the United States with over 500,000 people completing a marathon in 2011.[1] While many enjoy running as a recreational activity, others do it to maintain and improve their physical health.[2] This includes improved cardiovascular-pulmonary health, body composition, and overall fitness.[2] Further reasons people gravitate towards this activity may be due to ease of access, low cost, and positive feelings of accomplishment.[3] As running gains popularity, the number of injuries reported has also increased.[4]

The overall incidence of lower extremity injuries due to running varies from 19.4% to 79.3% annually.[4] These injury rates have not declined in the last 30 years despite the considerable efforts to reduce them.[5] It is speculated that the modern running shoe may have a negative effect on foot function despite added cushion and stabilizing features.[6] This may be a probable cause to question the efficacy of modern day running shoes.

Over the last few years barefoot running practices have increased[7] due to claims of injury prevention, enhanced running efficiency, and improved performance.[8-10] Barefoot running advocates emphasize that humans are meant to run on the ground with bare feet since ancestors thousands of year ago did so without high-technology sports shoes that were not invented until the 1970s.[11] Shoes termed "minimalist" have also become popular in recent years and are designed to mimic barefoot running but with added foot protection.[7] Barefoot running has become prominent in popular media, including magazines, journals, websites, and news reports around the country. An author and key advocate of barefoot running, Christopher McDougall, wrote a book titled *Born to Run: A Hidden Tribe, Superathletes, and the Greatest Race the World Has Never Seen*. In his book he describes a personal story about an Indian tribe in Mexico called the Tarahumara. This tribe runs in sandals or barefoot yet they do not experience common running injuries seen in typical runners today. The book became a national bestseller in 2009 and is commonly cited as a primary contributor to the barefoot running movement. Subsequently, a growth in research investigating injury mechanisms, physiology, biomechanics, and performance effects of barefoot running followed.[7]

The literature is ambiguous as to what risks and benefits exist for barefoot running.[7] The literature currently lacks randomized controlled trials to provide sound evidence for barefoot running risks and/or benefits. Additionally, sustaining a running-related injury is multi-factorial, and may result not from shoewear alone, but characteristics such as age and physical shape.[4] Furthermore, there is no single factor such as shoe design that will explain more than a fraction of the injuries.[12] This becomes problematic for physicians and physical therapists trying to give a generalized treatment plan and determine whether the patient should run with or without shoes. In addition, runners looking to transition into barefoot running are not properly guided due to the lack of tested and proven training programs.[10] The purpose of this study is to review the literature on the risks and benefits of running barefoot or in minimalist shoes and assess all qualifying articles for methodological quality using the Downs and Black checklist.

BACKGROUND

Biomechanics and Impact Forces

It is well established in the literature that kinetic and kinematic differences exist between barefoot and shod running.[6,10,11,13-18] Typically, shod runners tend to land with the heel first, which is known as a rearfoot strike (RFS). This may be due to the cushioned, elevated shoe heel that absorbs the impact.[11] In contrast, barefoot runners tend to display a mid foot strike (MFS) or a forefoot strike (FFS), which allows for absorption of collision forces with the ground and avoids excessive pressure on the heel.[11] Despite the cushioned heel in shod runners, barefoot runners landing at the forefoot yield smaller collision forces.[10] In a kinetic analysis of the vertical ground reaction force during these three running strike patterns, it was observed that landing with a RFS results in a defined impact peak upon contact with the surface.[13] Forefoot striking eliminates this impact transient through the loading of the posterior calf musculature.[13] Other key kinetic and kinematic differences unique to forefoot striking include a larger external loading rate,[14] a flatter foot placement at contact,[15] and a more plantarflexed ankle position.[10] Hence, the mechanics of all the joints of the lower extremity are changed during forefoot striking.[13] Further kinetic analysis reveals the moment arms of the vertical and mediolateral ground reaction force are reduced in forefoot striking, which decreases the tendency to evert during RFS.[13] Lastly, observable changes to runner's gait include an increase in cadence, a decrease in stride length, and a decrease in range of motion at the knee, hip, and ankle.[10] There are higher braking and pushing impulses and higher preactivation of the triceps surae in forefoot strike runners.[16] In summary, these findings suggest that impact forces are reduced in forefoot striking.[10]

Running Injuries

The literature suggests that barefoot running may prevent running-related injury.[17-20] One theory supporting this claim is the assumptions that the intrinsic stabilizing muscles of the foot are more developed and stronger in the barefoot condition.[17] These muscles may provide improved foot control and thus, prevent overuse injuries in runners such as stress fractures. The heels on the modern running shoe have been shown to increase joint torques at the hip, knee, and ankle while running, which may contribute to injury.[18] Therefore, running barefoot may eliminate these torques and subsequently decrease muscle and tendon strain, as well as knee injuries due to osteoarthritis.[18] Additionally, wearing shoes decreases the proprioceptive ability of the foot.[19] Plantar tactile receptors function to avoid ankle sprains and falls, and have the enhanced ability to determine foot position when barefoot.[20] Despite the proposed benefits that barefoot running may offer, the evidence that running-related injuries is reduced when running barefoot is inconclusive in the literature.

