

PTH 1-34 replacement therapy in post-surgical hypoparathyroidism: preliminary results from the 6-month follow up study.



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Introduction: Hypoparathyroidism is characterized by parathyroid hormone (PTH) levels inadequate to maintain plasma calcium concentration within the normal range. Even if the conventional treatment with calcium supplements and active vitamin D analogues is usually able to maintain normocalcemia, episodic low plasma calcium, neuromuscular complaints, renal disease and gastric discomfort are not infrequent.

Methods: 29 patients with post-surgical hypoparathyroidism were started on PTH 1-34 (Teriparatide) replacement therapy (RT) because of decreased quality of life (QoL) and/or persistent low plasma calcium, related to low calcium intake due to gastrointestinal intolerance. The still ongoing protocol includes periodic visits with biochemical and urinary exams at baseline and at 15, 30, 60, 90, 120 days and subsequently every six months, quantitative ultrasound of calcaneus (QUS) at baseline and after one year and a questionnaire to assess quality of life at baseline and after 3 months. Teriparatide delivery device is illustrated in Fig. 3.

Results: We present the preliminary data on the 14 patients (12 females, mean age: 60.7 ± 9.29 years old), who have completed the 6-month follow up, reaching the one-year visit in 6 cases. At the baseline, the mean plasma calcium was 7.68 ± 0.68 mg/dl (normal range: 8.6-10.2) and the mean 24-h urinary calcium was 218.71 ± 161.4 mg/dl (normal range: 100-300). PTH 1-34 was added at an initial dose of 0.5 - 0.7 μ g/kg (approximately 20 - 80 μ g/die), twice a day. The PTH 1-34 and vitamin D analogues were titrated based on clinical and biochemical results, while the calcium supplements were progressively stopped in all patients. The mean plasma calcium and 24-h urinary calcium at baseline and at 15, 30, 90, 120 days and six months are respectively showed in fig 1 and fig 2. In particular, at the 6-month follow up, the mean plasma calcium was $8,84 \pm 0,93$ mg/dl (+15%) and the mean 24-h urinary calcium was $267,36 \pm 98,3$ mg/dl (+ 22%). Quality of life had improved in all patients. The muscular pain, referred in 3 patients, was the most common complaint, causing a temporary discontinuation of PTH 1-34 only in one case. No serious adverse events were reported.

