

THE STUDY OF OSTEOPOROTIC FRACTURES (SOF): A BRIEF INTRODUCTION

SOF is a multi-center prospective observational study of a cohort of 10,366 women age 65 or older who were recruited from four metropolitan areas in the United States: Baltimore, Pittsburgh, Minneapolis and Portland (the original cohort of 9704 was enhanced by the addition of 662 African American women between 1997-98). The primary purpose of SOF has been to describe the risk factors for osteoporotic fractures. Participants were initially recruited from mailings to age-eligible women identified from community-based listings, such as memberships of large health maintenance organizations. SOF is funded by NIA.

Participants in SOF have attended a series of nine examinations:

Exam	Primary Aim(s)
Baseline (1986-7)	Risk factors for fractures; appendicular bone mass; establish banks of serum and x-rays of spine, pelvis and hands.
Year 2 Exam (1989-90)	Dual x-ray absorptiometry (DXA) as a predictor of fractures; longitudinal studies of bone loss; additional risk factors; create a bank of DNA for future genetic studies.
Year 3.5 Exam (1991)	Risk factors for and consequences of vertebral fractures.
Year 6 Exam (1992-94)	Serum markers of risk of hip and vertebral fractures; quantitative ultrasound and fractional calcium absorption as risk factors for fracture.
Year 8 Exam (1995-96)	Vitamin D receptor genotypes as risk factors for fracture; risk factors for change in ultrasound and incidence and progression of osteoarthritis of the hip.
Year 10 Exam; Baseline AA Exam; (1997-98) Year 12 Exam (1999)	Long-term prediction of fractures; relationship between osteoporosis and breast cancer; effects of chronic metabolic acidosis on bone loss, loss of lean body mass and muscle strength and risk of hip fracture; relationship between common eye diseases and risk of fractures and falls; expand African-American representation of SOF.
Year 16 Exam (2002-04)	Long-term risk of vertebral fractures; risk of fractures in African-American women; bone loss and arterial calcification; sleep disorders and risk of falls and fractures
Year 20 Exam (2006-08)	Determine why some women have high lower extremity and cognitive function in the 9th and 10th decades of life; conduct longitudinal studies of function, falls, and hip fractures; examine biological determinants of lower extremity and cognitive function, falls, and hip fractures
Sleep & Cognition Substudy (2006-08)	Test that poor sleep is associated with increased risk of decline in cognitive function during 4.5 years of follow-up; test associations of poor sleep quality and intermittent hypoxia; test associations of poor sleep and increased risk of 7.5-year mortality; explore three potential biochemical pathways that may mediate the inter-relationships between sleep conditions, cognition, and mortality: hypercytokinemia and inflammation; oxidative burden; and poor glycemic control

The SOF Osteoarthritis Project was funded separately to collect data about risk factors for osteoarthritis (OA) and analyze baseline hip and hand films for the presence and severity of OA.

We also obtained separate funding to ascertain incident stroke cases occurred before February 1998.

We have followed up with participants every four months by postcard or telephone to ascertain the occurrence of falls, fractures and changes in address. To date, follow-up rates have exceeded 98% for vital status and fractures. All fractures are validated by x-ray reports or, in the case of most hip fractures, a review of pre-operative radiographs.

We also classify causes of death based on death certificates and a review of discharge summaries from hospitalizations. During the past ten years, we have also ascertained breast cancer cases from questionnaire and validated these cases by review of medical records and path reports or death certificates.

All data is collected at the four clinical centers according to a common protocol and detailed manuals of operation. Clinical staff are centrally trained by the coordinating center at the beginning of each cycle of examination and then certified by coordinating center investigators at the beginning of each examination and then re-certified at annual site visits based on proficiency in the performance of the measurement protocols.

SOF data is managed by a distributed data system. Data are collected using interactive data entry with local editing and then sent to the San Francisco Coordinating Center for additional cleaning and preparation of a SAS data set.

SUMMARY OF MEASUREMENTS IN SOF

Measurement	Baseline	Year 2	Year 3.5	Year 6	Year 8	Year 10	Baseline AA	Year 12 (main & AA)	Year 16	Year 20	Sleep Cognition
	1986-7	1989-90	1991	1992-4	1995-6	1997-8	1997-8	1999	2008-04	2006-08	2006-08
	V1	V2	V3	V4	V5	V6	AA	V7	V8	V9	Sleep Cognition
BMD, Calcaneal	X			X	X	X (subset)	X (subset)				
BMD, Hip		X		X	X	X	X	X	X	X	
BMD, Radial	X	X (subset)			X						
BMD, Spine		X		X (subset)					X		
BMD, Whole body				X (subset)		X (subset)	X (subset)	X		X	
Calcaneal ultrasound				X	X	X	X	X			
Cognitive function tests	X	X		X	X	X	X	X	X	X	X
Dietary history		X (subset)				X	X				
Functional status	X	X	X	X	X	X	X	X (AA)	X	X	
Interviews: Medical history & risk factors	X	X	X	X	X	X	X	X	X	X	
Neuromuscular tests	X	X	X	X	X	X	X	X	X	X	
Medication Inventory					X	X			X	X	
Oximetry											X
Polysomnography									X		

Measurement	Baseline	Year 2	Year 3.5	Year 6	Year 8	Year 10	Baseline AA	Year 12 (main & AA)	Year 16	Year 20	Sleep Cognition
	1986-7	1989-90	1991	1992-4	1995-6	1997-8	1997-8	1999	2008-04	2006-08	2006-08
	V1	V2	V3	V4	V5	V6	AA	V7	V8	V9	Sleep Cognition
Serum archived	X	X		X		X	X	X	X (subset)		
Sleep Patterns				X		X			X	X	X
Urine archived		X (subset)		X		X	X				
Visual function	X	X (subset)				X	X	X	X		X
Weight, height	X	X	X	X	X	X	X	X	X	X	
Whole Blood						X (subset)			X		
Wrist Actigraphy									X		X
X-ray, Hip	X				X						
X-ray, Lateral Spine	X		X					X (subset)	X		