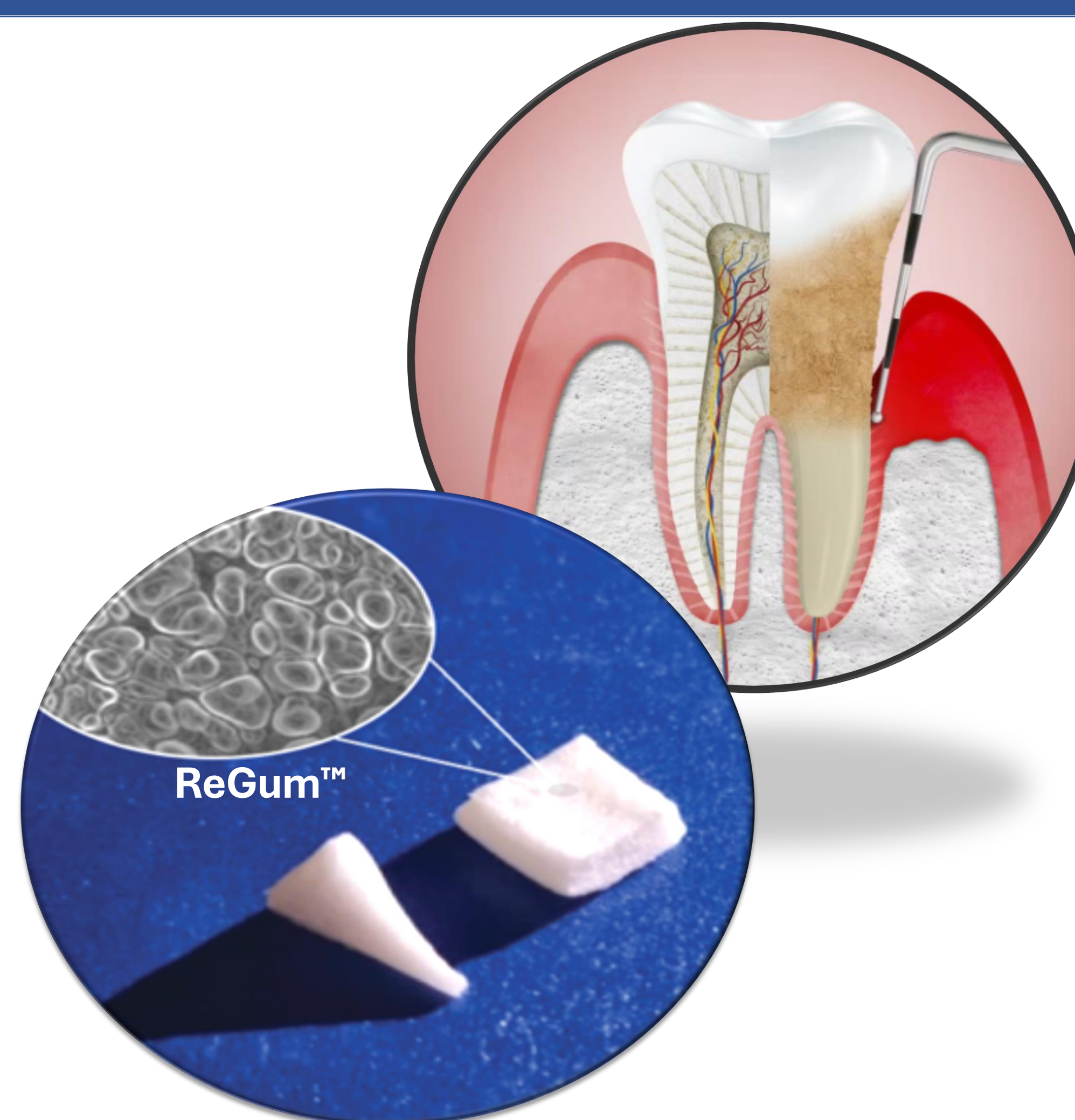


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Introduction

Periodontitis is a chronic inflammatory disease that gradually degenerates structures supporting teeth, including the gingiva, periodontal ligament (PDL), alveolar bone, and root cementum [1,2]. This degeneration is linked with pain, aesthetic impairments, tooth loss, and higher susceptibility to vascular and neurodegenerative disorders [3]. Tissue engineering is increasingly recognized as a promising avenue for rectifying periodontal tissue damage [4,5]. Among these, Natural-based materials, possessing inherent bioactive properties and closely resembling the constituents, structure, and size of the extracellular matrix (ECM) in periodontal tissues, present a promising avenue for periodontal regeneration [6-8].

In pursuit of an advanced natural scaffold for dental repair, BioChange has developed **ReGum™**, a next-generation solution for periodontal restoration. This novel scaffold consists of cross-linked gelatin formed into a 3D foamed structure, exhibiting enhanced mechanical support to the tissue. The foam structure provides a vast surface area rich in cellular attachment sites (RGDs), encouraging