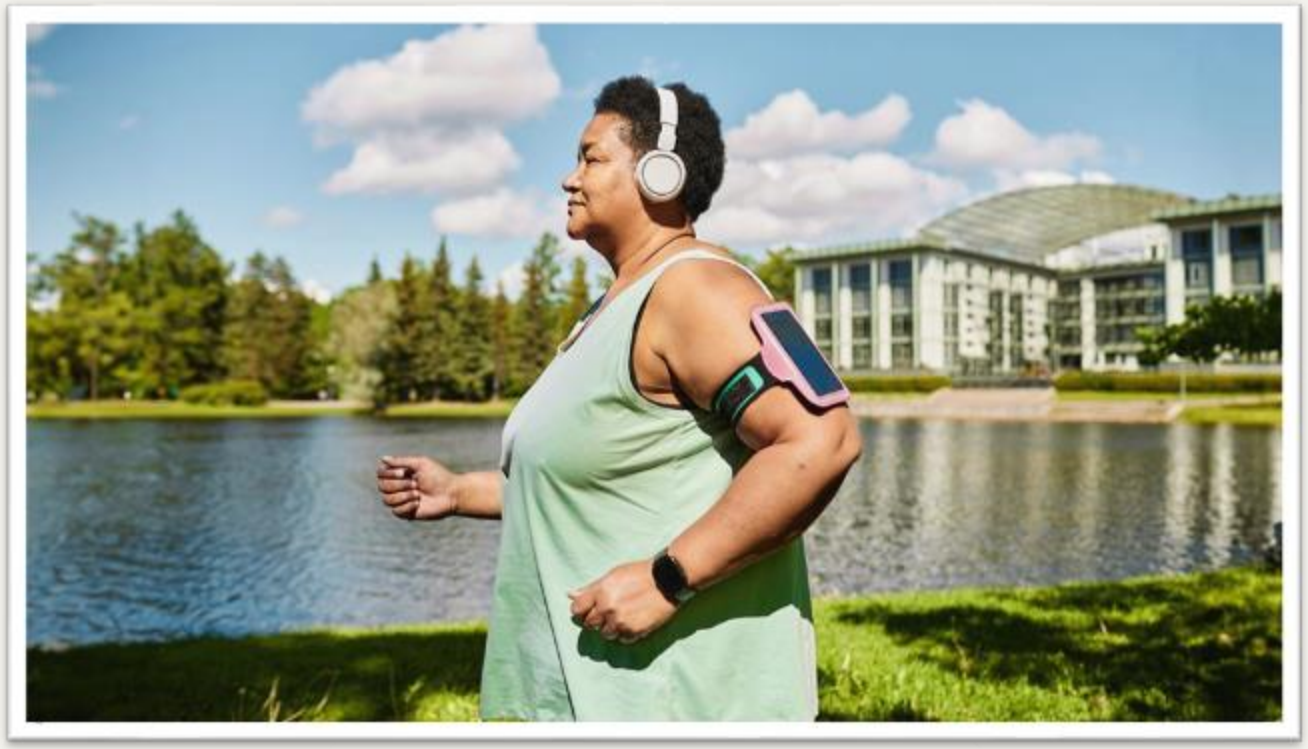

Biophytis®



During the 17th international conference of SCWD SOCIETY ON SARCOPENIA, CACHEXIA & WASTING DISORDERS

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Investor Call

Washington D.C.

December 6th, 2024

Agenda

GLP-1 RA Weight loss therapy-induced muscle loss: A Medical need to explore ?

Moderated by **Rob Van Maanen**
CMO Biophytis

- **Make a life-changing impact for people suffering from obesity**
  Stanislas Veillet - CEO Biophytis

- **The underappreciated role of skeletal muscle in health and disease: implications for weight loss therapies**
  Pr Roger Fielding – Tufts University

- **Effects of Incretin-Based Therapies on Lean and Skeletal Muscle Mass: What's the Clinical Evidence?**
  Pr Marc Andre Cornier – Medical University of South Carolina

- **Muscle Mass and Weight Loss: Implications for Aging Populations**
  Pr William Evans – University of California, Berkeley

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Make a life-changing impact for people suffering from obesity

Stanislas Veillet

CEO Biophytis

Forward Looking Statements

This presentation contains forward-looking statements. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as **«outlook », «believes», «expects», «potential», «continues», «may», «will», «should», «could», «seeks», «predicts», «intends», «trends», «plans», «estimates», «anticipates» or the negative version of these words or other comparable words.** These forward-looking statements include statements regarding Biophytis' anticipated timing for its various BIO101 (20-hydroxyecdysone) clinical trials and expectations regarding commercialization. Such forward-looking statements are based on assumptions that Biophytis considers to be reasonable.

However, there can be no assurance that the statements contained in such forward-looking statements will be verified, which are subject to various risks and uncertainties including, without limitation, delays in patient recruitment or retention, interruptions in sourcing or supply chain, its ability to obtain the necessary regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic on the Company's clinical trials. The forward-looking statements contained in this presentation are also subject to risks not yet known to Biophytis or not currently considered material by Biophytis.

Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. Please refer to the «Risk Factors» section of the Company's 2023 Full Year Financial Report available on BIOPHYTIS website *(www.biophytis.com)* and to the risks discussed in the Company's registration statement on Form F-1 and other reports filed with the Securities and Exchange Commission (the "SEC"). We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

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LIVE HEALTHIER LONGER

A clinical-stage biotechnology company specialized in the development of therapeutics for muscular and metabolic diseases

HQ location: Paris, France
Other locations in Sao Paulo, BR and Cambridge, MA US

Founded:
2006

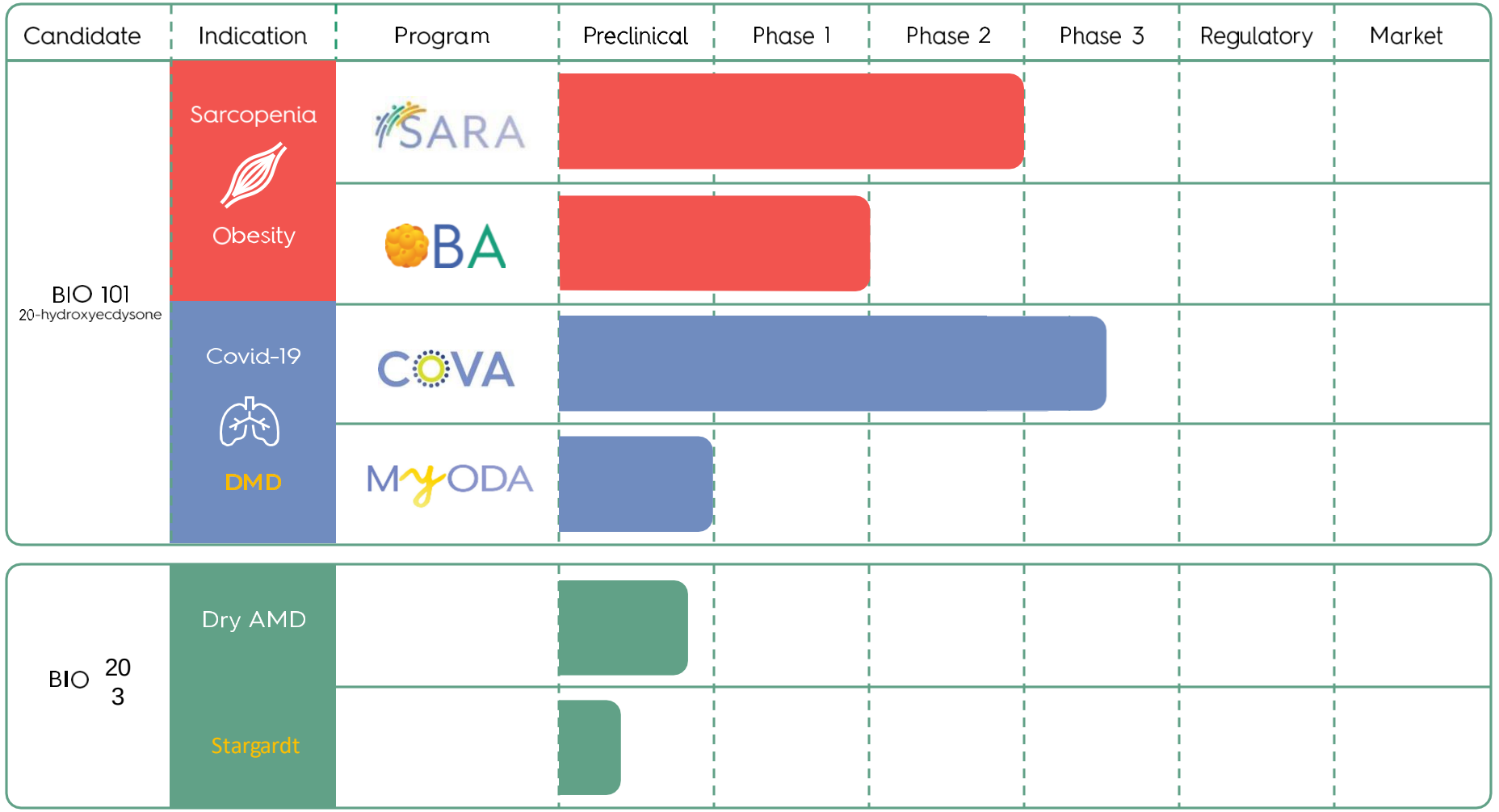
Euronext growth Paris (ALBPS)
OTC market (BPTSY)

Drug discovery: biology of aging for developing drugs for age-related diseases

Multiple partnerships

Academical partnerships	SCIENCES SORBONNE UNIVERSITÉ; MÉDECINE SORBONNE UNIVERSITÉ
Industrial partnerships	eurofins; SEQENS
Pharmaceutical partnership	BLANVER

Our Clinical Pipeline



xxx orphan diseases

BIO101 (20-hydroxyecdysone): First-in-class drug candidate

New molecular target

- Activation of MAS receptor[1] (renin-angiotensin system)
- Regulation of smooth, cardiac and skeletal muscle metabolism
- Stimulation of muscular and respiratory functions

POC & safety in clinical studies

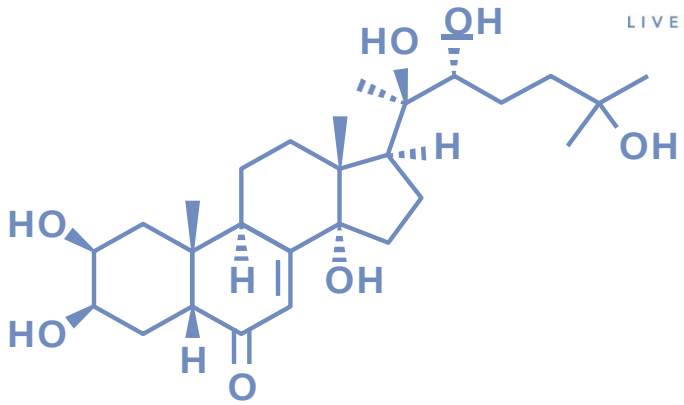
- Clinical studies in healty elderlies and obese adults (Phase 1)
- Clinical study in sarcopenic & obese sarcopenic elderlies (Phase 2)
- Clinical study in severe Covid-19 (Phase 2-3)

Convenient administration & affordable cost

- API manufactured at industrial scale
- Oral with adult and pediatric formulations

Rock-solid IP

- 14 patent families, 44 granted in key countries



BIO101 (20-hydroxyecdysone) activates MAS receptor and triggers downstream two signaling-pathways in myocytes: AKT & AMP

Source : [1] Lafont et al. 2022, doi: 10.1530/JME-21-0033

Muscle wasting associated with pharmacology treatment of obesity: A medical need to explore

Obesity burden

1 **1bn**

Adults and children are currently living with obesity globally.

2 **3x**

The global prevalence of obesity has more than tripled since 1975.

3 **4tn$**

The global cost of treating obesity-related complications is expected to rise by over $4 trillion by 2035.