Running Economy and Performance

Global oxygen consumption and economy differences between barefoot and shod running is disputed in the literature. Frederick et al. explained that for every 100 grams of mass added to the shoe, the volume of oxygen in the body increases by ~1%.[21] Other studies suggest that the additional weight of the shoe is irrelevant and that other significant factors such as barefoot running experience, and shoe construction, that may affect the metabolic cost of barefoot and shod running.[21] However, Franz et al. found no metabolic advantage for barefoot over shod running and foot strike pattern yielded no difference in running economy.[22] Perl and colleagues found running barefoot or in minimalist shoes to be more economical than shod running and reasoned that it was because humans evolved into running barefoot millions of years ago.[22]

Transitioning Program

To our knowledge, there are no studies examining the most effective transitioning program from shod to minimalist or barefoot running. During transition, runners have a greater chance of stress fracture injury due to an increase of weight on the midfoot and forefoot from an absence of shoe heel.[6] It is advised to transition slowly and perform specific exercises aimed at increasing strength of the musculature in the foot before attempting to run without shoes.[6] Runners aiming to start should be aware of the specific environmental conditions that can potentially cause injuries when running without shoes.[7]

METHODOLOGY

<u>Study Design & Search Procedures</u>

A systematic search of the literature was conducted to identify studies that examined running barefoot or in minimalist shoes. The following electronic databases were utilized: Ovid MEDLINE, SPORTDiscus, and CINAHL. Appropriate “Booleans” or keywords included “Barefoot”, “Running” and “Minimalist.” exclusively. All of the articles were obtained from peer reviewed academic journals in the English language with a link to full text and no limit for year of publication. Reviews, commentaries, case studies, and case series were excluded from the review. All studies in which the key words were found in the title or abstract were considered for review. The final selection was made based on inclusion of at least one of the following outcome variables: pain, injury rate, running economy, joint forces, running velocity, electromyography muscle performance, or edema. The remaining articles meeting all criteria were considered for quality assessment.

<u>Instrument</u>

The Downs and Black checklist was used to assess the methodological quality of the literature investigating running barefoot or in minimalist shoes. This checklist has been found to be a valid and reliable tool for assessing non-randomised studies.[23] Determination of the methodological quality of the qualifying studies, may provide insight to physicians, physical therapists and their patients about the potential risks and/or benefits of running barefoot or in minimalist shoes.

The Downs and Black checklist contains 27 items, 26 of which are "yes" or "no" questions that can be used to score up to 26 possible points. The checklist is broken down into the following 5 sub-scales: Reporting (10 items), External validity (3 items), Bias (7 items), Confounding (6 items), and Power (1 item).[23] The last item explains if the study is strong enough to prove a clinically important effect where the probably of the effect being due to chance is less than 5%. This checklist was used to assess past studies proposing the risks and benefits of running barefoot or in minimalist shoes.

Further Data Collection

Significant results (where the probability of a result being due to chance is <5%) under the categories of kinetics, kinematics, EMG, and running economy, were pooled from each of the articles and compared using definitions of 'levels of evidence'[24] (Table 1). This tool guided by Furlan et al.[24], and adapted by Barton et al.[25], was used to compare high and low quality studies. Results range from strong evidence to conflicting evidence.

Table 1: Levels of evidence by Furlan et al.

Level of evidence	Description
Strong evidence	Pooled results derived from three or more studies, including a minimum of two high-quality studies which are statistically homogenous ($p > 0.05$) - may be associated with statistically significant or non-significant pooled result
Moderate evidence	Statistically significant pooled results derived from multiple studies, including at least one high-quality study, which are statistically heterogeneous ($p < 0.05$); or from multiple low-quality studies which are statistically homogenous ($p > 0.05$)
Limited evidence	Results from multiple low-quality studies which are statistically heterogeneous ($p < 0.05$); or from one high-quality study
Very limited evidence	Results from one low-quality study
Conflicting evidence	Pooled results insignificant and derived from multiple studies, regardless of quality, which are statistically heterogeneous ($p < 0.05$, i.e. inconsistent)

RESULTS

An initial search through Ovid Medline (limited to human studies), SPORTDiscus (limited to articles relating to fitness and sports medicine), and CINAHL (limited to nursing and allied health) resulted in 656, 343, and 110 publications, respectively. After applying the inclusion criteria, 23 articles were identified. From which, 16 articles investigated kinetic, 19 investigated kinematic, 6 tested running economy, and 4 compared EMG differences between shod and barefoot running (Table 2).

<u>Characteristics of included studies</u>

All of the included publications were published within the last 14 years with the exception of 1 that is thought to be one of the first to associate running-related injuries and the modern running shoe.[17] Each of the studies utilized human subjects with experience in running ranging from ‘recreational[17]’ to ‘highly trained[26]’, which included running as little as an average of 16km[27], and a maximum of 105km[26] per week. The sample sizes of the studies ranged from 9 to 68 adult male and/or female participants with the exception of two studies that used male and female adolescents.[11,28] Subjects were asked to wear different shoes as part of the intervention. Among all 23 studies, 18 compared barefoot running with shod and/or minimalist shoes, and 5 studies[6,22,27,29,30] compared multiple minimalist shoes with other shod conditions. With the intervention in place, subjects were asked to run on a normal or instrumented treadmill, run or stand on a force plate, or run on their own time and report back 10 weeks later.[6]

Table 2: Characteristics of Included Studies

Table format adopted by Hall et al.