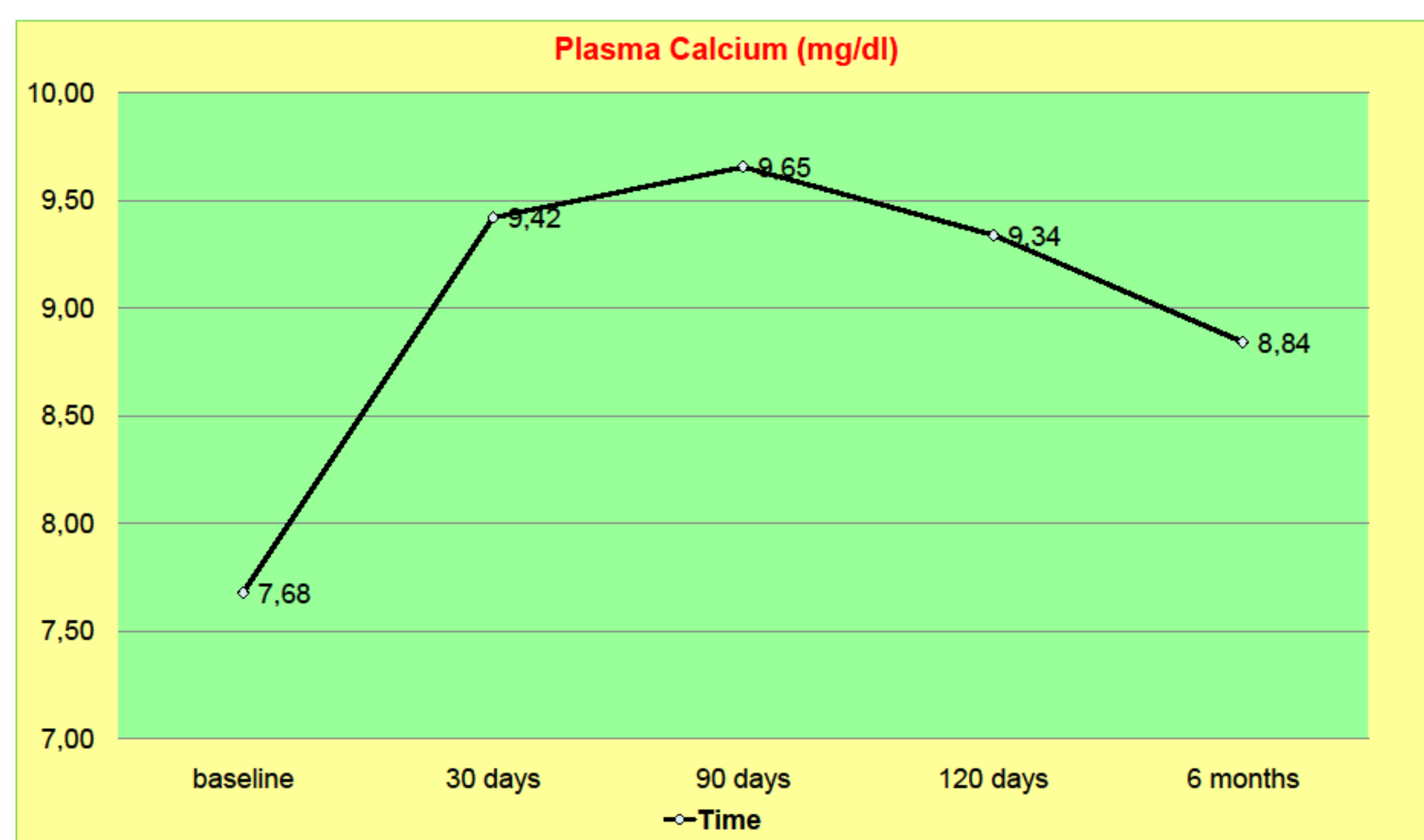


Fig.1

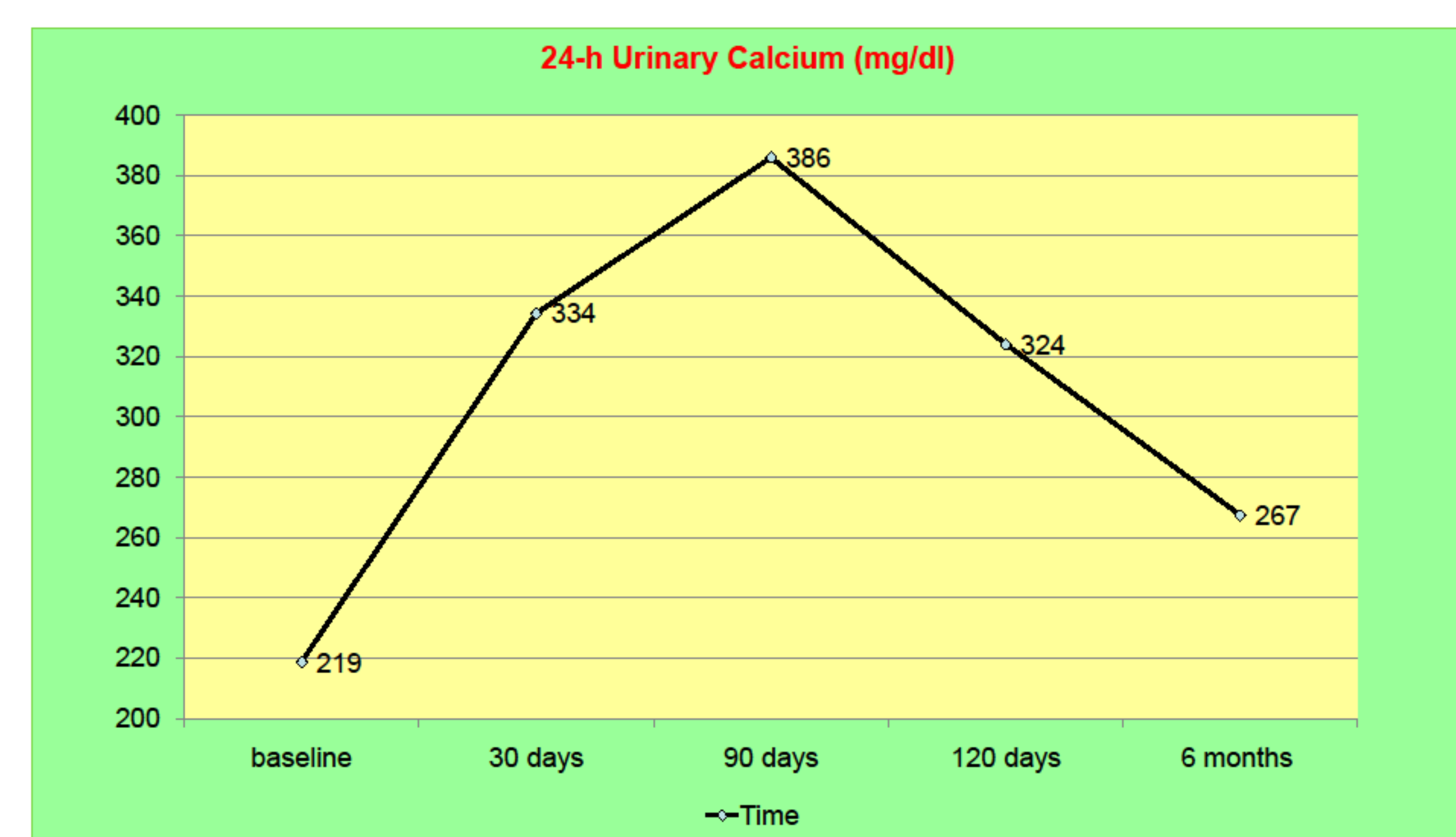


Fig.2

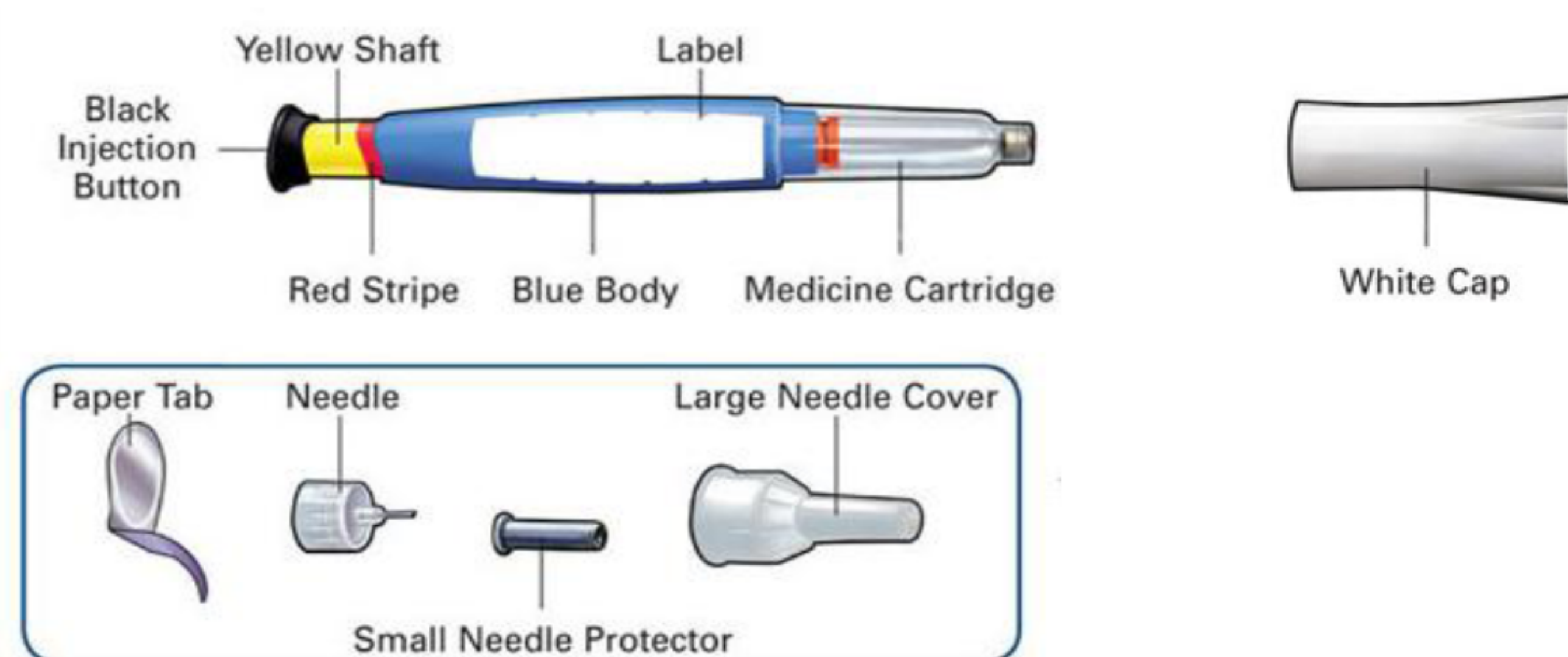


Fig. 3: Teriparatide delivery device (20 mcg/80 mL)

Conclusions: These preliminary results have confirmed the efficacy and safety of PTH 1-34 in post-surgical hypoparathyroidism. The ongoing follow up will define the long-term effects of PTH 1-34 -RT.