Medical Need

Total weight loss that comes from muscle when obese patients are treated with GLP-1RA

Up to 40%

« [There is a need to] counter the side effects of dramatic weight loss [induced by GLP-1s]. [Biotechs] are searching whether it is possible for people to lose weight on these GLP-1RA agonists without losing muscle. »

nature biotechnology

Source: World Obesity Federation report: https://www.worldobesity.org/news/economic-impact-of-overweight-and-obesity-to-surpass-4-trillion-by-2035, World Health Organization report: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight, McCarthy et al. Weight Loss Strategies and the Risk of Skeletal Muscle Mass Loss. Nutrients 2021, 13, 2473: https://doi.org/10.3390/nu13072473, After obesity drugs' success, companies rush to preserve skeletal muscle, Nature Biotechnology. 2024 42(3):351-353

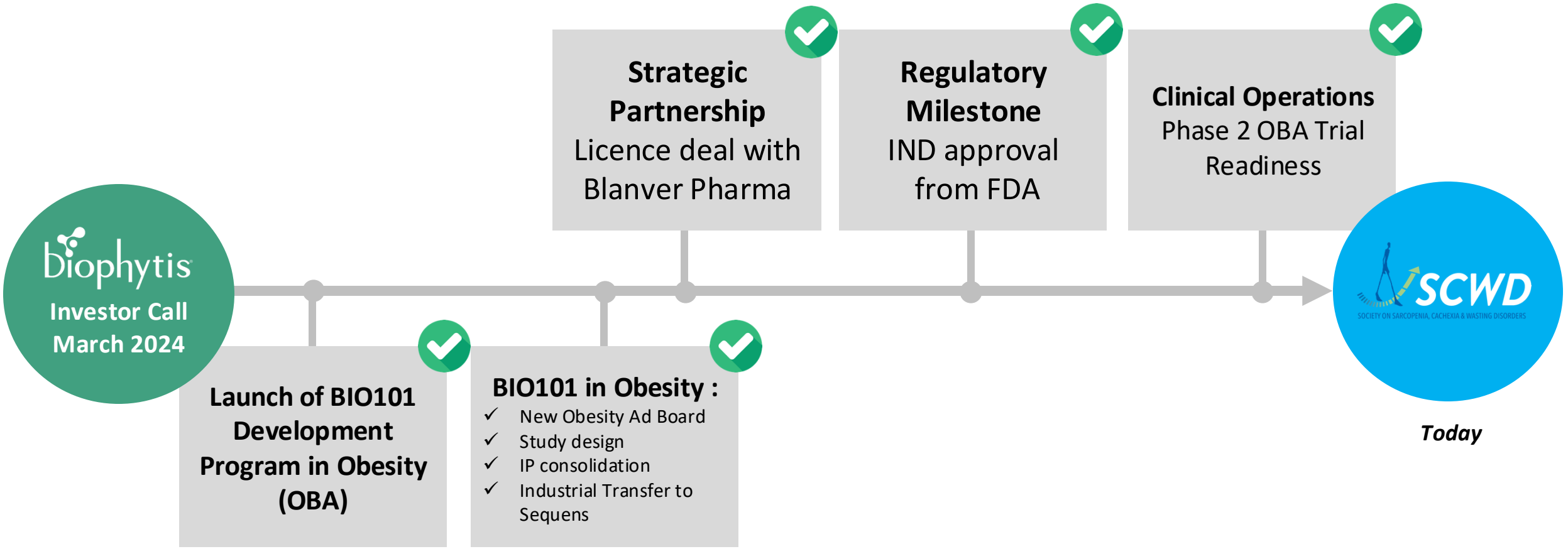
BIO101 is the only muscle agent in development focusing on muscle strength

Drug	Company	Mode of action	Main Endpoints	Safety & Side effects	Administration route	Status
BIO101	Biophytis	MAS Receptor activator	Muscle strength (*knee extension determined by dynamometry)*	BIO101 has been very well tolerated in 277 individuals across multiple clinical studies	oral	Phase 2
Azelaprag	BIOAGE	APJ agonist	% change in overall weight loss	Azelaprag has been very well tolerated in 240+ individuals across multiple clinical studies (5)	oral	Phase 2
Bimagrumab	Lilly Versanis	Activin type II receptor blocker	Changes in body weight, waist circumference, and body composition	Muscle spasms and diarrhea (2)	Intravenous	Phase 2
Enobosarm	veru	Selective Androgen Receptor modulator	Total lean body mass	increased hepatic transaminases, fatigue, hypercalcaemia (1)	oral	Phase 2

There is no drug registered for muscle preservation in obesity

Source: (1) Lancet Oncol 2024; 25: 317–25 (2) JAMA Network Open. 2020;3(10):e2020836. doi:10.1001/jamanetworkopen.2020.20836 (4) DrugBank entry on Trevogrumab (5) https://bioagelabs.com/azelaprag

Key BIO101 development Milestones in Obesity (2024)



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The underappreciated role of skeletal muscle in health and disease: implications for weight loss therapies.

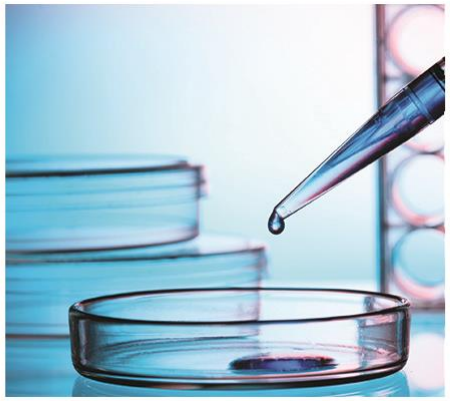
Pr Roger Fielding

PhD
Senior Scientist Metabolism and Basic Biology of Aging Directive
Tufts University

Disclosures

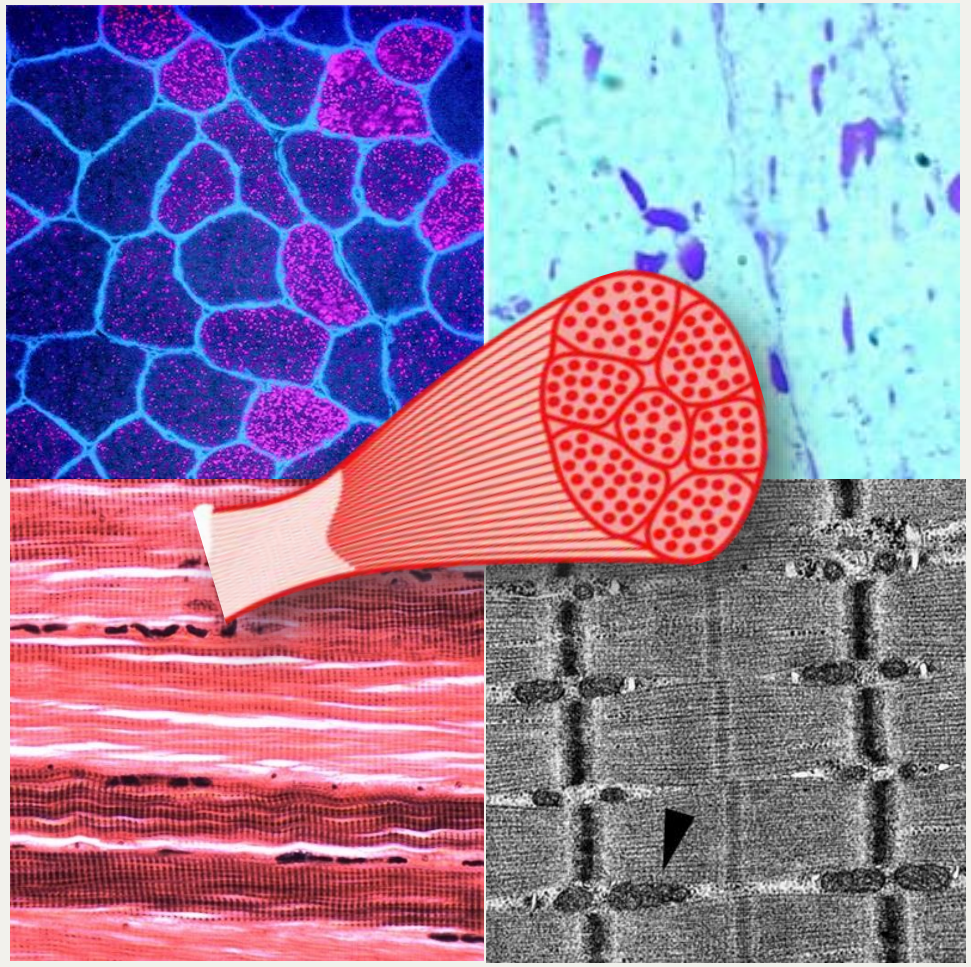
JEAN MAYER USDA HUMAN NUTRITION RESEARCH CENTER ON AGING

HNRCA



- **Consultancies:** Merck, Eli Lilly, Axcella Health, Embion Biophytis, Amazentis, Pfizer, Nestlé' Inc., Rejuvenate Biomed, Epirium Bio.
- **Advisory board memberships:** Cytokinetics, Segterra, Aging in Motion, Ammonett, Biophytis.
- **Grant support:** NIH (NIA, NHLBI, NIDDK), USDA.

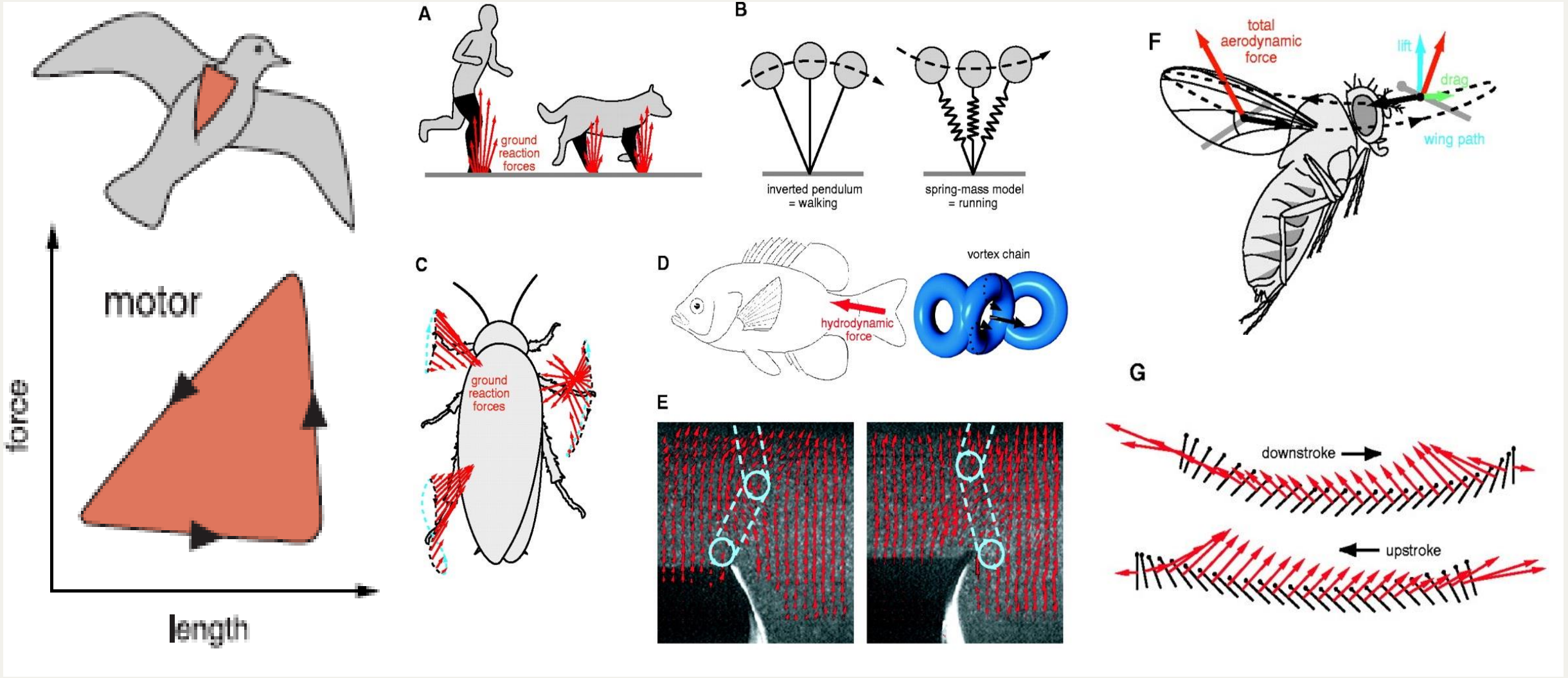
Skeletal Muscle:
an underappreciated tissue in health and disease



- Makes up 45-50% of body mass
- Fundamental role in locomotion,
  O2 consumption, whole-body energy metabolism, and substrate turnover and storage
- Secretory organ (“myokines”)
- Energy utilization can increase 10-fold
- Contractile performance occurs across a wide range of force/power outputs (100-fold) during daily activity
- Maximal Force, Power, and Fatigue are overlapping but distinct physiological properties

Rivas & Fielding. Muscle. Encyclopedia of Human Nutrition (3rd Ed.) 2012

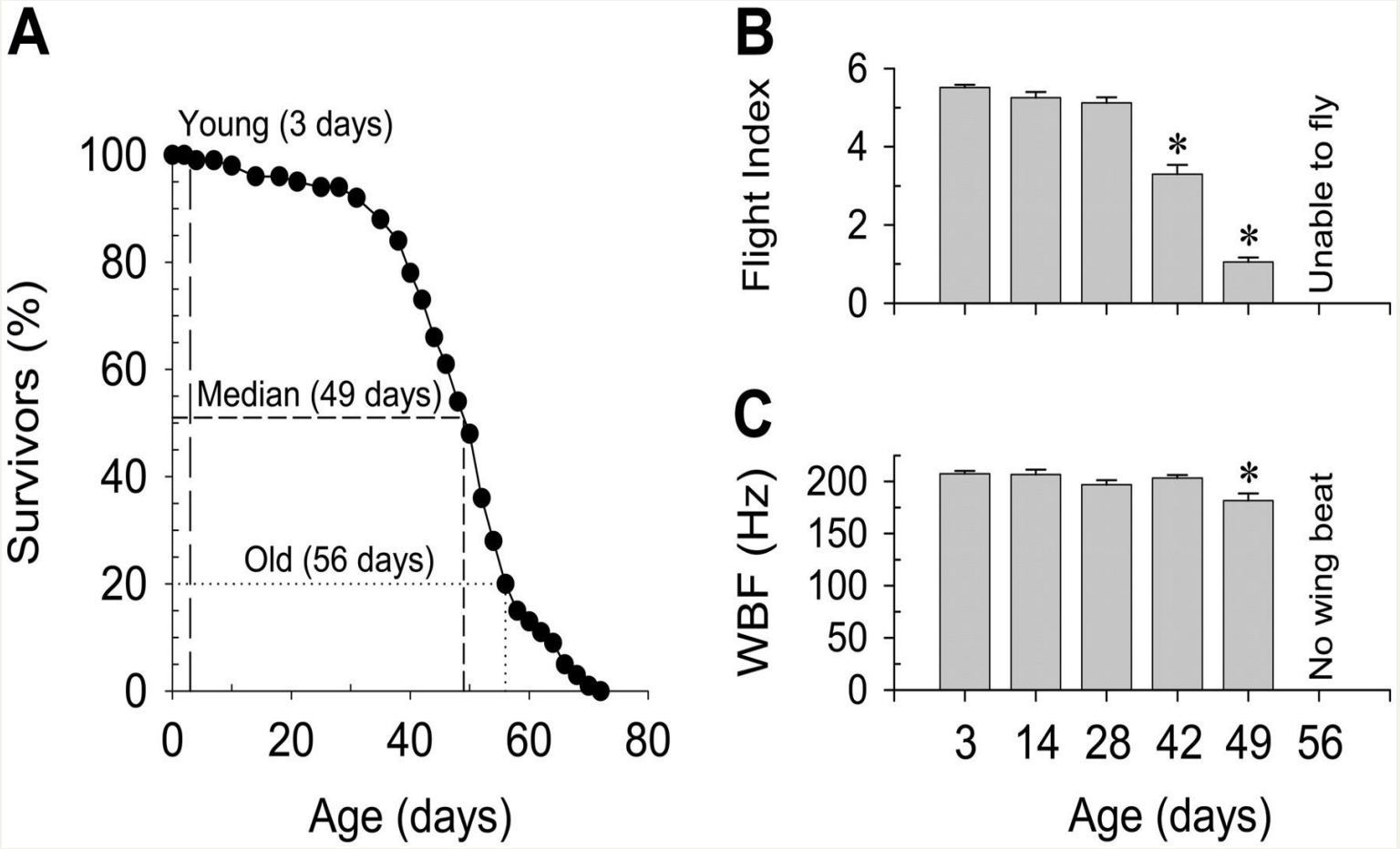
Mobility across species (highly conserved motor proteins)