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Willy and Davis 2013	Instrumented treadmill. Speed = set at 3.35 m/s	Male habitually shod heelstrikers that ran ≥10 miles per week	(1) Standard Shoe (Nike Pegasus) (2) Minimalist (Nike Free 3.0)	14	Higher vertical impact peak and loading rate in minimalist runners	No sig. diff. for step length, rate, or foot inclination angle at footstrike between minimalist and shod; minimalist runners had a more dorsiflexed foot and more knee flexion at ground contact; after 10 min. of running, in both footwear conditions, there was a reduced foot inclination, reduced dorsiflexion, and increased knee flexion at footstrike	N/A	N/A
Bonacci et al., 2013	Runway with forceplate. Speed = 4.48 ± 1.6 m/s (mean ± SD)	Highly trained' male and female runners who ran on average 105.3 km per week	(1) Barefoot (2) Nike LunaRacer	22	Barefoot: less patellofemoral joint reaction force and stress; less peak knee extension moment	Barefoot: stride lenther shorter, stride frequency higher; less dorsiflexed at footstrike; less peak knee flexion during stance	N/A	N/A
Mullen and Toby 2013	Treadmill. Speed = increased steadily to 5.36 m/s for boys and 4.2 m/s for girls	Adolescent boys and girls from local track and cross-country teams that averaged 4.08 years of running	(1) Heavy trainers (2) track or cross country flats without spikes (3) Barefoot	12	N/A	Barefoot: shorter stride; lower heel height; lateral movement of the foot increased with speed; FFS increased with speed in this condition; fifth metatarsal was the highest point of contact; in two of the females, the changed speed and footwear had little effect on strike type	N/A	N/A
Olin and Gutierrez 2013	Treadmill. Speed = self-selected pace 9.5 ± 1.3 km/h (mean ± SD)	Male and female runners who ran an average of 20.9 km per week	(1)Barefoot RFS (2) Barefoot FFS (3) Shod RFS	18	Peak tibial shock was higher in BHS than SHS and BHS than BTS; BTS had greatest average shock	Knee flexion angle was higher in BHS than SHS, BTS than BHS, and BTS than SHS; ground contact time was lower in BHS than SHS, BTS than SHS, and BTS than BHS	N/A	Average and peak tibialis ant. Were lower in BHS than SHS, BTS than SHS, and BTS than BHS; average MG muscle activity was higher in BHS than SHS and BTS than SHS

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Almonroeder et al., 2013	Runway with forceplate. Speed between 3.52 and 3.89 m/s	Healthy female runners who ran >10 miles per week	(1) Barefoot RFS (2) Barefoot non-RFS	19	Barefoot: higher Achilles tendon average loading rate	Barefoot: stance time, step length, and estimated steps per mile were not sig diff.	N/A	tibialis anterior muscle activity was smaller during first half of stance for FFS
Sobhani et al., 2013	Treadmill. Speed = set at 9.0km/h	Female runners that ran 2 times per week and at least a 5km run in the past year	(1) Rocker (2) Minimalist (3) Standard running shoe (Dutchy™)	18	N/A	N/A	VO_2 was lower with standard and minimalist shoes vs. rocker; no sig. diff. between VO_2 in minimalist shoe vs. standard shoe; no sig. diff. in RER, HR and RPE across all shoe conditions	N/A
Shih et al., 2013	Treadmill. Speed = set at 9.0km/h	Healthy male habitually shod runners with a heel strike pattern	Barefoot: (1) RFS (2) FFS Shod: (1) RFS (2) FFS	12	No sig. diff. in average and max. loading rate between shod and barefoot; loading rates were higher in heel strikes	No sig. diff. in hip angles upon landing and leg stiffness between shod are barefoot Barefoot: Increased cadence; lower knee angle during for FFS but higher for RFS; smaller ankle angles at landing for both FFS and RFS; higher ankle ROM for both FFS and RFS during stance phase	N/A	Preactivation of rectus femoris, tibialis ant., and gastrocnemius was greatest in FFS, RFS, and FFS between both barefoot and shod conditions, respectively; push off phase yielded no sig. diff. in all muscles observed Barefoot: stance phase activity of biceps femoris and tibialis anterior yielded greater and lesser activity, respectively.

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Ridge et al., 2013	Subjects ran on their own time (outside, treadmills, etc.): 15-30 miles a week for 10 weeks	Male and female 'experienced' recreational runners who ran an aveage of 15-30 miles per week	(1) Minimalist (VFF) (2) Shod	36	Posttraining MRI scores: Increases in bone marrow edema in at least one bone after running in minimalist shoes for 10 weeks. The talus was the most common bone; no sig. diff. in soft tissue scores; 10/19 subjects in the vibram group were classified as "injured" at the end of the study	N/A	N/A	N/A
Hatala et al., 2013	Runway with forceplate. Speed = self selected pace	Male and female Daasanach subjects (Kenya)	Barefoot: (1) FFS (2) RFS (3) MFS	38	Barefoot: FFS reduces magnitude of impact forces compared to RFS	Barefoot: Daasanch subjects primarily RFS at most speeds; running velocity was sig. with strike type	N/A	N/A
Bonacci et al., 2013	Runway with forceplate. Speed = 4.48 ± 1.6 m/s (mean ± SD)	Highly trained' male and female runners who ran on average 105.3 km per week	(1) Barefoot (2) Nike free 3.0 (3) Nike LunaRacer2 (4) Regular shoe	22	Barefoot: decreased peak knee extension and abduction moments; decreased power generation and negative work at the knee; increased power generation and absoprtion in ankle	Barefoot: decreased peak knee flexion during midstance; less dorsiflexed at initial contact; more plantarflexed at toe-off; stride length was shorter and stride frequency was greater compared to all shoes. Minimalist and racing flats came second in these variables	N/A	N/A
Warne and Warringt on 2012	Treadmill. RE: Speed = 11 km/h and 13 km/h VO_{2max}: Speed = 14 km/h at 1% incline	Male runners that ran 6-7 days a week and competed in middle-distance events (800-5000m)	(1) Simulated Barefoot (VFF) (2) Shod	15	N/A	Barefoot: Higher stride frequency vs. shod for both pre and post-tests; FFS most common	Barefoot: during familiarization, RE(VO_2, 11 km/h$VO_{2sub\text{-}max}$, 13 km/h$VO_{2sub\text{-}max}$)improved more than shod; RPE decreased during familiarization; RE was not sig. diff. during pre-test in barefoot	N/A