tissue cells to proliferate and facilitate repair processes. **ReGum™** is designed as an absorbable scaffold with an in-vivo lifespan synced with de-novo tissue growth and supporting the repair process.



www.corsodyl.co.uk/gum-disease/what-is-periodontitis/

Results

Preclinical Safety and Efficacy

No. of ReGum™ units used for this analysis: N>114 (n=6 veterinary participants, worldwide)				
	Average	Stdev	Score	Comment
Usability (1 low-5 high)	4.4	0.8	High usability	Exclusion: 1 participant (N=1-10) who did not understand the IFU (did not use the correct tools)
Efficacy (1 low-5 high)	4.5	0.5	High efficacy	Exclusion: 2 participants (N=1-10; N=10-30) who have not yet finished the follow-up

No. of ReGum™ units used for this analysis: N>114 (n=6 veterinary participants, worldwide)		
Side effects related to ReGum-Vet usage	Inflammation in the surgical site	No Side effects
	Flap Dehiscence	No Side effects
	Hemorrhage	No Side effects
	Infection	Mild Side effects (N=10-30)
	Pain	Mild Side effects (N=10-30)
	Other	No Side effects
Adverse events related to ReGum-Vet usage		No adverse events

Table 1: Pre-clinical results of safety and efficacy of ReGum™ by validated questionnaire of end users veterinarians