Dickinson et al. Science 2000;288:5463

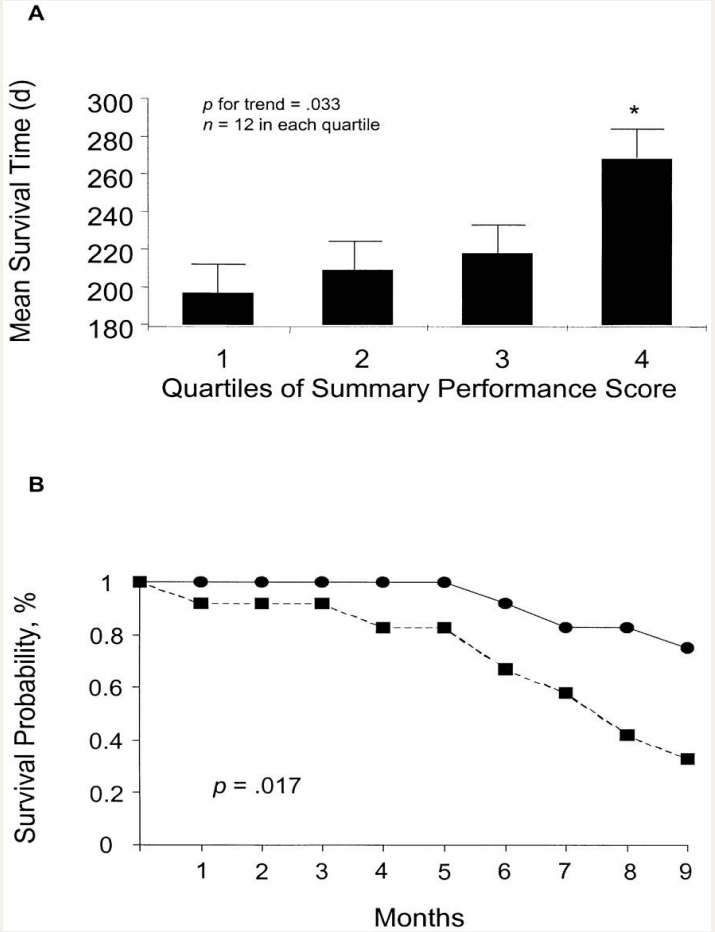
Aging and physical performance

Drosophila



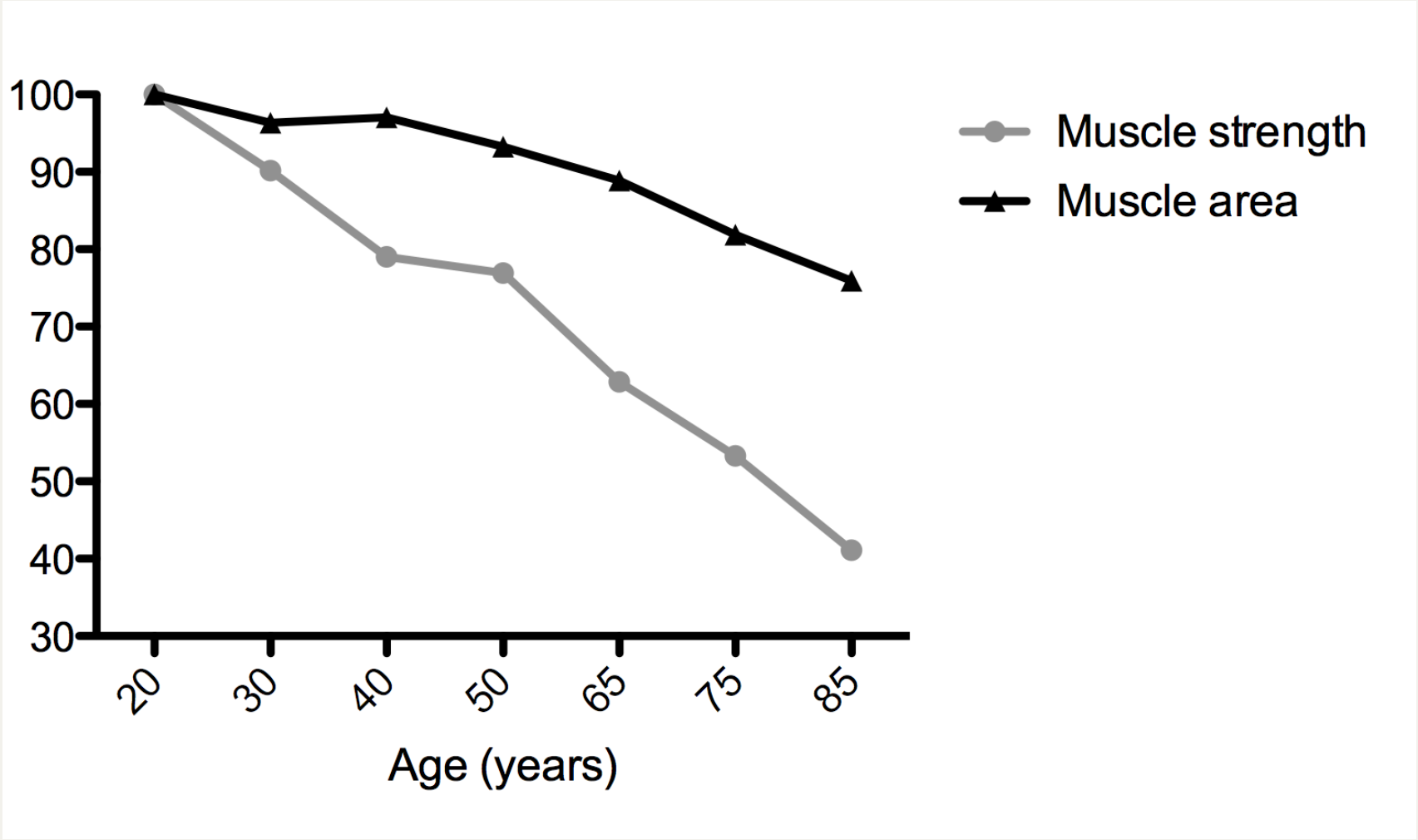
Miller et al. Biophys J 2008;95:2391

Rats



Carter et al. J Gerontol 2002; 57:B193

Age-related loss in muscle size and strength

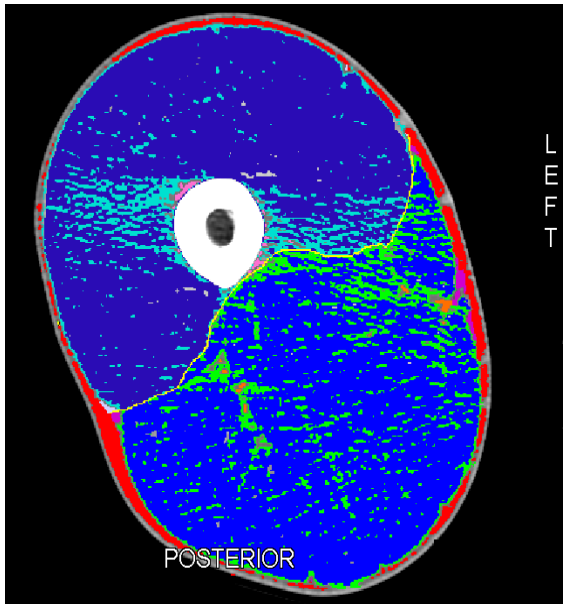


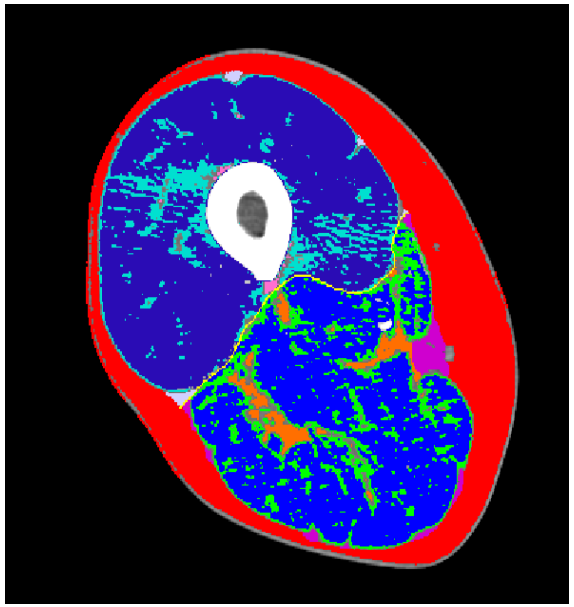
From Lauretani et al. 2003

Sarcopenia:

Age-associated loss in muscle mass and function

Male
43 years
BMI = 25





Male
76 years
BMI = 25

Components:

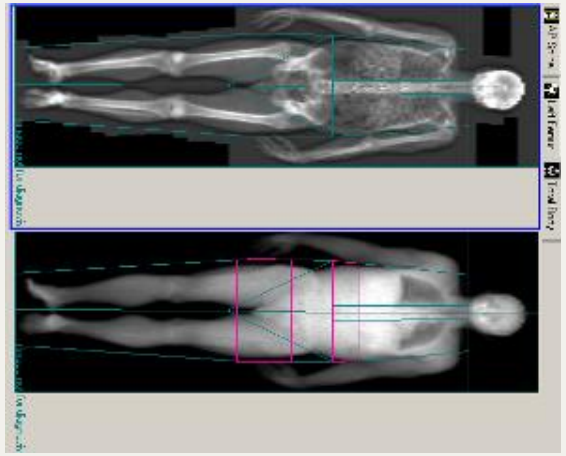
- Muscle mass
- Muscle strength
- Physical performance

"A syndrome characterised by progressive, generalized loss of skeletal muscle mass and strength with the risk of adverse outcomes such as physical disability, poor quality of life and death."