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Delgado et al., 2012	Treadmill. Speed = self-selected pace	Male and female recreational/expert runners who ran ≥4 times a month	(1) Barefoot RFS (2) Barefoot FFS	43	Barefoot: less shock attenuation for FFS	Barefoot: less lumbar ROM for FFS; lumbar extension no sig. diff.; lesser leg acceleration peak in FFS	N/A	N/A
Williams III et al., 2012	Runway with forceplate. Speed = 3.35 m/s (± 5%)	Male and female 'experienced' runners who ran ≥6 miles per week and ≥3 days per week	(1) Barefoot (2) Shod FFS (3) Shod RFS	20	Barefoot: peak ankle power absorption occurs greatest in FFS compared to RFS; less power absorption at the knee; less overall lower limb power absorption vs. shod RFS	Barefoot: less ankle dorsiflexion compared to shod RFS; No diff. in knee or hip angle at initial contact	N/A	N/A
Franz et al., 2012	Instrumented treadmill. Speed = set at 3.35 m/s	Male runners that ran ≥25 km per week, of that, 8 km per week barefoot or in minimalist shoes for 3 months of the last year	(1-4) Barefoot-0g, 150g, 300g, 450g (5-7) Shod-no added mass, 150g, 300g	12	N/A	Barefoot: smaller stride length	Added mass increased VO_2 whether barefoot or shod; with footwear conditions of equal mass, barefoot demanded more VO_2 and gross metabolic power	N/A
Perl et al., 2012	Standard Treadmill and Instrumented treadmill. Speed = set at 3.0 m/s	Male and female 'experienced' barefoot or minimally shod runners that averaged 33.4 miles per week	(1) Minimalist (VFF)FFS (2) Minimalist (VFF)RFS (3) Shod FFS (4) Shod RFS	15	Minimalist: greater impulse generated by plantar flexors for FFS	The arch underwent more vertical and more overall curvature strain in the FFS vs. RFS Barefoot: less knee flexion between contact and midstance for FFS and RFS	Minimalist shoes were the most economical; changing strike within footwear condition had no sig. effect of economy	N/A

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Hanson et al., 2011	Treadmill: Speed increased every 2 min until exhaustion. Indoor Track: 70% vVO_2	Healthy male and female runners who ran 16 km per week for the last 6 months	(1) Barefoot (2) Shod	10	N/A	N/A	Barefoot: more economical than running with shoes (lower VO_2, HR and RPE) VO_2 and HR during treadmill running and overground running were not sig. diff. between footwear conditions	N/A
Braunstein et al., 2010	Runway with forceplate. Speed = 4.0 ± 0.2 m/s (mean ± SD)	Healthy, 'experienced' male endurance runners who ran 3-4 times per week for the last 5 years	(1) Barefoot on grass (2-6) Shoes on track	14	Barefoot: lower maximum vertical ground reaction force; lower max. knee moments; no sig. diff. of max. ankle moments	Barefoot: larger knee joint angle at phase 3 (40-60% stance); less ground contact time	N/A	N/A
Lieberman et al., 2010	Runway with forceplate. Speed = self selected pace	(1 and 3) US adults, (2) Kenyan adults, (4 and 5) Kenyan adolescents, Adults ran ≥20 km per week	(1) Habitually shod adults (2) Recently shod adults (3) Habitually barefoot adults (4) Barefoot adolescents (5) Shod adolescents	8 per group (1 and 3)	Barefoot: forefoot strikers generate smaller collision forces than shod rearfoot strikers; peak of vertical force 3 times lower than of habitually shod runners that RFS with or without shoes on	Barefoot: habitually barefoot runners FFS more than RFS; Habitually shod RFS with less dorsiflexion Shod: habitually barefoot runners are more likely to RFS compared with when barefoot	N/A	N/A
Kerrigan et al., 2009	Instrumented treadmill. Speed = self selected pace at 3.2 ± 0.4 m/s (mean ± SD)	Male and femal runners who ran ≥15 miles(24.1km) each week	(1) Barefoot (2) Shod (Brooks Adrenaline)	68	Barefoot: decreased peak torques at the knee, hip and ankle; decreased ML GRF and vertical GRF max; increased AP GRF min	Barefoot: shorter stride	N/A	N/A

Study (year)	Design	Subjects	Comparison	Sample size	Kinetic findings	Kinematic findings	Economy findings	EMG findings
Divert et al., 2007	Instrumented treadmill. Speed = set at 3.61 m/s	Healthy male runners with experience in long distance competition running	(1) Barefoot (2-4) Diving socks-50g,150g,350g (5 and 6) 'light' shoe-150g, 'normal' shoe-350g	12	N/A	Barefoot: least contact time; highest stride frequency	No diff. in metabolism and mechanical paramaters between barefoot and 50g diving sock; net efficiency decreased with added mass; no sig diff. between $V0_2$ and leg stiffness	N/A
Divert et al., 2004	Instrumented treadmill. Speed = set at 3.33 m/s	Healthy male and female runners with experience in leisure running	(1) Barefoot (2) Shod	35	Barefoot: lower passive and active vertical force peaks	N/A	N/A	Barefoot: higher pre-activation of plantar flexor muscles (gastrocnemius lat., grastrocnemius med., and soleus); peroneus and tibialis muscles reported no sig. diff. for pre-activation amplitudes
De Wit et al., 1999	Runway with forceplate. Speeds = 3.5, 4.5, and 5.5 m/s	Trained' male long distance runners who ran 30-40 km per week	(1) Barefoot (2) Shod	9	Barefoot: larger loading rate with >1 impact peak; lower peak heel pressure	Barefoot: smaller steps at a higher frequency; impact peak and end of midstance reached faster; smaller initial eversion at impact; more flexed knee at touchdown	N/A	N/A
Robbins and Hanna 1986	Forceplate.	Male and female recreational runners	Barefoot: (1) Pre-training (2) Training (3) De-training	17		Barefoot: 13/18 subjects yielded shortening of the medial longitudinal arch Shod: 10/11 subjects yielded lengthening of the medial longitudinal arch	N/A	N/A

Methodological Quality

With a maximum possible score of 27 points on the Downs and Black checklist, all articles scored between 13 and 19 points with a mean of 17.4 (Table 3). Hence, most studies were considered low in quality. A contributing factor to the low quality of the reviewed studies is the lack of randomised controlled trials comparing barefoot and shod running.

