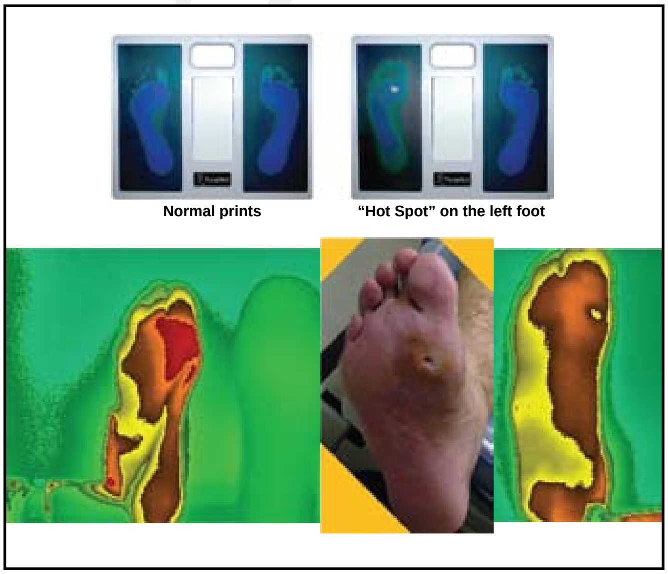
presence of peripheral neuropathies. Intranasal calcitonin may reduce bone turnover, a product of the RANK-L/OPG system, by inhibiting RANK-L. Unlike bisphosphonates, intranasal calcitonin may be used in patients with renal insufficiency [Bern et al. *Diabetes Care* 2004; Bern et al. *Diabetologia* 2006].

Preventing a recurrence remains a priority in diabetic foot ulcer management. Cumulative risk for ulceration by foot risk category may be one way of predicting recurrence. The risk groups range from 0 to 3 based on history and the presence of neuropathy or peripheral vascular disease (0=no neuropathy, no PVD; 1=neuropathy+/- deformity; 2=PVD +/- neuropathy; 3=history of pathology). Skin temperatures may provide important predictive data and indicate impending ulcerations. High temperature gradients between feet may predict the onset of neuropathic ulceration, and regular monitoring of bilateral foot temperatures may allow for early intervention and prevention (Figure 1) [Armstrong DG et al. *Phys Ther* 1997; Armstrong DG et al. *Am J Med* 2008; Lavery et al. *Diabetes Care* 2008]. Monitoring physical activity during drug therapy in the diabetic foot may also be a useful tool in predicting disease progression.

Figure 1. Are Skin Temperatures Predictive of Ulceration?



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Optimal diabetic foot management incorporates innovative strategies, such as a team approach, new technologies, and predictive risk assessment tools. Treating the acute foot wound is a complex endeavor, and preventing recurrence is an important part of successful management.

HEALTHY Study Group Achieves Modest Improvement in School-Based Intervention

The HEALTHY study, a name that was selected by the targeted middle school student population, was initiated after a pilot investigation in 2003 documented a high prevalence of risk factors for diabetes in 8th grade students in the United States [*Diabetes Care* 2006]. Indeed, of the 1740 subjects who were observed, 49% had a body mass index (BMI) ≥ the 85th percentile (the cutoff for overweightness and obesity); 40.5% had fasting blood glucose (FPG) ≥100 mg/dl; and 36.2% had fasting insulin ≥30 μU/ml, suggesting that middle schools could be logical venues for population-based efforts to prevent or delay the onset of type 2 diabetes mellitus (T2DM).

As described by Kathryn Hirst, PhD, George Washington University Biostatistics Center, Rockville, MD, the HEALTHY study enrolled 6th grade students from 42 middle schools and followed them through 8th grade (n=4603). School eligibility required a ≥50% minority student body and/or ≥50% of students who were eligible for free/reduced rate lunch. Schools were randomized 1:1 to either control (observation only) or a comprehensive intervention program that was conducted by teachers and school officials that targeted nutrition, physical activity, and personal behavior [The HEALTHY Study Group. *Internatl J Obesity* 2009].

At baseline, subjects were assessed for physical measurements and fasting blood was drawn to determine FBG, insulin, HbA1C, and lipids; self-reports of diet, exercise, and quality of life were also collected. The same data were collected at the end of study following two and a half years of HEALTHY intervention delivery. Primary endpoints for the study included measures of adiposity, glucose, and insulin.

Gary D. Foster, PhD, Temple University, Philadelphia, PA, reported the primary results of the study [The HEALTHY Study Group. *N Engl J Med* 2010]. For BMI ≥85th percentile (defined as overweight and obese categories), the changes that were observed for the intervention versus control group were not statistically significant, though significance was seen for BMI z-scores (p=0.04; Table 1). Average waist circumference and FBG were not significantly different; however, significant differences were observed for fasting insulin levels (p=0.04) as well as for reductions in measures for the most at-risk individuals: BMI ≥95th percentile (- 5.5% vs -3.8%; p=0.05) and waist circumference > 90th percentile (-8.1% vs -5.9%; p=0.04) for intervention versus control, respectively.

Table 1. BMI (Overall Sample).

	Baseline	End of study	Change	p value
BMI ≥85th Percentile				0.92
Control	49.3%	45.2%	-4.1%	
Intervention	50.3%	45.8%	-4.5%	
BMI ≥95th Percentile				0.05
Control	30.4%	26.6%	-3.8%	
Intervention	30.1%	24.6%	-5.5%	
BMI z-score				0.04
Control	0.87	0.86	-0.01	
Intervention	0.90	0.85	-0.05	

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In reporting the HEALTHY secondary endpoints for cardiovascular disease risk factors and fitness, Marsha D. Marcus, PhD, University of Pittsburgh, Pittsburgh, PA, referenced data from 2003, which determined that roughly 4% of all adolescents and nearly 30% of overweight adolescents in the United States meet the criteria for metabolic syndrome – the constellation of metabolic dysfunctions that are associated with obesity [Cook et al. *Arch Pediatr Adolesc Med* 2003].

There were no significant differences in abnormal lipids in intervention versus control. Overall, there was no difference in level of hypertension; however, the intervention showed significant improvements in measures of hypertension for male African-American (p=0.002) and male Caucasian students (p=0.045) but not for male Hispanics.

Levels of physical activity were low at baseline and remained so at the end of the study, suggesting that the HEALTHY intervention had a negligible effect in this population.

HEALTHY investigators commented that while the intervention did not meet its primary endpoint of altering the combined prevalence of being overweight or obese, it did have moderate effects on obesity and other important risk factors for T2DM.

For further details and access to the intervention program materials that were used in the HEALTHY study, go to http://www.healthystudy.org.