SEM of the Pores Structure

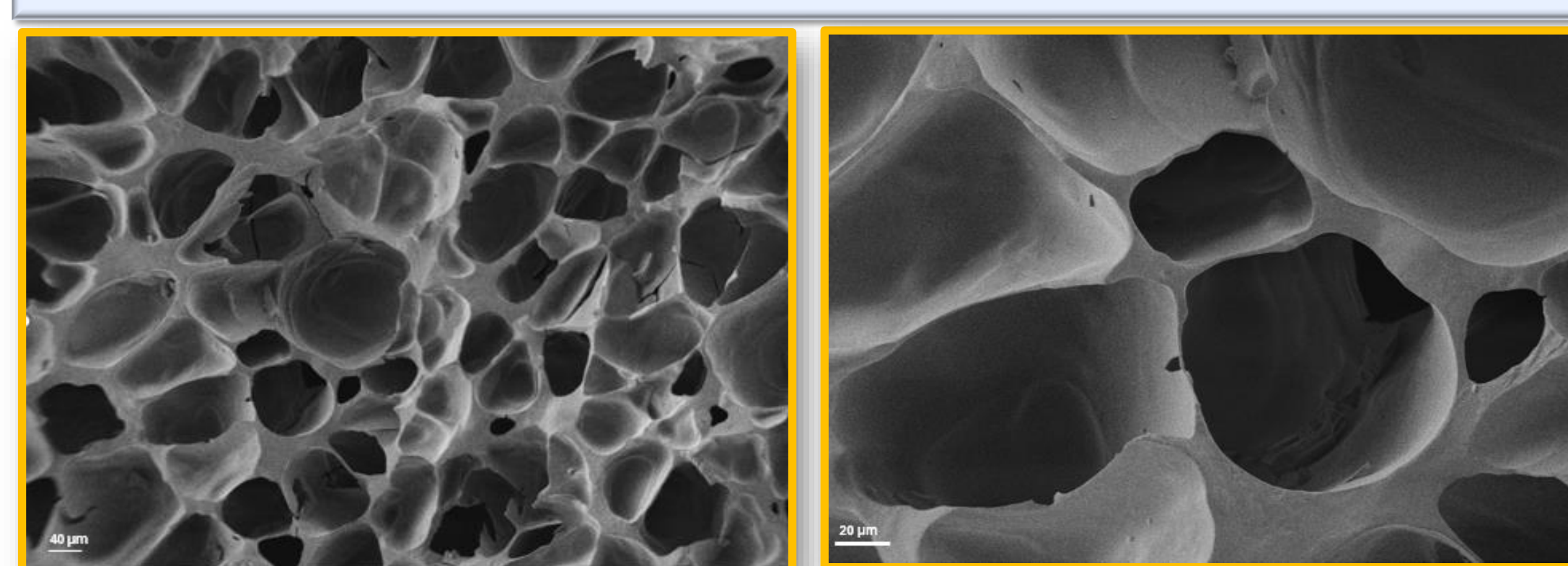


Figure 2: SEM images of ReGum™ (A), scale bar 40 μm; and zoom in of the pore structure (B), scale bar= 20μm

The surface morphology and pore architecture of **ReGum™** were studied using Scanning Electron Microscopy (SEM) (**Figure 2**). The micrographs show the scaffold morphology of a highly micro-scaled porous structure.

Table 1 This end-user questionnaire demonstrates **ReGum™**'s safety and efficacy in real life outcomes. As can be seen, based on over 144 units deployed, the scoring of both efficacy and usability is high (Average=4.5, 4.4; Stdev=0.5,0.5), without any significant side effects and no adverse events.

Methods and Materials

ReGum™ scaffold was fabricated via a crosslinking reaction of gelatin foam by microbial Transglutaminase (mTG).

Scanning electron microscopy (SEM) was used to assess the scaffold shape and pores inner structure.

The safety and efficacy of **ReGum™** in treating periodontitis were evaluated through a multicenter, randomized, split-mouth design controlled clinical trial involving canine patients afflicted with moderate to severe periodontitis. Two case studies of **ReGum™** implantation procedure was done under veterinarians cares with 6 months follow-up. Moreover, a validated questionnaire was sent to a group of end-user veterinarians (n=6) to estimate the efficacy, safety, and usability of **ReGum™**.