Kinetic Findings

Ground reaction forces

Sixteen of the studies yielded significant kinetic differences between barefoot, shod, and/or minimalist shoes. Seven of these studies comparing ground reaction forces between barefoot, minimalist, and shod running yielded significantly lower maximum vertical ground reaction forces in the barefoot condition,[11,16,18,31-34] while one study yielded higher vertical impact peak in the minimalist condition.[27] Unlike the moderate evidence that suggests there is an association between barefoot running and lowered maximum vertical ground reaction forces, there is limited evidence that suggests lowered maximum vertical ground reaction forces only occur during the barefoot FFS condition.[31,32] Very limited evidence associates decreased medial-lateral and increased anterior-posterior ground reaction forces with the barefoot condition.[18]

Impulse

Very limited evidence correlates minimalist shoes with a greater impulse generated by plantar flexors during a FFS.[22] In addition, very limited evidence suggests any difference in peak vertical or medial-lateral impulses in the barefoot condition.[16]

Table 3: Results of Downs and Black checklist for methodological quality

	A.										B.			C.							D.							
	1) Objective clealy described	2) Main outcomes clearly described	3) Patients clearly described (inclusion/exclusion criteria)	4) Interventions clearly described	5) Distribution of confounders clearly described	6) Main findings clearly described	7) Estimates of the random variability in the data	8) Adverse events due to intervention reported	9) Characteristics of patients lost to follow-up described	10) Actual probability values reported	11) Subjects asked to particpate representative of entire population	12) Subjects prepared to participate representative of entire population	13) Environment representative of the treatment most patients receive	14) Subjects blinded	15) Examiners blinded	16) Data dredging	17) Time adjusted for follow-up of patients	18) Statistical tests appropriate	19) Compliance with the intervention reliable	20) Accurate main outcome measures	21) Subjects recruited from same popualtion	22) Patients recruited over the same time	23) Subjects randomised to intervention groups	24) Randomised intervention concealed from patients and examiners	25) Adequate adjustment for confounding in the analyses	26) Losses of patients to follow-up accounted for	27) Sufficient power to detect clinically important effect	**Total (out of 27)**
Willy and Davis 2013	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**18**
Bonacci et al., 2013	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**18**
Mullen and Toby 2013	1	1	0	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**16**
Olin and Gutierrez 2013	1	1	0	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**16**
Almonroeder et al., 2013	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**18**
Sobhani et al., 2013	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**19**
Shih et al., 2013	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**18**
Ridge et al.,2013	1	1	1	1	1	1	1	0	1	0	0	0	0	0	1	1	1	1	1	1	1	1	1	0	0	1	1	**19**
Hatala et al., 2013	1	1	0	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**16**
Bonacci et al., 2013	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**19**
Warne and Warrington 2012	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**19**
Delgado et al., 2012	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**18**
Williams III et al., 2012	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**18**
Franz et al., 2012	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**18**
Perl et al., 2012	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**18**
Hanson et al., 2011	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**18**
Braunstein et al., 2010	1	1	0	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**18**
Lieberman et al., 2010	0	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**16**
Kerrigan et al., 2009	1	1	0	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**17**
Divert et al., 2007	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**17**
Divert et al., 2004	1	1	0	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	0	1	1	**17**
De Wit et al., 1999	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	1	**17**
Robbins and Hanna 1986	1	1	0	1	0	1	0	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	**13**

Key: 1=Yes; 0=No; A.-Reporting; B.-External Validity; C.-Internal Validity(Bias); D.-Internal Validity(Confounding)

Rate of Loading

Two studies claim there is a significantly higher loading rate in the FFS barefoot condition compared to shod.[34,35] Very limited evidence associates the increased loading rate with the Achilles tendon.[35] Similarly, one study associates a high loading rate in the minimalist condition compared to shod.[27] Finally, very limited evidence suggests that there is no significant difference in average and maximum loading rates between shod and barefoot running, along with higher loading rates in heel strikers.[36]

Joint Moments and Power

Some evidence suggests that there is less extension moment and power absorption at the knee during barefoot versus shod running.[18,26,33,37,38] Similarly, one study associated less patellofemoral joint reaction forces and stress with barefoot running.[26] However, limited evidence suggests that there is increased power generation and absorption at the ankle in the barefoot condition.[37,38] Only one study mentions a significant decrease in ankle and hip moments,[18] while another indicates no significant difference in ankle moments in the barefoot condition.[33]

<u>Kinematic Findings</u>

Foot-Strike Pattern

Seven studies included RFS and FFS into their comparison between barefoot and shod running.[22,31,32,36,38,39] Limited evidence suggests that a FFS is associated with barefoot running.[11,30] One study revealed Kenyan Daasanach subjects primarily RFS when running barefoot at most speeds.[31] Very limited evidence correlates an increase in barefoot running speed with a FFS running condition.[28]