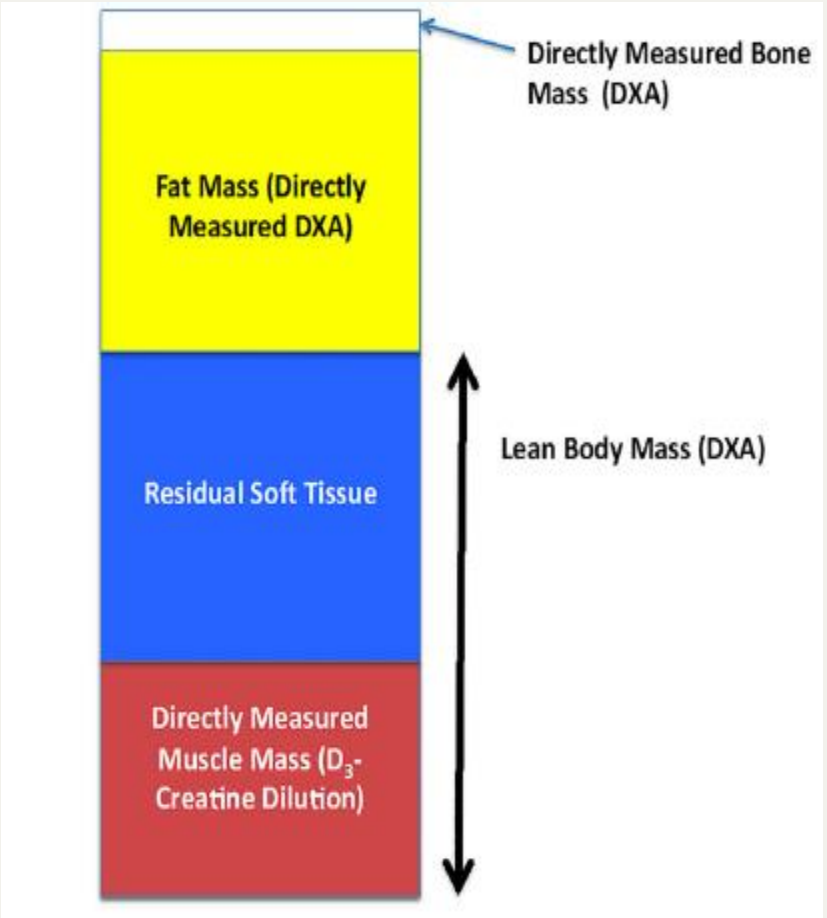
ICD-10 Registration 2016

Muscle Mass is a Component of Total Body Lean Mass

Dual Energy X ray Absorptiometry (DXA)

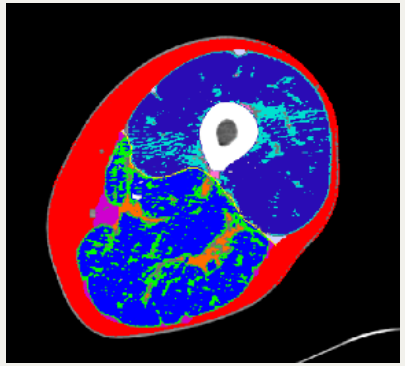


- Based on attenuation of bone mineral free lean tissue (not muscle mass)
- Precision 1-4%
- Radiation (1 mrem; 3 days background)
- Machines are widely available
- Analytical differences across manufacturers and models



Evans et al. J Cachexia Sarcopenia and muscle 2019

Imaging Techniques to Assess Muscle Size



Computed Tomography (C-T)

Measures direct physical property of muscle (e.g.: CSA)

- Precision 1-3%
- Density of muscle area (association with intramyocellular lipid) and subcutaneous and intra-muscular adipose tissue deposition
- Radiation (15mrem)

Magnetic Resonance Imaging (MRI)

- Similar principles of measurement
- Precision 1-3%
- Agreement with C-T (r=0.97-0.99; SEE 5-10%)
- No radiation exposure
- Additional technical complications
- Additional capacity for multiple slice acquisition (3-d volume estimates)
- Higher cost

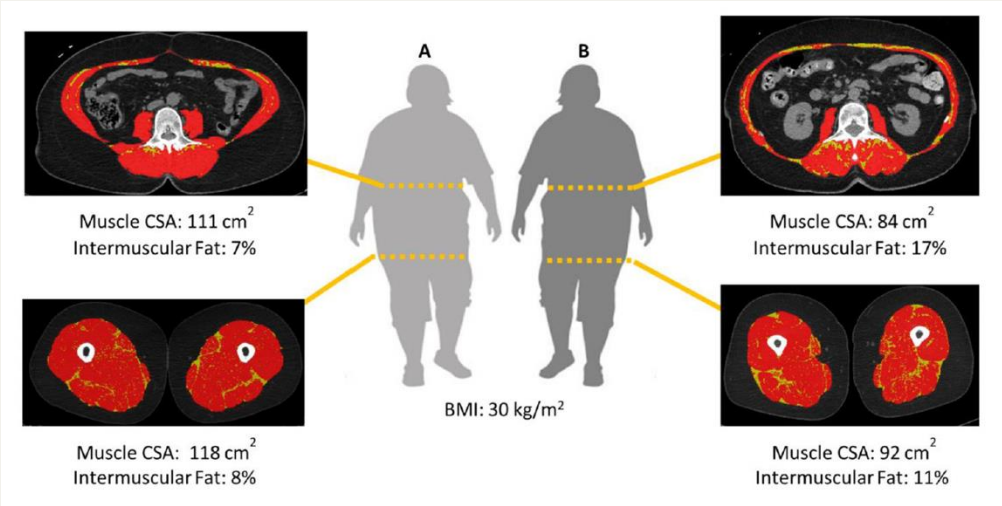
Changes in lean mass with diet-induced weight loss in older adults

	Age	Duration	Weight Loss (Kg)	Lean Mass Loss (Kg)
Villareal, 2006 *166: 860-6, Arch Int Med*	> 65 yrs	6 months	-8.2 ± 5.7	-1.2 ± 2.1
Frimel, 2008 40: 1213-29, *Med Sci Sports Exerc*	> 70 yrs	6 months	-10.7 + 4.5	-3.5 + 2.1
Lambert, 2008 105: 473-8 *J Appl Physiol*	> 65 yrs frail	3 months	-7.5 ± 1.2	-2.9 ± 0.6
Shah, 2008 56: 1157-9 *J Am Geriatr Soc*	65-82	6 months	-9.2 ± 1.6	-3.5 ± 1.0
Villareal, 2011 364: 1218-29, *NEJM*	> 65 yrs	12 months	-9.7 ± 5.4	-3.2 ± 2.0

- Approximately 31% (15-38%) of diet-induced weight loss is lean mass in older adults.
- It is unclear if this decrease in lean mass represents a loss of muscle mass exclusively.

Changes in muscle cross sectional area with diet-induced weight loss in older adults

Effect of Exercise Modality during Weight Loss on Changes in Muscle and Bone Quality in Older Adults with Obesity



Madrid et al. Exp Gerontol 2023

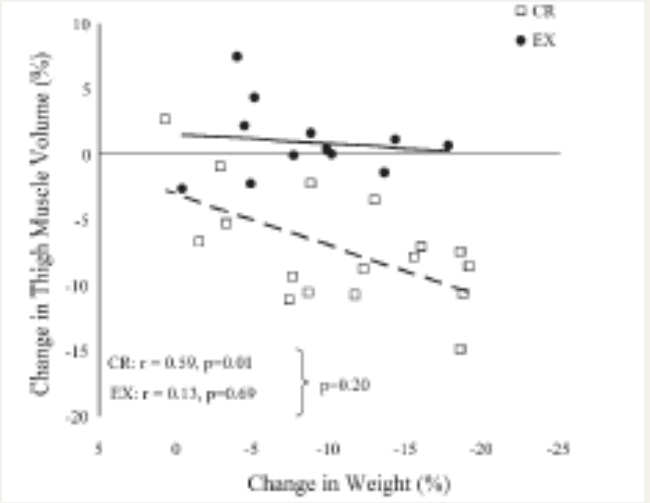
Muscle Cross Sectional Area cm^2	Baseline (n=55)	Weight Loss (n=9)	Weight Loss + AT (n=13)	Weight Loss + RT (n=12)	p-value
Trunk	145.0 ± 39.5				
Change from baseline		-5.24 (-10.54, 0.04)	-8.14 (-12.64, -3.63)	-4.97 (-9.30, -0.63)	0.001
Mid-thigh	124.6 ± 31.2				
Change from baseline		-3.94 (-9.12, 1.25)	-8.8 (-13.11, -4.60)	-0.57 (-5.10, 3.96)	0.006

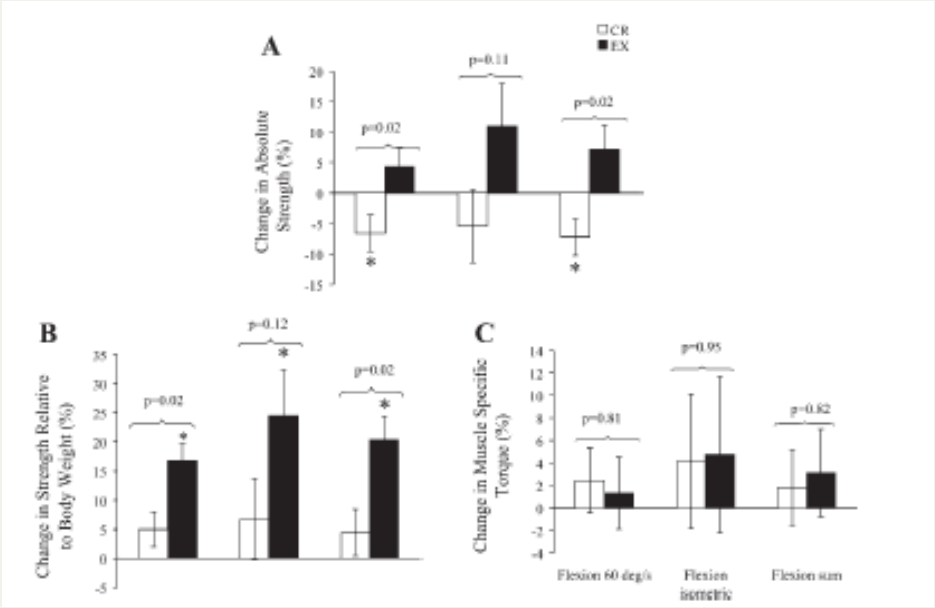
Changes in muscle cross sectional area with diet-induced weight loss in older adults

Effect of Exercise Modality during Weight Loss on Changes in Muscle and Bone Quality in Older Adults with Obesity

Weiss et al. J Appl Physiol 2007

	CR (n=18)	EX (n-16)	Between group P value
Lean Mass kg			
Baseline	49.1 ± 2.4	47.9 ± 2.8	
Final	47.4 ± 2.4	46.8 ± 2.6	
Change from Baseline	-1.6 ± 0.3	-1.2 ± 0.3	0.41
Thigh Muscle CSA cm^2			
Baseline	191 ± 10	190 ± 10	
Final	177 ± 8	192 ± 11	
Change from Baseline	-6.9 ± 0.8	1.0 ± 2.2	<0.0001

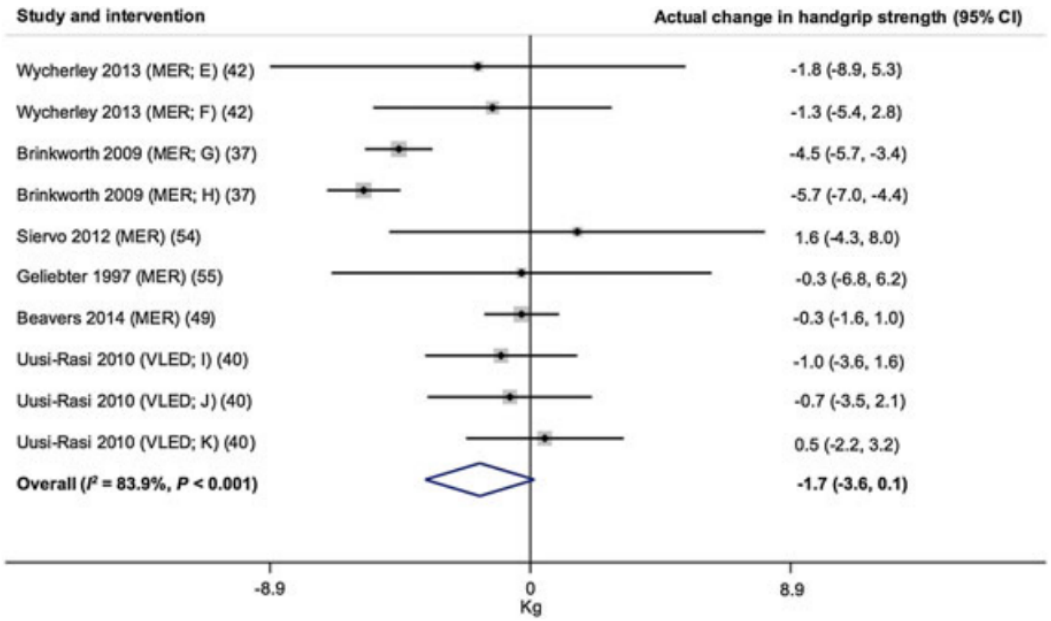




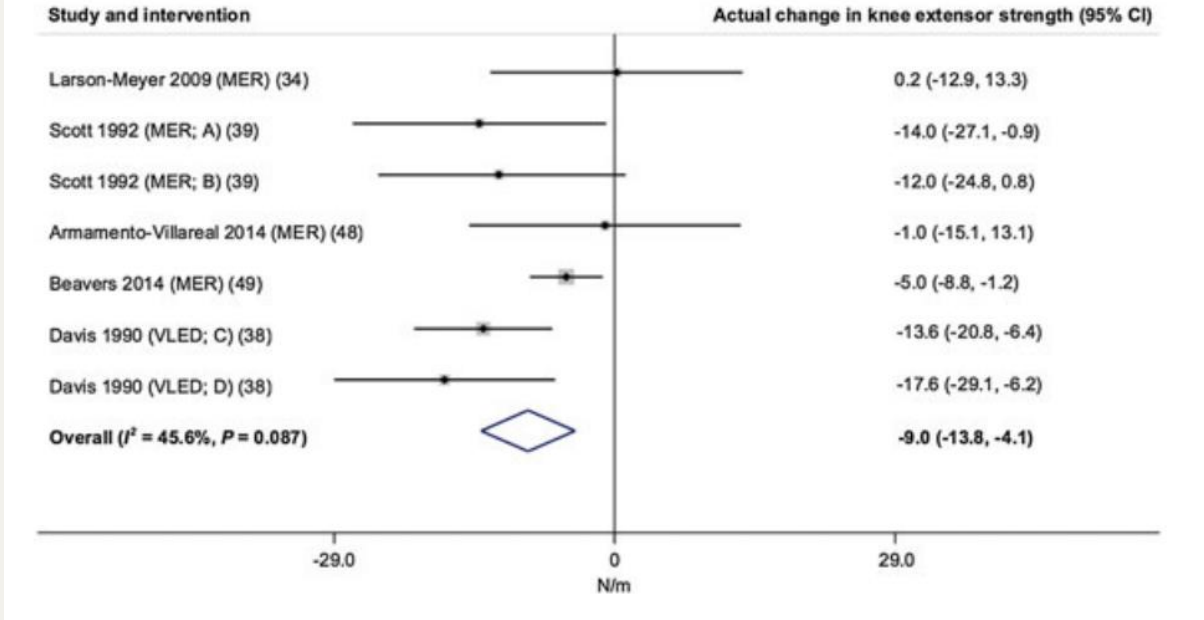
Effect of diet-induced weight loss on muscle strength in adults with overweight or obesity – a systematic review and meta-analysis of clinical trials