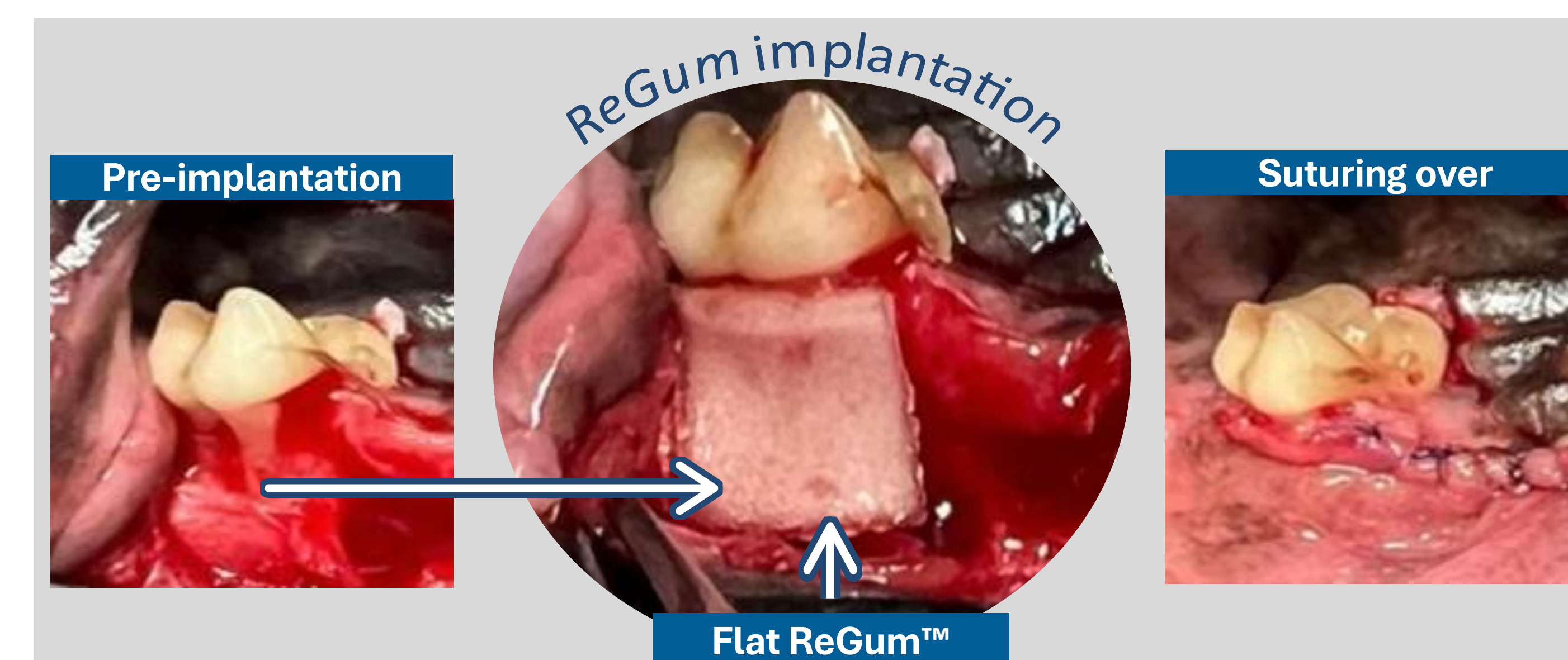


Figure 1: ReGum™ (flat) implantation procedure

Discussion

ReGum™ scaffold was fabricated via a crosslinking reaction of gelatin foam by microbial Transglutaminase (mTG) (**Figure 1**).

The scaffold was characterized to reveal a highly unique micro-porous structure contributing to the tissue repair and regeneration.

Subsequently, the safety and efficacy of **ReGum™** in treating periodontitis were evaluated through a multicenter, randomized, split-mouth design controlled clinical trial involving canine patients afflicted with moderate to severe periodontitis [9].

Veterinary patients, case studies, after a 6-month follow-up of **ReGum™** implantation showed a significant reduction of pocket depth (8mm to 3mm: **Figure 4**) and new bone formation after mesial furcation (**Figure 3**). Preclinical safety and usability studies showed high score values with no adverse events. This demonstrates that the **ReGum™** scaffold supports the rebuilding of disease-damaged tissue at the implantation site.

Conclusions

ReGum™ is a regenerative biodegradable scaffold made of crosslinked gelatin foam. It was studied as an innovative approach for periodontal restoration.