Stride

Moderate evidence suggests barefoot running is associated with increased stride frequency (cadence), shorter stride length, and less ground contact time compared to shod.[18,21,26,28,30,33,34,36,37,39,40] One study found that ground contact time, step length, and estimated steps per mile to be differences between barefoot RFS and FFS insignificant.[35] Very limited evidence suggests a difference in stride length or rate between shod and minimalist shoes.[27]

Joint Range of Motion

Moderate evidence suggests less foot and ankle dorsiflexion at initial contact with the ground in barefoot running compared to shod.[10,26,36-38] A different study found increased dorsiflexion in minimalist runners compared to shod.[27] After 10 minutes of running, dorsiflexion decreased in both shod conditions in the same study.[27] Very limited evidence suggests smaller ankle eversion during ground contact[35] as well as increased ROM during stance phase in barefoot running.[36]

Moderate evidence indicates increased knee flexion at ground contact[6,10,33,34] and less knee flexion during stance phase in the barefoot vs. shod condition.[26,36,37,22] Minimalist running also suggests increased knee flexion at ground contact compared to shod.[27] One study found no significant difference in knee angle at initial contact with the ground.[38]

Running Economy

When comparing subjects running a set speed on an instrumented treadmill and switching between different footwear conditions, one study found barefoot and minimalist running to be more economical (lower relative VO_2, HR and RPE) than running with shoes.[8] In a different study that added weights to the subjects' feet to compare running economy, the barefoot condition demanded more relative VO_2 and GMP compared to shod with equal added mass .[21] In a similar study, there was no difference in economy between barefoot and 50g added to the foot.[40] Interestingly, in both studies net efficiency decreased with added mass to either condition.[21,40]

Two studies revealed a decreased demand in relative VO_2 while subjects wore minimalist shoes compared to shod.[22,30] In one, the demand for oxygen decreased more during a four week transitioning phase into minimalist shoes when compared to the control group.[30] Lastly, no significant difference was found in the respiratory exchange ratio, heart rate, and rate of perceived exertion across multiple shoe conditions in a study looking for differences in minimalist shoes.[29] In summary, very limited evidence supports a difference in running economy(VO_2 or VO_2, RER, RPE, and HR) between barefoot, shod, and minimalist shoes.

Electromyography

Limited evidence suggests peak tibialis anterior muscle activity was lowest in the barefoot FFS condition[35,38,39] One study revealed preactivation of recus femoris, tibialis anterior, and gastrocnemius[37] while another revealed preactivation of gastrocnemius and soleus[16] was greatest in the barefoot FFS and RFS condition over shod FFS and RFS.[16,36] Contrasting evidence reveals no significant difference in tibialis and peroneus muscle preactivation between barefoot and shod.[16] Very limited evidence supports the notion of the average EMG muscle activity in the lower limb to be lowest in Shod RFS than in other conditions.[39]

DISCUSSION

Methodological limitations

The low scores from the quality assessment using the Downs and Black checklist propose that improved methodological quality is necessary to provide strong evidence in kinetic, kinematic, economy, and EMG differences between barefoot, minimalist and shod running. Hence, future studies are warranted to identify potential risks and benefits of barefoot, minimalist, and shod running.

Common attributes were identified in each of the rated articles that yielded low scores. First, each study failed to report all adverse events that may be a consequence of the intervention. Due to the nature of the study, making a comprehensive attempt to measure all adverse events may be impractical. Injuries and other problems that can arise from running barefoot or in minimalist shoes for just the duration of the study vary greatly may be unlikely to happen. Secondly, in the external validity section, subjects asked and prepared to participate were not representative of the entire population. Subjects were not randomly selected and therefore were prone to selection bias. Having a complete list of recreational and/or competitive runners to randomly select from does not exist. Third, the staff, places, and facilities were not representative of the treatment patients normally receive. Since patients can run anywhere and on multiple different surfaces other than treadmills, it is difficult to match an ideal environment for studies to take place. Next, in the internal validity-bias section, subjects and examiners were not blinded except in one case where radiologists were blinded to scoring bone marrow edema after participants ran in minimalist shoes.[6] Since participants know whether or not they are wearing shoes, blinding them in a study may be irrational or at least impractical. Lastly, in the internal validity: confounding section, randomised intervention was not concealed from patients and examiners before recruitment, and there was no adjustment for confounding in the analyses. Concealing of the intervention assignment could have eliminated selection bias after recruitment. Main confounders such as weight, height, etc. were not investigated nor were adjusted for in the discussion of any study.

Other causes contributed to low scores in the methodological quality assessment. First, only ten studies reported actual probability values for their data.[8,18,26,27,29,31,34,36,37,39] Since all of the studies had a relatively small sample size (n between 9 and 68), finding statistically significant results is not as likely than when given a larger sample size. Next, only ten studies randomised subjects to intervention groups.[16,21,22,26,29,36,30,32,33,37] The lack of intervention randomisation from the other studies may cause biomechanical and economical changes between consecutive footwear conditions.[41] Since all studies carried out each intervention on the same day except for two,[6,30] changing from the previous footwear condition to the next may modify results in biomechanics and economy because of fatigue.[41]

There were further limitations to the results of the studies. One limitation across all the studies that used a treadmill was the potential difference in subjects' running strategies and biomechanics between ground and treadmill running.[32] Another limitation involved the lack of extensive familiarization periods[32] across all studies except for one[30] to accommodate the change in potential comfort, proprioception, and natural foot strike between footwear conditions.

