

Whitepaper

PureRegen[®] Gel Sinus is able to expand about 50% in volume in about half hour

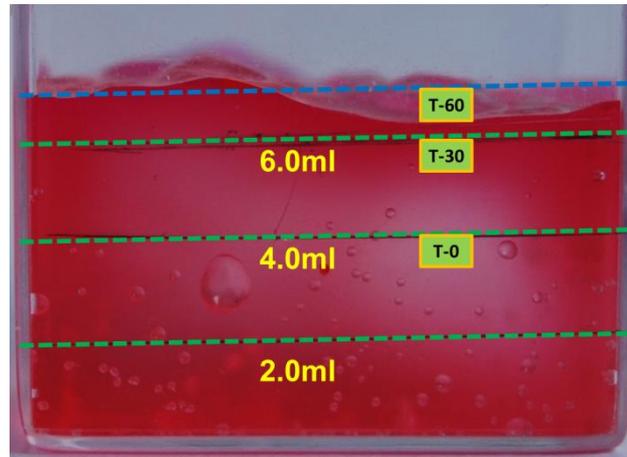


Figure 1

As shown in Figure 1, PureRegen[®] Gel Sinus was injected into a glass container. The initial volume (V_0) of the gel was 4ml (T-0). Five (5) milliliters of cell culture medium (DMEM) with phenyl-red was added on top of the gel. Since the gel is clear and transparent, solution with phenyl red will stain the gel and serve as an indicator to clearly observe changes in volume of the gel. The gel together with the DEME solution was stored at 37°C. After 30 minutes (T-30), the DMEM solution was discarded and the volume of gel (V_{30}) was measured. The expansion rate of the gel was calculated by $(V_{30}-V_0) / (V_0) \times 100\%$. Fresh DMEM was added after the measurement; the gel volume measurement (V_{60}) was repeated at 60 minutes (T-60); and the expansion rate was calculated again.

The DMEM solution quickly and evenly mixed with gel. During the first 30 minutes, the expansion rate was about $(6 - 4) / 4 \times 100\% = 50\%$. During the next 30 minutes, the expansion rate was about $(6.5 - 6) / 6 \times 100\% = 8.3\%$

The fastest and major gel expansion happened during the first 30 minutes of hydration. This expansion could have been caused through absorption of water by the hydrophilic reactive groups, such as $-\text{OH}$, $-\text{COOH}$, on the hyaluronic acid molecules and occupation by the water in spaces between hyaluronic acid monomers. This *in vitro* study may not completely reflect the performance of PureRegen[®] Gel Sinus instilled in the sinus cavity though, the gel surrounded by effusion and blood in the sinus cavity could create a hydration environment similar to the *in vitro* test setting, which will result in the expansion of PureRegen[®] Gel Sinus in the sinus cavity.

Although it is hard to measure the pressure generated by such expansion in volume, the expanded volume will most likely exert pressure onto the mucous surface, stopping minor bleeding after surgery, and maintaining the middle turbinate medially, which was observed from both preclinical experiment and clinical studies.