J. Zibellini, R. V. Seimon, C. M. Y. Lee, A. A. Gibson, M. S. H. Hsu and A. Sainsbury

Isometric handgrip strength

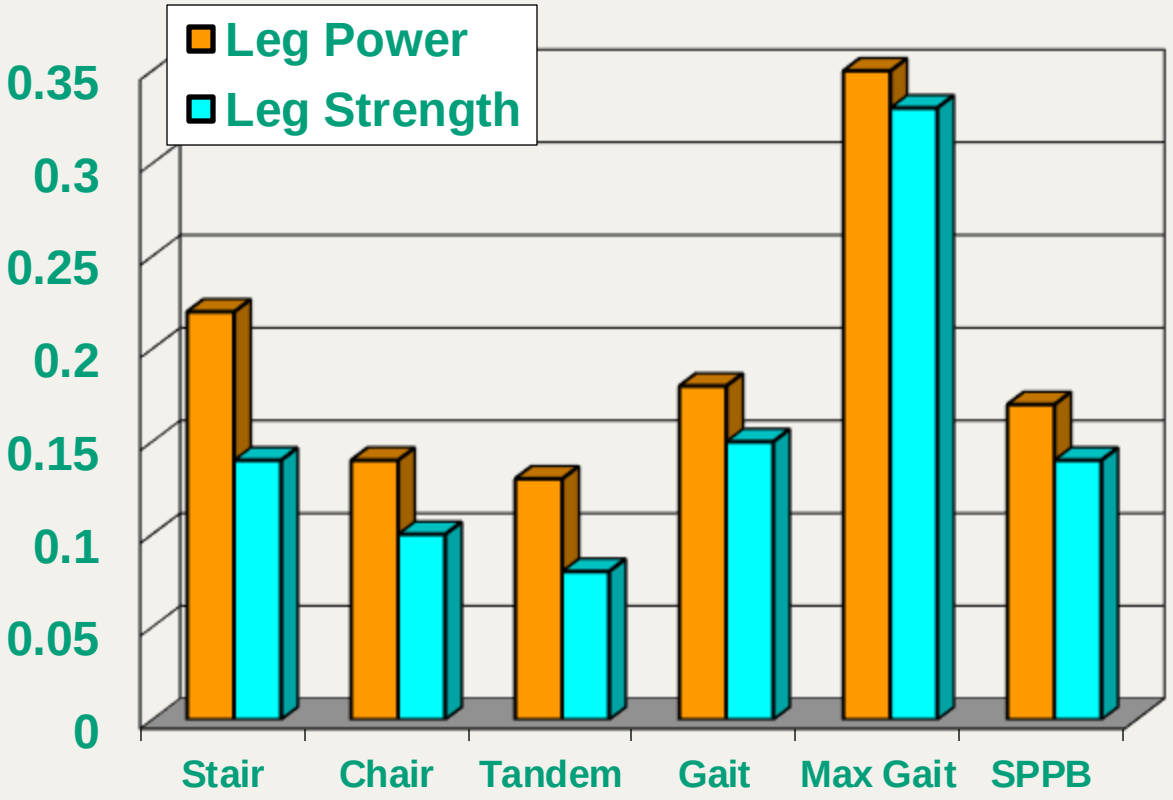


Dynamic knee extensor strength (isokinetic dynamometry)



Obesity Reviews 2016

Muscle function and physical performance



Physical Performance	Coefficient	Standard Error	R^2	P-value
400 meter walk time (n=67)				
Leg Strength	-0.08	0.05	0.05	0.08
Leg Power	-0.19	0.05	0.16	0.001
Habitual Gait (4 m) (n=101)				
Leg Strength	-0.0003	0.000	0.19	<0.001
Leg Power	-0.0006	0.000	0.29	<0.001
Habitual Gait (400 m) (n=101)				
Leg Strength	-0.0003	0.000	0.16	<0.001
Leg Power	-0.0006	0.000	0.26	<0.001

Physical Performance

Multivariate models adjusted for Age, BMI, Gender, Chronic Conditions. (also adjusted for Falls Efficacy with HG)

Bean et al. J Am Geriatr Soc 2002

Sayers et al. Aging Clin Exp Res 2006

Summary

- Skeletal muscle plays a critical role in metabolic balance, insulin action, locomotion, and energy metabolism.
- Muscle function is ubiquitous across species and declines with advancing age.
- Assessments of body composition vary with regard to their ability to detect specific properties of skeletal muscle.
- Short term diet-induced weight loss(8-10%) in older adults induces significant losses of lean mass, muscle size, and strength.
- The effects of diet-induced weight loss on changes in physical functioning in older adults vary and remain poorly understood.

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Effects of Incretin-Based Therapies on Lean and Skeletal Muscle Mass:

What's the Clinical Evidence?

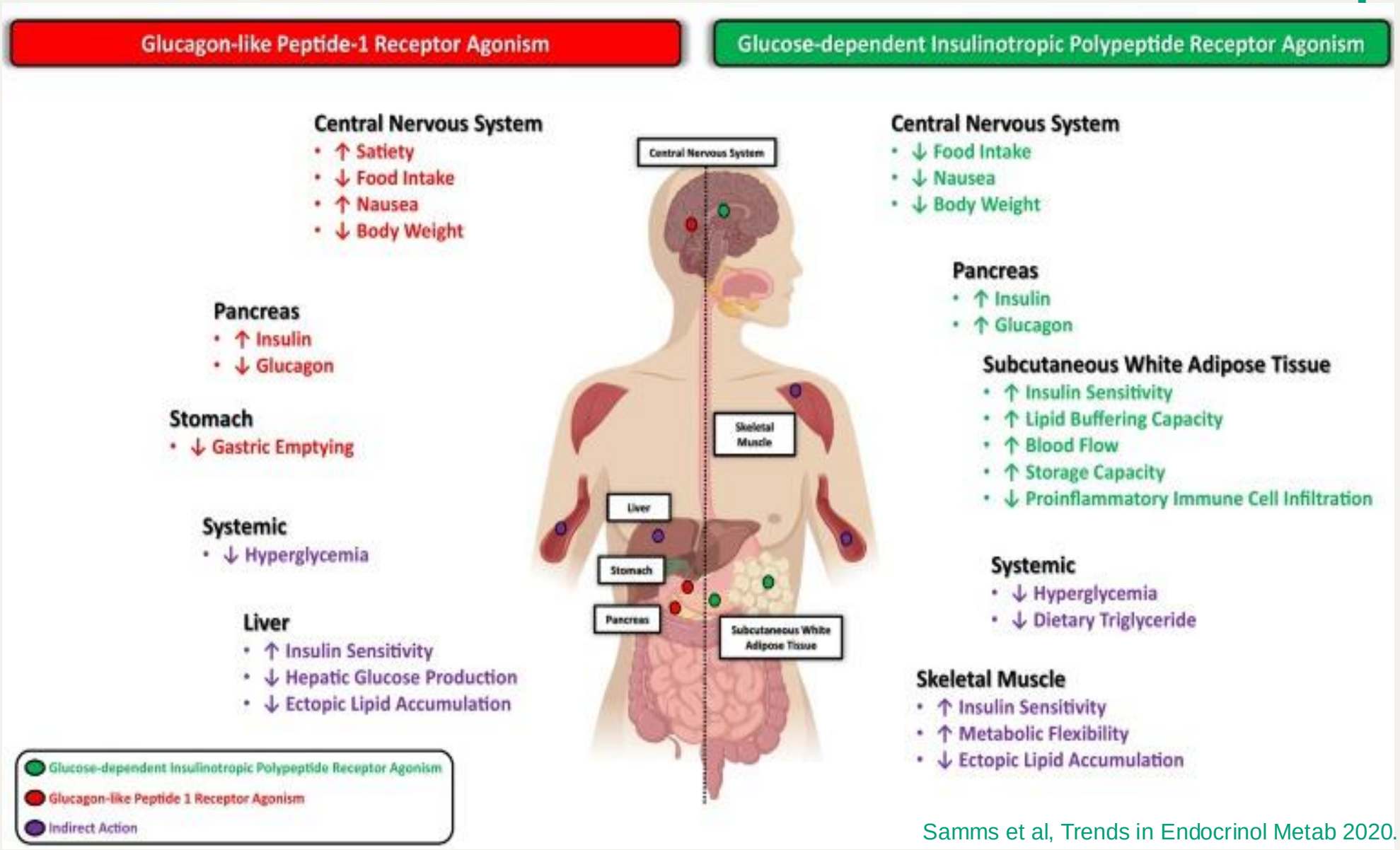
Pr Marc-Andre Cornier

Professor of Medicine
James A. Keating Endowed Chair in Diabetes
Director, Division of Endocrinology, Diabetes & Metabolic Diseases
Medical University of South Carolina

Objectives

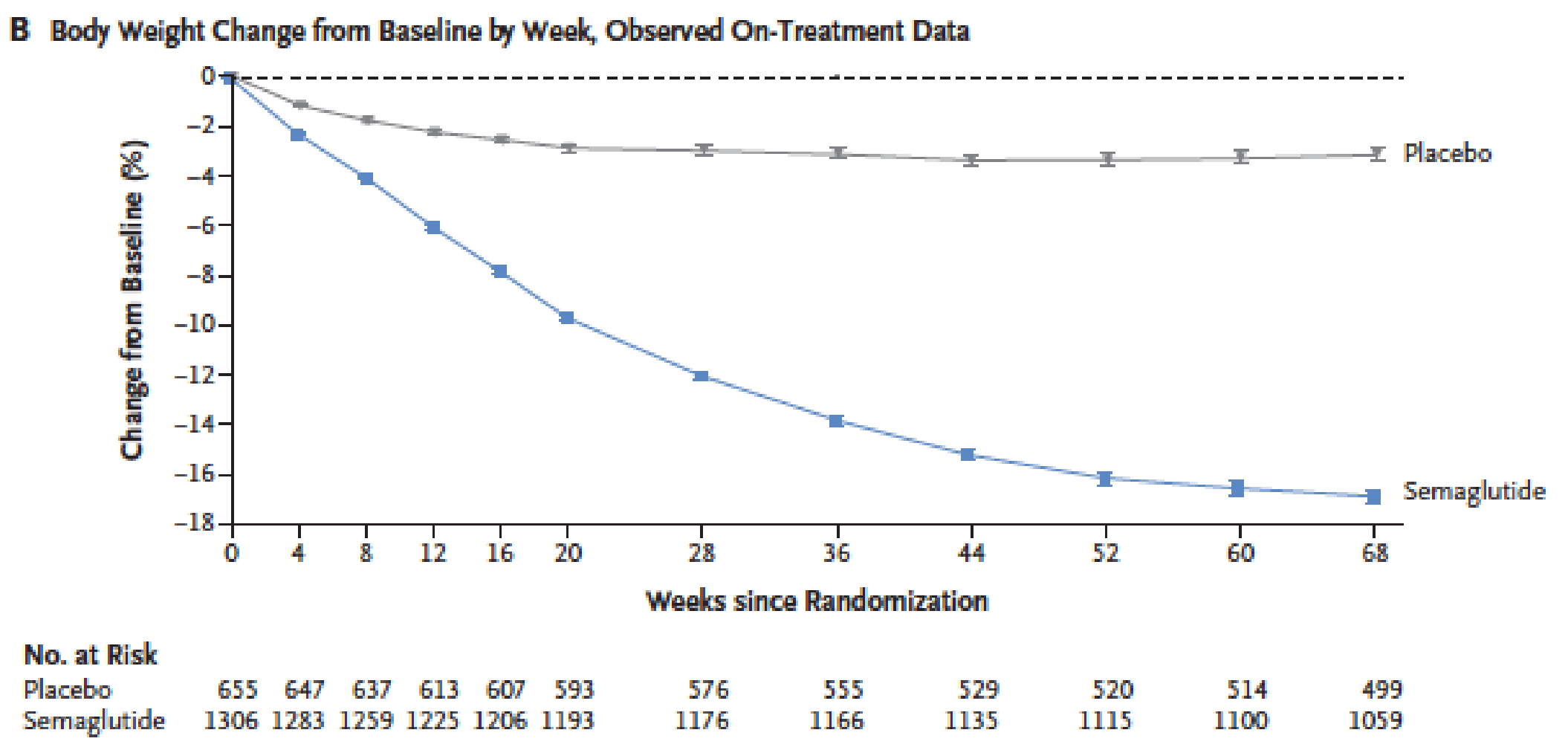
- There is a big unmet need in the medical management of obesity
- Review the data on the effects of incretin-based therapies on weight loss and body composition changes
- Discuss the data on the effects of incretin-based therapies total on metabolic and functional outcomes
- Begin to discuss ways to mitigate these effects

Incretin-Based Therapies - Mechanisms of Action



Samms et al, Trends in Endocrinol Metab 2020.

Once-Weekly Semaglutide in Adults with Overweight or Obesity



Wilding et al, N Engl J Med 2021.