Kinetic Differences

Ground Reaction Force

While it is common to believe that the purpose of added cushion put into the modern running shoe is to absorb human body weight safely compared to thin minimalist shoes or barefoot, modern evidence suggests that adding or changing the characteristics of the shoe changes the way runners foot strike and thus experience different ground reaction forces. There is moderate evidence that suggests there is an association between barefoot running and lowered maximum vertical ground reaction forces.[11,16,18,31-34] It is suggested that the decrease in forces is highly associated with the switch from RFS to FFS in the barefoot condition.[11,32] This explains why there is evidence associated specifically with the barefoot FFS condition and decreased maximum vertical ground reaction forces. Lastly, the length and direction of the GRF moment arm may be altered by the geometry of the shoe and the thickness of the foot-ground interface by compression of the midsole.[33]

Foot-strike Pattern

A common claim sometimes misinterpreted in the literature is that a FFS is always associated with barefoot running. Differences in foot-strike pattern can be seen in different running populations. First, One study found that Kenyan Daasanach subjects primarily RFS when running barefoot at most speeds.[31] Second, when comparing kinetic variables in habitually barefoot Kenyans, habitually barefoot Americans, and shod Americans, lower ground reaction forces occured during FFS but not RFS in the barefoot condition.[11,41] This may indicate that foot-strike pattern is a confounding variable when comparing barefoot, shod,[41] and minimalist shoes.

Rate of Loading

It is unclear in the barefoot running literature whether an increased loading rate (as seen in a barefoot FFS) is beneficial to skeletal health regardless of reductions in lower extremity strain.[42] Although barefoot running is associated with reduced impact forces per step as seen before, an increased loading rate per a given distance makes it uncertain whether pathological effects such as stress fractures are more likely to occur.[42]

Impulse

The impulse generated by plantar flexors is seen primarily during a minimalist FFS.[22] Since impulse is derived from ground reaction forces, it may be involved with overuse injuries.[41] More research is needed to further associate impulse with running injuries.[41]

Joint Moments and Power

The lesser extension moment and power absorption at the knee yielded during barefoot running[18,27,33,37,38] may have implications with knee injuries by increasing the length of the GRF moment arm. As a tradeoff to less knee extension, an increase in power generation and absorption at the ankle in barefoot running[37,38] may be associated with ankle overuse injuries such as Achilles tendinopathy.[41]

<u>Kinematic Differences</u>

Stride

An increased stride frequency (cadence), shorter stride length, and less ground contact time associated with barefoot running[18,21,26,28,30,33,34,36,37,39,40] causes the cadence to appear smoother and more flowing compared to shod running. While it is inconclusive as to precise risks and benefits associated with this condition, minor evidence from the literature suggests reducing stride length decreases probability of a stress fracture by 3% to 6%.[42]

Joint Range of Motion

It is assumed that runners adopt a lesser foot and ankle dorsiflexion during barefoot running[10,26,36-38] in order to reduce local pressure underneath the heel.[34] In the shod condition, this local pressure is eliminated by cushioning (along with an elevated heel) which enables runners to land with a dorsiflexed ankle.[11] Increase in ankle plantarflexion moment during running implies an increase in work of the triceps surae muscles.[26]

An increased knee flexion at ground contact[6,11,33,34] and less knee flexion during stance[26,36,37,22] proposes running barefoot may be safer than running in shoes. The smaller knee flexion angle during barefoot running reduces the knee's incoming moment arm.[26] The resultant knee extension moment is therefore lower in the barefoot condition which potentially reduces the stress across the patellofemoral joint and may have therapeutic benefits for runners with knee pain and injury.[26] Shod runners with suspicion to believe that knee pain is coming solely from wearing shoes may benefit from transitioning.

Running Economy

The lower metabolic demand (VO2, HR and RPE) as seen with limited evidence in barefoot and minimalist runners[8] may be explained by the longitudinal arch of the foot permitting more elastic energy storage and recoil.[22] It is suggested that during a FFS, the longitudinal arch stretches until the heel makes contact with the ground, and then it recoils until take off.[22] A RFS however, does not stretch the longitudinal arch until both the rear foot and forefoot make contact with the ground.[22] The foot then recoils until take off as similarly seen in the FFS condition.[22]

Electromyography

The increased activity shown by EMG of the muscles in the lower limb represents an increased load on these muscles.[36] First, Limited evidence suggests peak tibialis anterior muscle activity was lowest in the barefoot FFS condition. Very limited evidence associates preactivation of gastrocnemius and soleus was greatest in the barefoot over shod condition. Different muscle activations seen in the lower limb can potentially determine footstrike pattern. For instance, the tibialis anterior is a primary muscle used in foot dorsiflexion and the triceps surae muscles are used primarily for plantarflexion. The increase in work of these triceps surae muscles during barefoot running may be an explanation for numerous anecdotal reports of calf and Achilles tendon soreness when transitioning to barefoot running.[37] The preactivation of these muscles support the reduction of heel impact observed by switching to the FFS technique.[16]

Clinical Implications

No studies have directly investigated the injury risks associated with barefoot running.[41] However, it has been shown that by changing the foot-ground interface (e.g., shoes, no shoes, heel heights, lateral flares, rocker soles, etc.) changes the kinematics and kinetics of runners in different ways and might also change the direction of the GRF vector, and therefore, the moment arm length of the GRF.[33] Whether this change is beneficial or increases risks depends on the patient. Since high-impact forces are associated with running overuse injuries, there is a range of "very limited" to "moderate evidence" suggesting switching to barefoot running would reduce these injuries. There are several confounding factors (e.g. height, weight, foot size, arch height, etc.) that could potentially affect the GRF vector, where the point of contact is, as well as how the patients' lower limb absorbs the load. While a structurally sound foot may be able to absorb these forces effectively, it is likely that different foot types respond differently to increased forces to the foot.[38] For instance, changing the length and direction of the GRF on the foot could potentially increase risk of injury by applying a force to a bone or muscle that is not normally active during running and is therefore weaker and prone to injury. In one of the studies comparing runners in shod in minimalist shoes, increases in bone marrow edema were found in at least one bone after running in minimalist shoes for 10 weeks.[6] At the end of the study, 10 out of the 19 subjects were classified as "injured."[6] In summary, runners interested in transitioning to barefoot or minimalist running need to do it slowly and cautiously and stop immediately if they experience pain.

