a cost savings of $21,200 per year in 41 patients with Type 2 diabetes. CONCLUSION: Control of diabetes as measured by the HbA1c was significantly better after the initiation of insulin glargine with benefits including a decreased overall frequency of hypoglycemia. Additionally, insulin glargine may be a cost-effective alternative to increases in the dose or number of oral hypoglycemic agents in patients with Type 2 diabetes. Conclusive evidence on the efficacy of insulin glargine will come from larger cohort studies.

**OBJECTIVES:** Although clinical trial data are often used in economic models, they may not reflect real-world utilization and outcomes of therapy. To determine real-world resource use and outcomes of diabetic foot ulcer (DFU) care using Graftskin (a living bi-layered skin substitute) and to supplement clinical data for a DFU treatment model, a medical record abstraction study was conducted at 21 U.S. treatment centers that practice good wound care (GWC). METHODS: Two physician samples were recruited: a Graftskin sample (physicians who frequently use and receive reimbursement for Graftskin in the treatment of DFUs), and a non-Graftskin sample (physicians who treat DFU using GWC and who do not receive reimbursement for using Graftskin). Separate abstraction forms were developed for each sample, sent by mail to the treatment centers, completed by center staff, and returned via fax. The center received a small honorarium per completed form. RESULTS: Twenty-one centers and 166 cases (83 Graftskin and 83 GWC) were included in the analysis. Graftskin patients had more severe DFUs (21 cm²) than those in the Graftskin pivotal trial (2.97 cm²), which compared GWC plus Graftskin to GWC alone. In addition, Graftskin patients had more severe DFUs than the GWC patients in this study (11 cm²). The mean number of Graftskin applications was much lower in this study (1.27 applications) than in the Graftskin pivotal trial (3.9 applications). Moreover, in this study, the incidence of severe adverse events was significantly lower with Graftskin (37%) than with GWC (52%), even when controlling for ulcer severity (P = 0.006). CONCLUSION: In actual practice, the number of Graftskin applications was considerably lower and DFU severity was substantially higher than in the Graftskin pivotal clinical trial. These data were applied to the DFU treatment model, which yielded improved estimates of the real-world impact of utilizing Graftskin versus GWC.

**MEDICATION COMPLIANCE IN TYPE 2 DIABETES SUBJECTS: RETROSPECTIVE DATA ANALYSIS**

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**OBJECTIVES:** Medication adherence and compliance are problems in young and elderly patients. With the increasing number of prescribed drugs, compliance drops and the number of adverse events increases. Furthermore, elderly patients are likely to have several co-morbidities, which could also affect their drug-consumption behavior considerably. In this study, our objective was to evaluate the compliance of anti-diabetic medication therapy in subjects with type 2 diabetes mellitus who initiated treatment with one of various oral anti-diabetic drugs or insulin. METHODS: Data for this study spanned the period January 1, 1995 to March 31, 2002 and were obtained from the Pharmetrics Patient-Centric Database, which is comprised of fully adjudicated medical and pharmaceutical claims for over 29 million unique patients from 52 health plans across the US. Patients with Type 2 diabetes mellitus (n = 199,000) were classified into mutually exclusive treatment groups based on the therapy first received during the period of observation. Compliance rate was determined by the total number of days between first filled and last filled prescription plus days filled in the last prescription, divided by last fill date and the first fill date plus a 90-day gap. RESULTS: The pioglitazone group (n = 2,730) ranked the highest in compliance with a mean of 85% (89% in the 55–64 age group) and a median of 91% compared to a mean compliance of 62% in the insulin group (n = 27,274) (P < 0.001) and 81% in the metformin group (n = 52,469) (P = 0.001). Similar results were found in newly diagnosed subjects. One-third of all pioglitazone patients added a second line therapy for diabetes compared to 43.9% on rosiglitazone (n = 4,068). CONCLUSION: Compliance to treatment regimen for patients taking pioglitazone was higher than for patients on other anti-diabetic medications.

**FACTORS ASSOCIATED WITH HIGH-RISK DIABETIC PATIENTS IN THE CALIFORNIA MEDICAID POPULATIONS (MEDI-CAL)**

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**OBJECTIVES:** Patient risk is identified by an increase in healthcare cost, the occurrence of hospitalization or emergency room (ER) event, and a decrease in time to hospitalization or ER event. The purpose of this research is to investigate factors associated with high-risk diabetic patients based on claims data from the California Med-