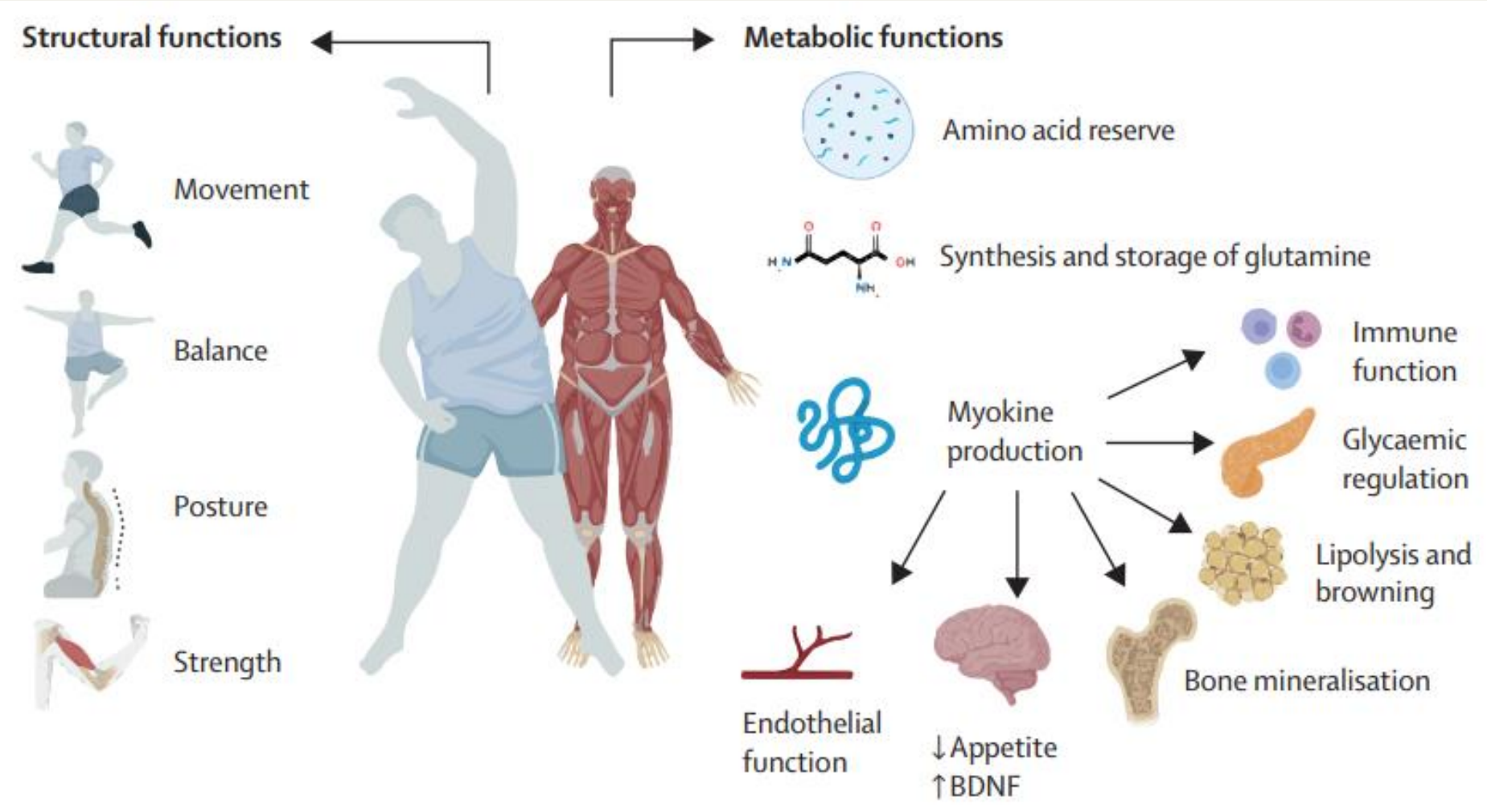
Once-Weekly Semaglutide in Adults with Overweight or Obesity

	Semaglutide 2.4 mg once weekly	Placebo once weekly	Treatment comparison for semaglutide vs. placebo [95% CI]
	N=95	N=45	
Body composition change from baseline to week 68 (DEXA)			
Total fat mass			
Kg change	–8.36	–1.37	ETD: –6.99 [–9.79; –4.19]
Percentage-points change in total fat mass proportion†	–3.48	–0.19	ETD: –3.29 [–4.94; –1.65]
Regional visceral fat mass‡			
Kg change	–0.36	–0.10	ETD: –0.27 [–0.39; –0.15]
Percentage-points change in regional visceral fat mass proportion§	–1.99	–0.01	ETD: –1.98 [–3.69; –0.27]
Total lean body mass			
Kg change	–5.26	–1.83	ETD: –3.43 [–4.74; –2.13]
Percentage-points change in total lean body mass proportion†	3.04	0.09	ETD: 2.94 [1.40; 4.49]

39% of weight loss is lean body mass

Wilding et al, NEJM, 2021.

Roles of Skeletal Muscle as a Structural and Metabolic Organ



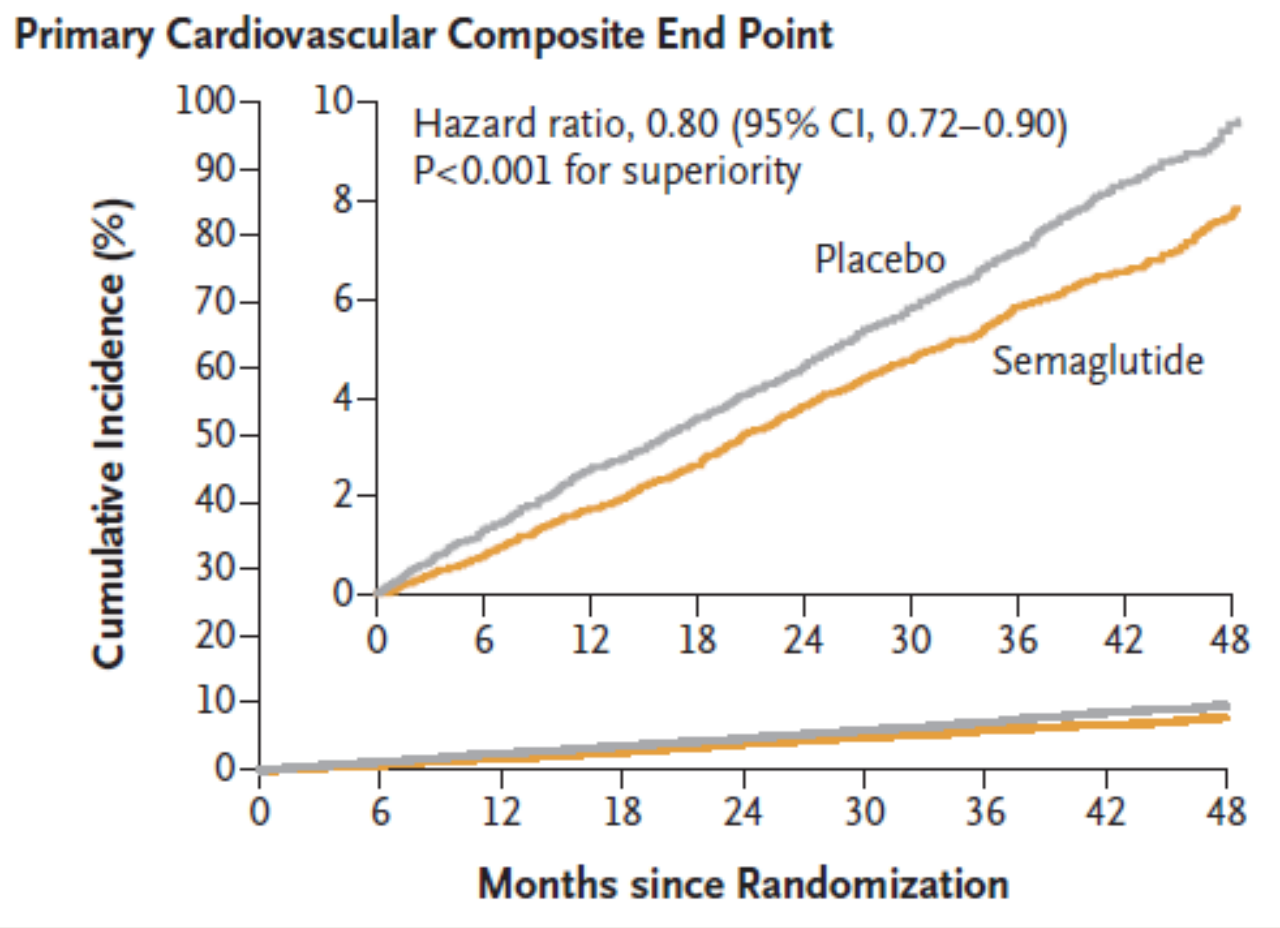
Prado et al, Lancet Diabetes Endocrinol, 2024.

Once-Weekly Semaglutide in Adults with Overweight or Obesity

- **Cardiometabolic Benefits:**
  - **Glycemia**
    - ↓A1c
    - ↓ Fasting Glucose
  - **↓ Blood Pressure**
  - **Lipids**
    - ↓ Triglycerides
    - ↑HDL
    - ↓ LDL
    - ↓ VLDL
    - ↓ Fatty Acids
  - **Inflammation**
    - ↓ C-reactive protein

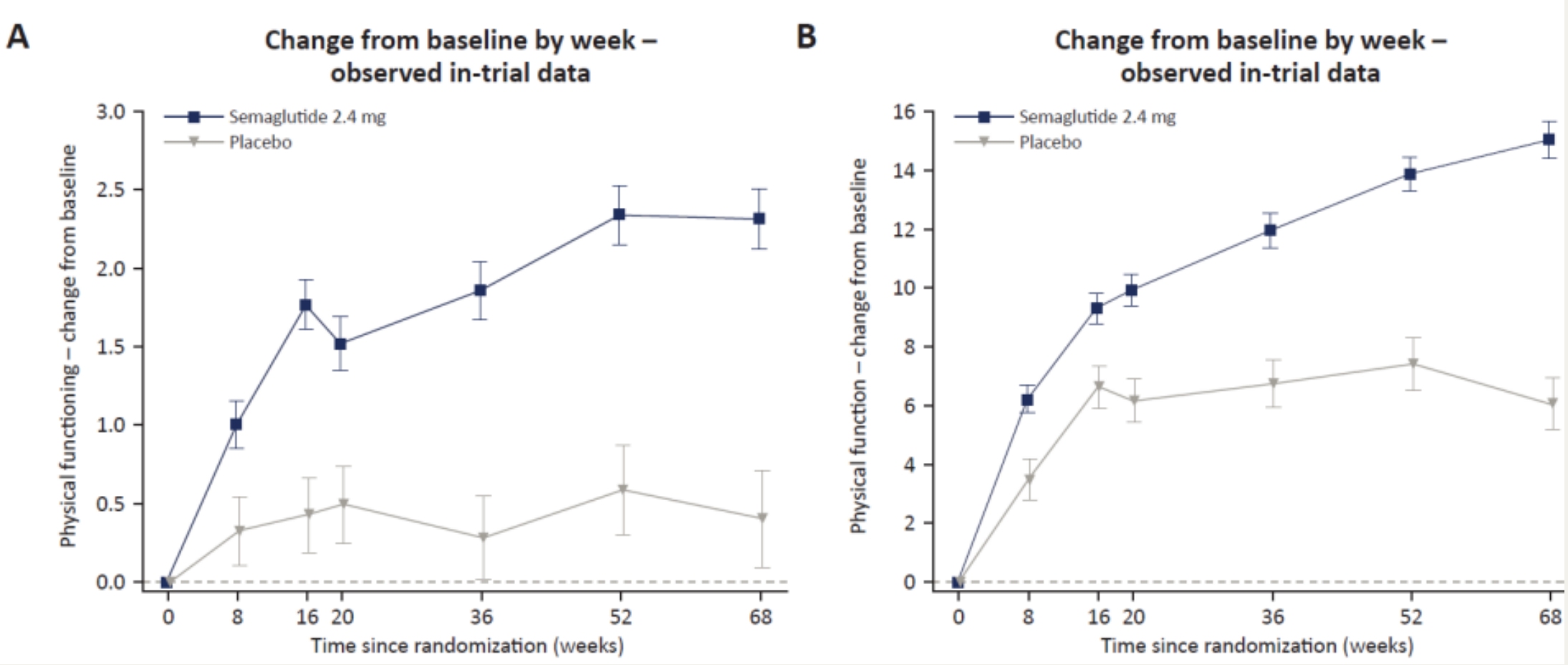
Wilding et al, NEJM 2021.