It is suggested that running barefoot FFS could potentially prevent or delay degenerative changes in shock absorption compared to shod RFS due to less load placed at the heel.[32] Furthermore, during barefoot running, a well-trained posterior calf musculature can provide perfect cushion for landing. However, it is suggested that excessive training and therefore excessive contraction after landing may cause tendinitis of the Achilles tendon or posterior tibialis.[37]

CONCLUSION

The mechanisms underlying the modification of stride frequency, stride length, foot strike pattern, lower extremity mechanics, and how they relate to running performance and injury are not yet fully understood.[38] Despite all different technologies available, the minimalist shoe designs cannot entirely replicate barefoot running possibly due to differences in mechanics and economy in barefoot running. While research in the area of kinematics and kinetics of barefoot running suggest overall less impact forces, decreased knee extension, increased stride rate, and increased plantarflexion, evidence pertaining to this material ranges from limited to moderate and is therefore inconclusive. Due to this scarce evidence with variable outcomes, no definitive conclusions can be drawn proposing risks or benefits to running barefoot, shod, or in minimalist shoes.

In order to improve research outcomes in this area, improved experimental designs with increased methodological quality is needed to further assess all implications associated with barefoot, minimalist, and shod running. Evidently, the methodological limitations such as blinding and creating an environment representative of one subjects usually run in are difficult and may be impractical due to the nature of these studies.

APPENDIX: DOWNS AND BLACK CHECKLIST

Downs and Black Checklist

ALL CRITERIA	DESCRIPTION OF CRITERIA (with additional explanation as required, determined by consensus of raters)	POSSIBLE
1	Is the hypothesis/aim/objective of the study clearly described? Must be explicit	Yes/No
2	Are the main outcomes to be measured clearly described in the Introduction or Methods section? If the main outcomes are first mentioned in the Results section, the question should be answered no. ALL primary outcomes should be described for YES	Yes/No
3	Are the characteristics of the patients included in the study clearly described? In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given. Single case studies must state source of patient	Yes/No
4	Are the interventions of interest clearly described? Treatments and placebo (where relevant) that are to be compared should be clearly described.	Yes/No
5	Are the distributions of principal confounders in each group of subjects to be compared clearly described? A list of principal confounders is provided. YES = age, severity	Yes/No
6	Are the main findings of the study clearly described? Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions.	Yes/No
7	Does the study provide estimates of the random variability in the data for the main outcomes? In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported	Yes/No
8	Have all important adverse events that may be a consequence of the intervention been reported? This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events (COMPLICATIONS BUT NOT AN INCREASE IN PAIN).	Yes/No
9	Have the characteristics of patients lost to follow-up been described? If not explicit = NO. RETROSPECTIVE – if not described = UTD; if not explicit re: numbers agreeing to participate = NO. Needs to be >85%	Yes/No
10	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	Yes/No
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited? The study must identify the source population for patients and describe how the patients were selected.	Yes/No/UTD
12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited? The proportion of those asked who agreed should be stated.	Yes/No/UTD
13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. Must state type of hospital and country for YES.	Yes/No/UTD
14	Was an attempt made to blind study subjects to the intervention they have received? For studies where the patients would have no way of knowing which intervention they received, this should be answered yes. Retrospective, single group = NO; UTD if > 1 group and blinding not explicitly stated	Yes/No/UTD
15	Was an attempt made to blind those measuring the main outcomes of the intervention? Must be explicit	Yes/No/UTD
16	If any of the results of the study were based on “data dredging”, was this made clear? Any analyses that had not been planned at the outset of the study should be clearly indicated. Retrospective = NO. Prospective	Yes/No/UTD
17	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? Where follow-up was the same for all study patients the answer should yes. Studies where differences in follow-up are ignored should be answered no. Acceptable range 1 yr follow up = 1 month each way; 2 years follow up = 2 months; 3 years follow up = 3months........10years follow up = 10 months	Yes/No/UTD
18	Were the statistical tests used to assess the main outcomes appropriate? The statistical techniques used must be appropriate to the data. If no tests done, but would have been appropriate to do = NO	Yes/No/UTD
19	Was compliance with the intervention/s reliable? Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. Surgical studies will be YES unless procedure not completed.	Yes/No/UTD
20	Were the main outcome measures used accurate (valid and reliable)? Where outcome measures are clearly described, which refer to other work or that demonstrates the outcome measures are accurate = YES. ALL primary outcomes valid and reliable for YES	Yes/No/UTD
21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? Patients for all comparison groups should be selected from the same hospital. The question should be answered UTD for cohort and case control studies	Yes/No/UTD

	where there is no information concerning the source of patients	
22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same time? For a study which does not specify the time period over which patients were recruited, the question should be answered as UTD. Surgical studies must be <10 years for YES, if >10 years then NO	Yes/No/UTD
23	Were study subjects randomised to intervention groups? Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation.	Yes/No/UTD
24	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.	Yes/No/UTD
25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? In nonrandomised studies if the effect of the main confounders was not investigated or no adjustment was made in the final analyses the question should be answered as no. If no significant difference between groups shown then YES	Yes/No/UTD
26	Were losses of patients to follow-up taken into account? If the numbers of patients lost to follow-up are not reported = unable to determine.	Yes/No/UTD
27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance <5% Sample sizes have been calculated to detect a difference of x% and y%.	1-5

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