Canine studies confirmed the safety and efficacy of **ReGum™** without any reported adverse events, **indicating the great potential of ReGum™ to serve as a promising device for periodontal repair.**

Case Studies - Canine Periodontal Treatment – 6 Months Follow-Up



Figure 3: CBCT images pre-implantation and 6 months after placing ReGum™ on the right maxillary 4th premolar tooth. DVM Lommer

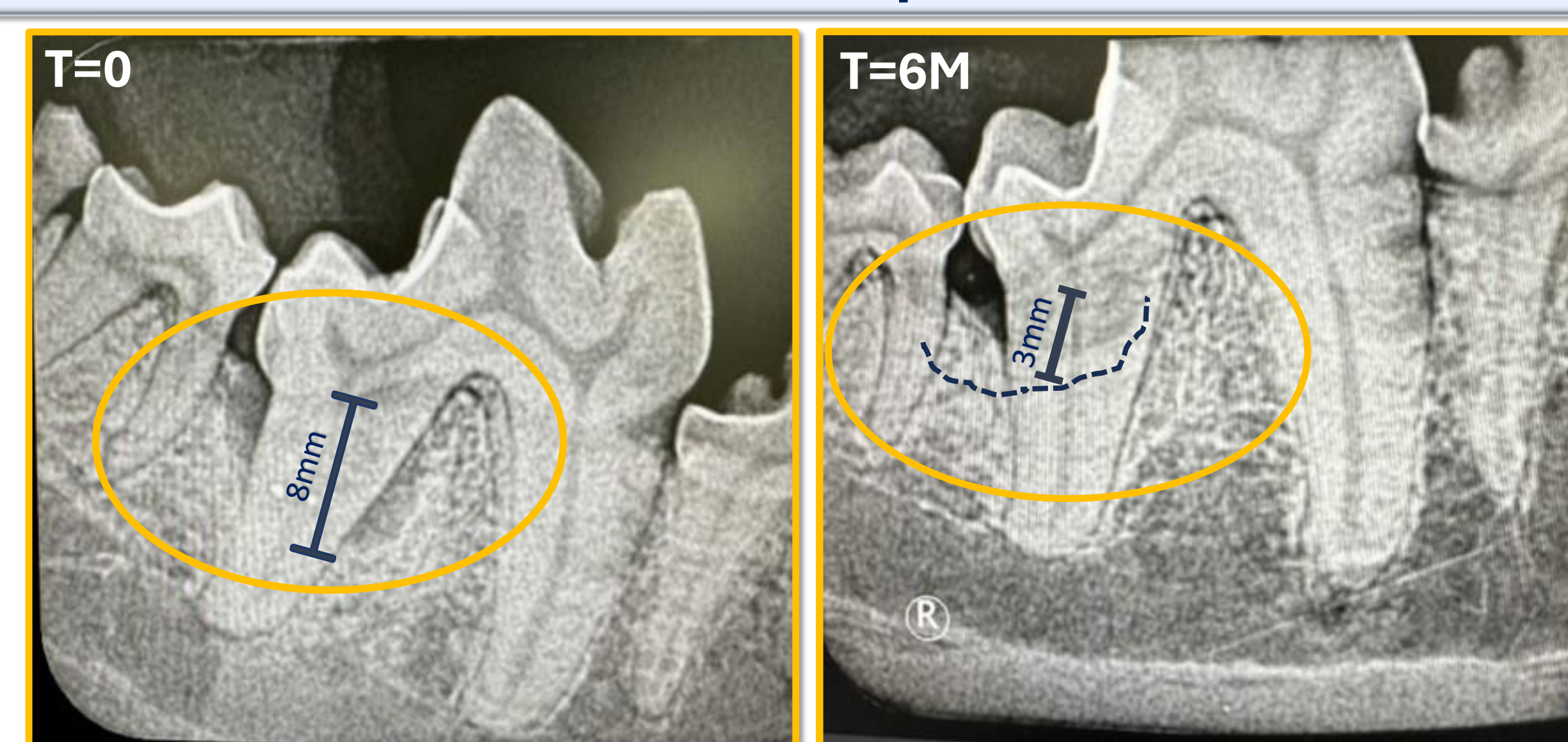


Figure 4: CBCT images pre-implantation and 6 months after placing ReGum™ 12Y German Shepherd 14.5 kg – Tooth 409 – [2023] DVM Sharon Hoffman

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