SELECT Trial: Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes



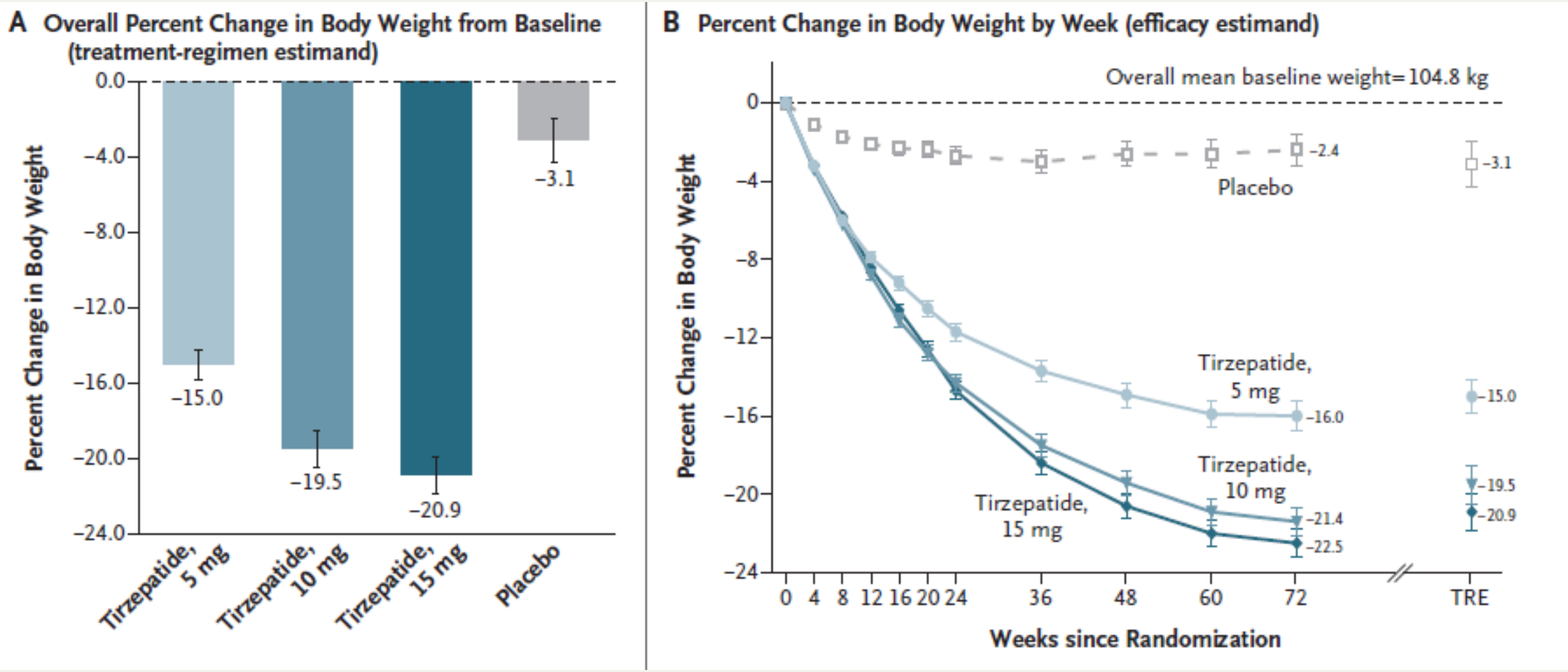
Lincoff et al. NEJM 2023.

Once-Weekly Semaglutide in Adults with Overweight or Obesity – Physical Function



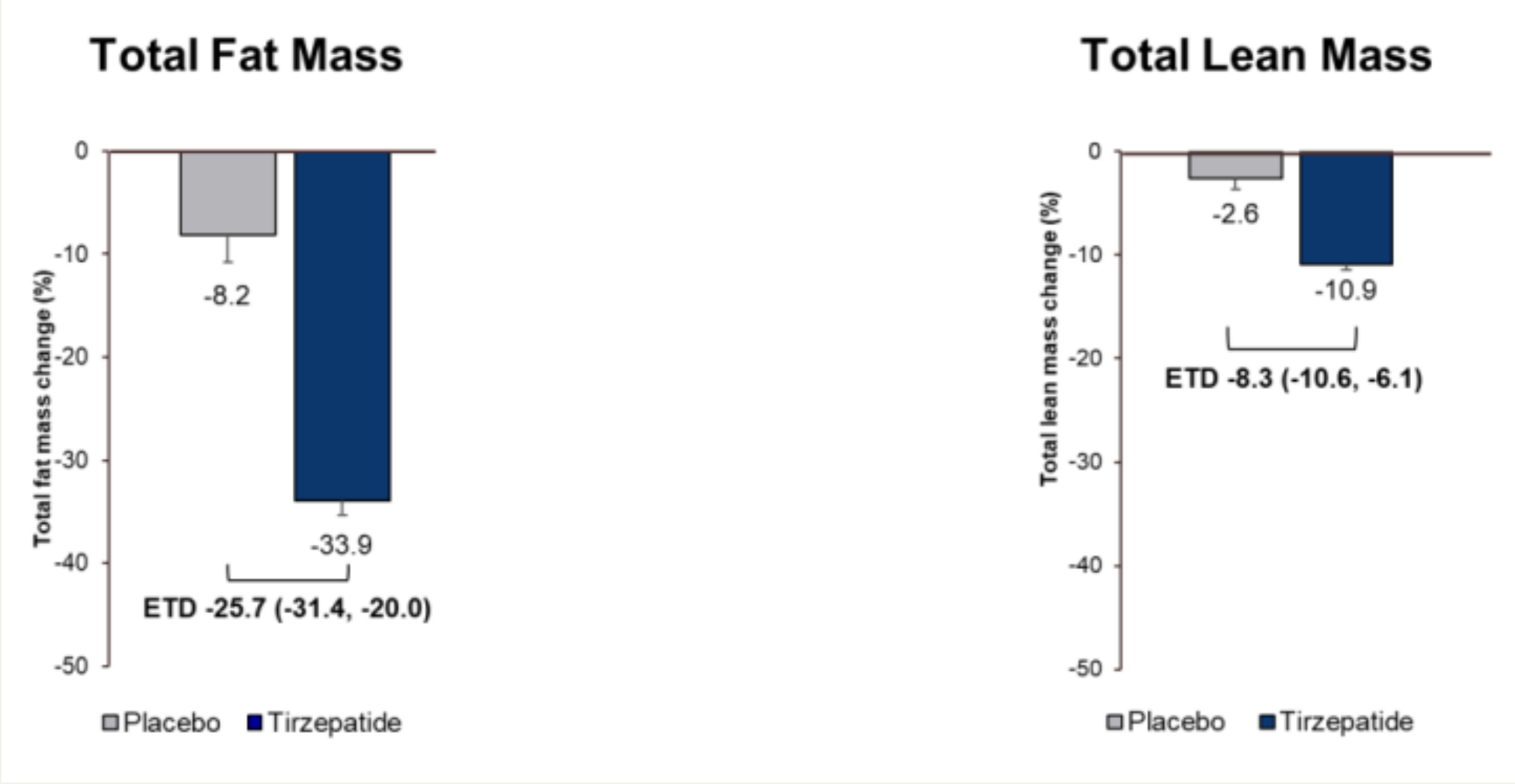
Wilding et al, NEJM, 2021.

Tirzepatide Once Weekly for the Treatment of Obesity



Jastreboff et al, NEJM, 2022.

Tirzepatide Once Weekly for the Treatment of Obesity



Jastreboff et al, NEJM, 2022.

Tirzepatide Once Weekly for the Treatment of Obesity

- **Cardiometabolic Benefits:**
  - **Glycemia**
    - ↓A1c
    - ↓ Fasting Glucose
    - ↓ Diabetes prevention
  - **↓ Insulin**
  - **↓ Blood Pressure**
  - **Lipids**
    - ↓ Triglycerides
    - ↑ HDL
    - ↓ Non-HDL cholesterol
    - ↓ LDL cholesterol
  - **Inflammation**
    - ↓ C-reactive protein

- **Fonctional Benefits:**
  - **↑ SF-36 physical function score**

- **OSA Benefits**

Jastreboff et al, NEJM, 2022.

Summary and Conclusions

- Incretin-based therapies are associated with significant loss of total and fat mass
- Incretin-based therapies are also associated with significant loss of lean mass
- It is unclear, however, how much of this lean mass loss is due to skeletal muscle loss and whether this is a greater loss than expected for the total amount of weight loss
- Nevertheless, cardiometabolic outcomes such as glycemia, insulin sensitivity, blood pressure, lipids, steatosis and inflammation improve
- Functional outcomes also appear to improve
- Further research is needed to assess these issues and to examine strategies to mitigate potential skeletal muscle loss

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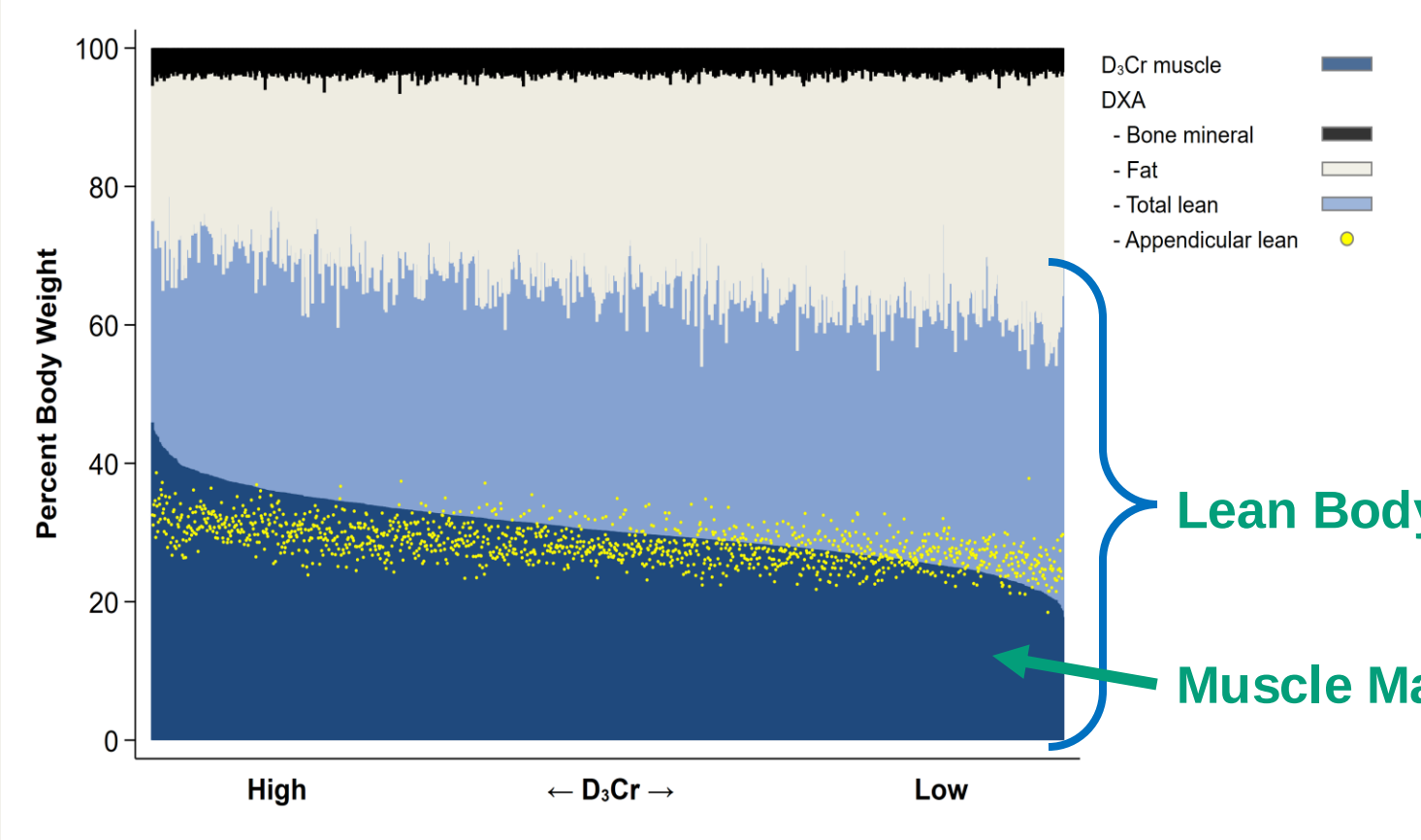
Muscle Mass and Weight Loss: Implications for Aging Populations

Pr William Evans

Department of Nutritional Sciences & Toxicology
University of California, Berkeley

Body Composition: DXA + D3Cr (MrOS cohort: > 1,300 men >80y)

Lean body mass and Muscle Mass



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OXFORD

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Research Article

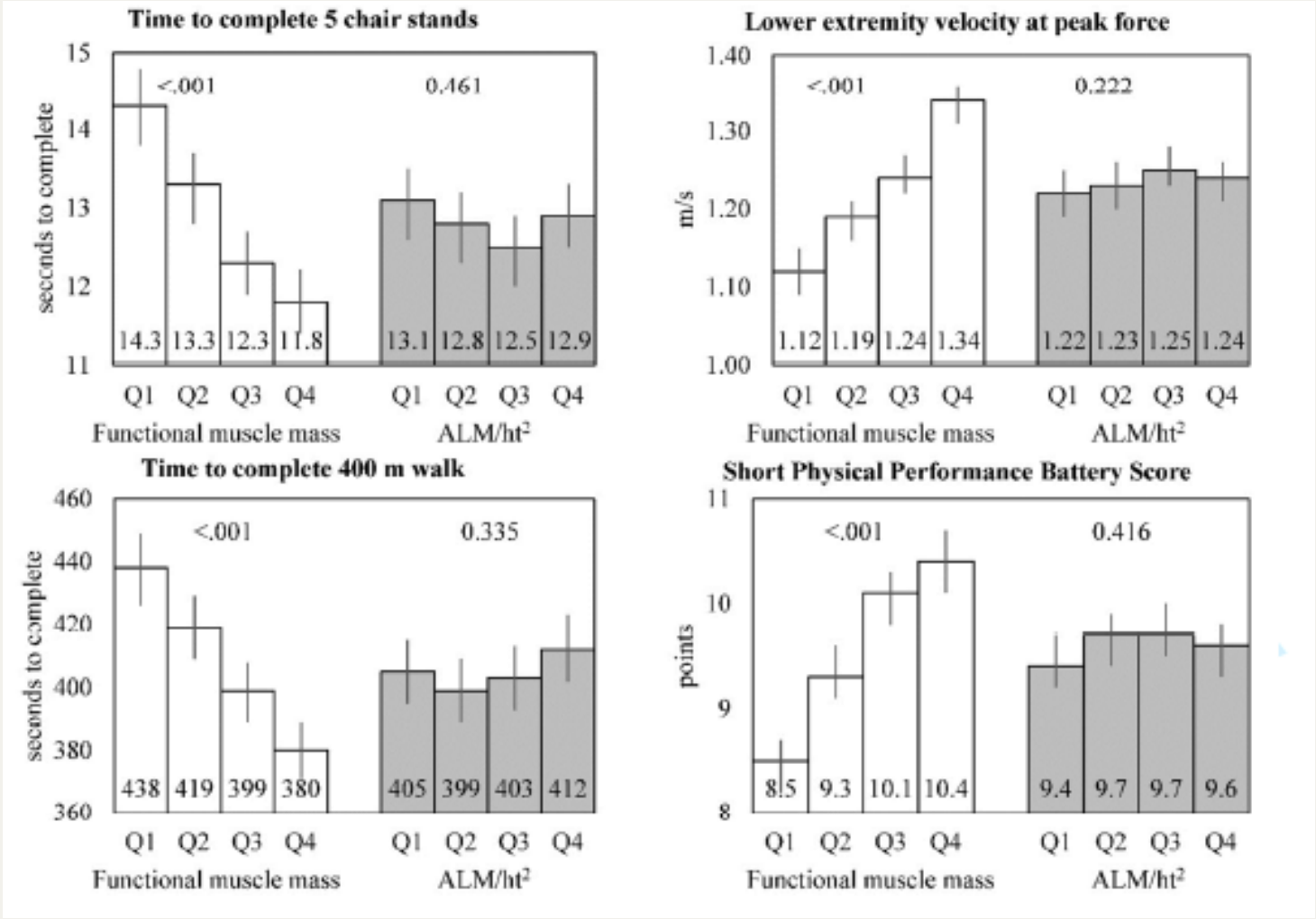
The Importance of Muscle Versus Fat Mass in Sarcopenic Obesity: A Re-evaluation Using D3-Creatine Muscle Mass Versus DXA Lean Mass Measurements

Eric S. Orwoll, MD,[1,*] Katherine E. Peters, MS,[2] Marc Hellerstein, PhD,[3] Steven R. Cummings, MD,[4,5] William J. Evans, PhD,[3,6] and Peggy M. Cawthon, PhD[4,7,] for the Osteoporotic Fractures in Men (MrOS) Study Research Group

- **Conclusion:** "When an accurate assessment of muscle mass (rather than lean mass) is used, **reduced muscle mass is highly associated with important outcomes and the negative effects of adiposity are minimal**, suggesting that obesity has little relevance for the understanding of important outcomes of sarcopenia."
- **Muscle mass is strongly associated with outcomes at all BMI levels – loss of muscle mass during weight loss will increase risk of disability and hip fracture.**

Strong relation between muscle mass determined by D3-creatine dilution, physical performance and incidence of falls and mobility limitations

Q1 – 4 lowest to highest quartiles of population



Energy Restriction Suppresses Muscle Protein Synthesis, and High Protein Diets Extend Protein Half-Lives Across the Muscle Proteome in Obese Female Zucker Rats

Alyssa N Varanoske,[1,2] Mahalakshmi Shankaran,[3] Stephen R Hennigar,[1,2,4] Claire E Berryman,[1,2,4] Lee M Margolis,[1] Tyler J Field,[3] Hector Palacios,[3] Edna Nyangau,[3] Hussein Mohammed,[3] Alyssa M Kelly,[1,2] Bradley J Anderson,[1,2] William J Evans,[3] James P McClung,[1] Marc K Hellerstein,[3] and Stefan M Pasiakos[1]

J Nutr. 2021 doi: 10.1093/jn/nxab181.

Effects of reduction of energy and protein intake on the rate of muscle protein synthesis – myofibrillar (contractile), sarcoplasmic, and mitochondrial synthesis rates are profoundly reduced

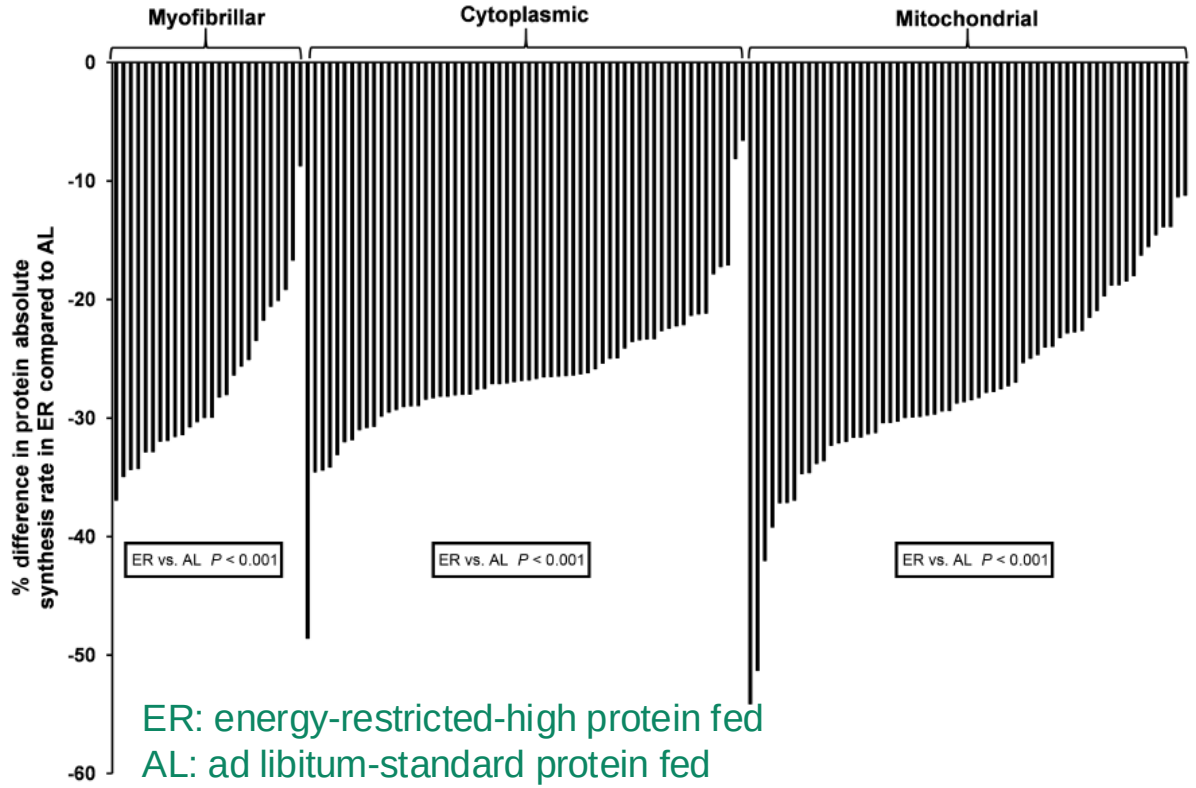


FIGURE 6 Percent difference in individual absolute myofibrillar, cytoplasmic, and mitochondrial protein absolute synthesis rates in the gastrocnemius muscle of obese female Zucker rats fed diets differing in protein concentration at two levels of energy intake for 10 wk. Data in both AL groups (AL-SP and AL-HP) and data in both ER groups (ER-SP and ER-HP) were pooled for analyses. Data within each ontological group were analyzed using 2-tailed binomial tests. Negative values represent lower protein synthesis rates for proteins in ER compared with AL groups. Individual protein names, magnitudes of difference, and sample sizes are shown in Supplemental Table 2. $n = 11$ or 12 rats per group; AL-HP, ad libitum-high protein; AL-SP, ad libitum-standard protein; ER-HP, energy restricted-high protein; ER-SP, energy restricted-standard protein.

Contribution of rate of muscle protein synthesis to energy expenditure before and after weight loss (bariatric surgery)

Wolfe, B et al, Resting metabolic rate, total daily energy expenditure, and metabolic adaptation 6 months and 24 months after bariatric surgery, Obesity, 26: 862, 2018

Muscle Protein Synthesis (MPS) and Energy Metabolism				
		Before weight loss	After weight loss	Difference
TEE	Kcal/d	2,879	2,369	-534
REE	Kcal/d	1,730	1,430	-300
Muscle Mass	Kg	50	43	-7
24h FSR	% x h^{-1}	0.075	0.037	-0.033
Total MPS	Kg/d	0.90	0.38	-0.052
Decreased EE	Kcal/d	485	204	-280

Decreased Energy Expenditure (EE) – reduction in EE due to reduced muscle protein synthesis

- **About 55% of the reduction in total energy expenditure 6 months after bariatric surgery can be attributed to decreased energy utilization for muscle protein synthesis**
- **Maintaining the pre-weight loss rate of muscle protein synthesis would result in approximately 14 additional pounds of fat loss.**

Regulatory Guidance for Addition of a Drug to Preserve Muscle Mass Resulting From GLP-1 Induced Weight Loss

- **Additional Weight Loss Compared to GLP-1 Agonist Monotherapy**

  -No guidance (as yet) on the composition of the additional weight loss

  -Concern that by preserving muscle and increasing fat loss, additional weight loss may not be seen

- **However, FDA has also advised some groups that the additional weight loss must be accompanied with a functional improvement**

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Editorial

A simplified definition of sarcopenia: muscle mass/body weight

William J. Evans[a,*], Luigi Ferrucci[b]

[a]University of California at Berkeley, Berkeley, CA, USA

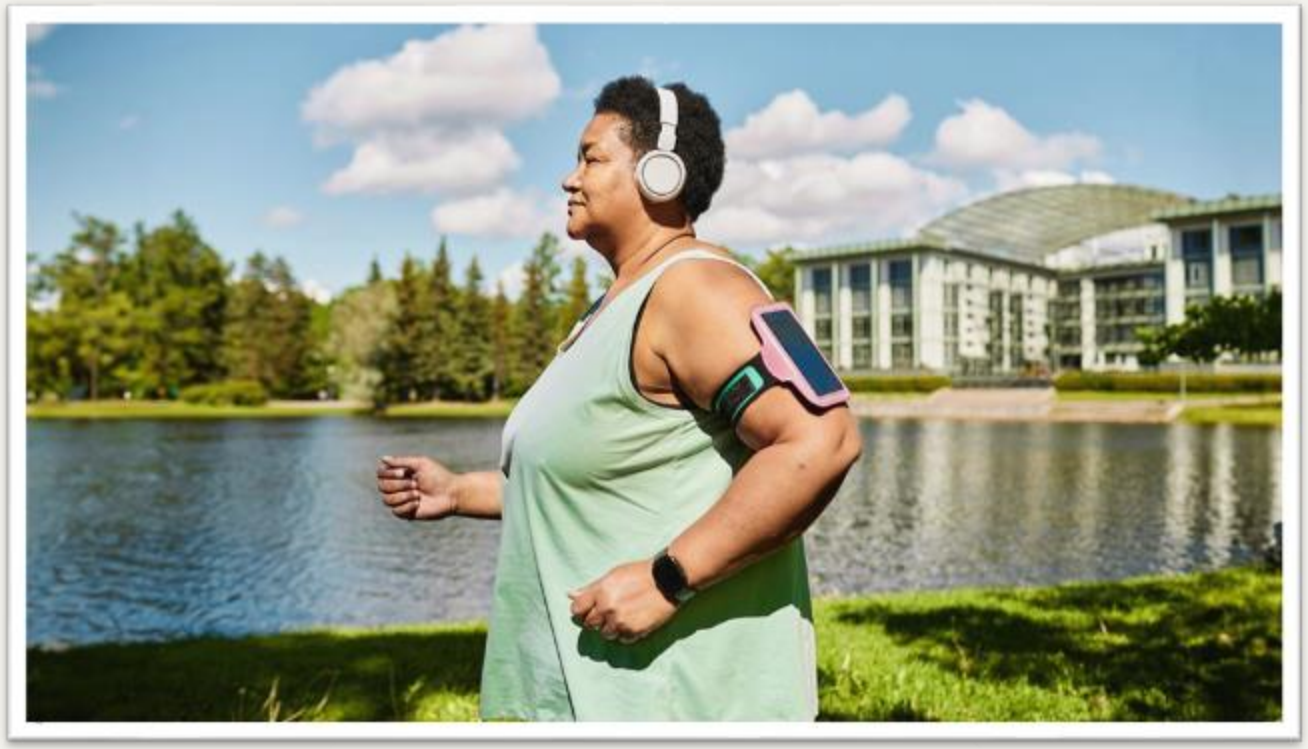
[b]National Institute on Aging, Bethesda, MD, USA

Muscle Mass/Body Weight

% Muscle Mass

"Preservation of muscle mass to combat sarcopenia may prove to be the most effective strategy to preserve independence and face advancing age with dignity. A simplified definition available to all health care providers will go a long way to meet this goal."

Loss of muscle mass resulting from energy restriction and weight loss may contribute to increased risk of disability, hip fracture, and mortality in older men and women with obesity.



During the 17th international conference of SCWD SOCIETY ON SARCOPENIA, CACHEXIA & WASTING DISORDERS

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