

Evaluation of MTP technology in two forms in a swine wound healing study



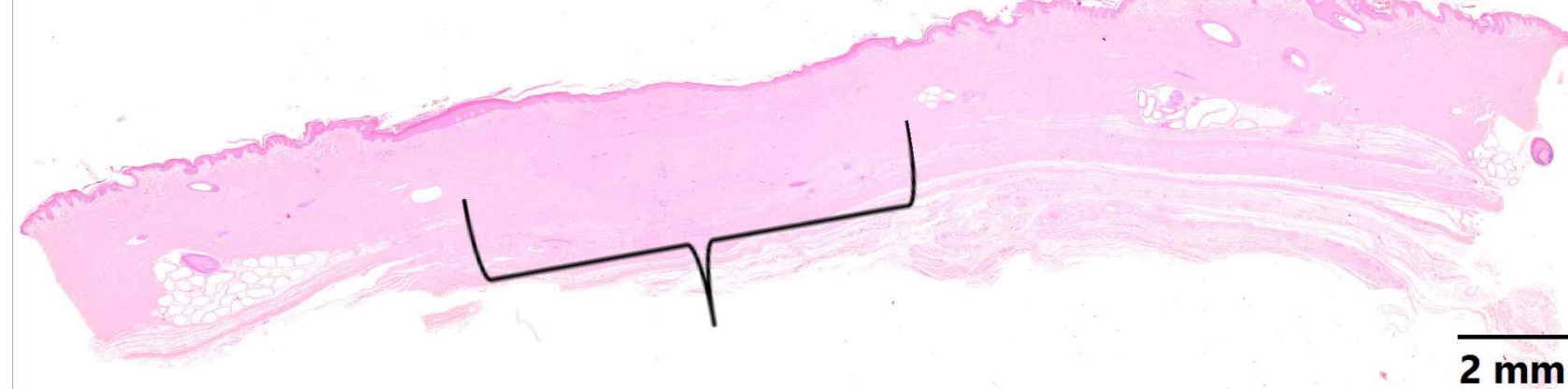
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SWINE WOUND HEALING STUDY METHODS

- Twenty (20) x 2cm diameter, full-thickness dorsal wounds were created on each of 3 pigs.
- MTP Gel and MTP Powder were each applied to 10 assigned wound beds on each pig, covering the wound surface and filling the wound space.
- Wounds were subsequently covered with sterile secondary dressings.
- Half the wounds in each group on each pig were excised on Day 6 for histopathology.
- Remaining wounds were examined and measured with digital calipers weekly for 4 weeks.
- On Day 28, wounds were excised with surrounding tissue and analyzed by histopathology.

Figure 1

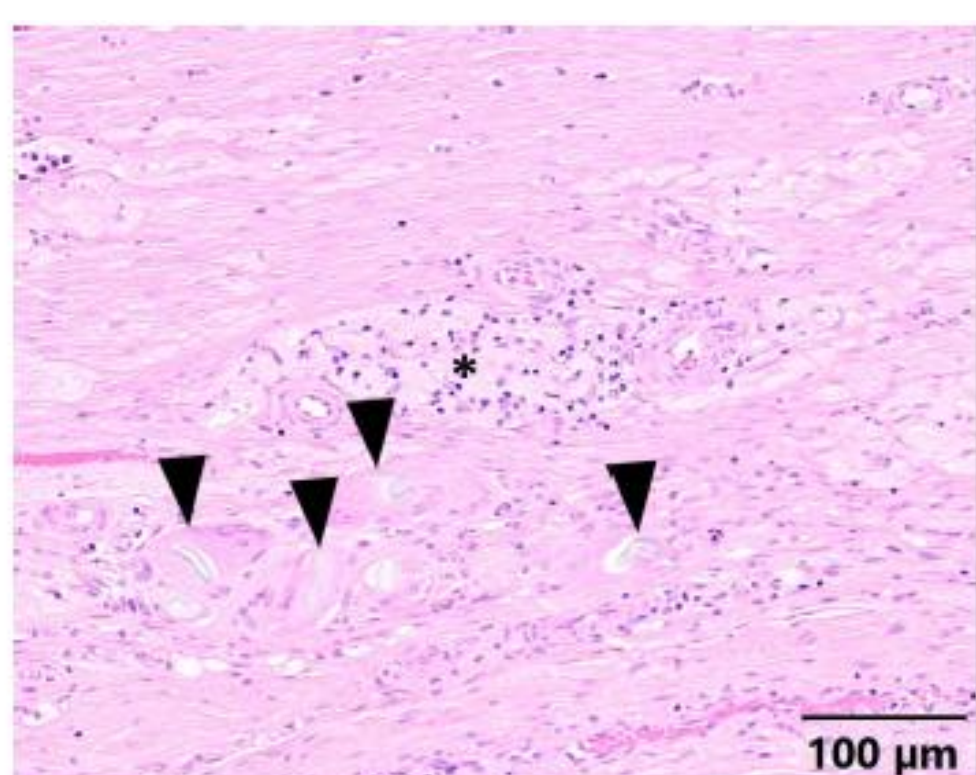


MTP Gel, Day 28. The bracket indicates the width of the wound bed.



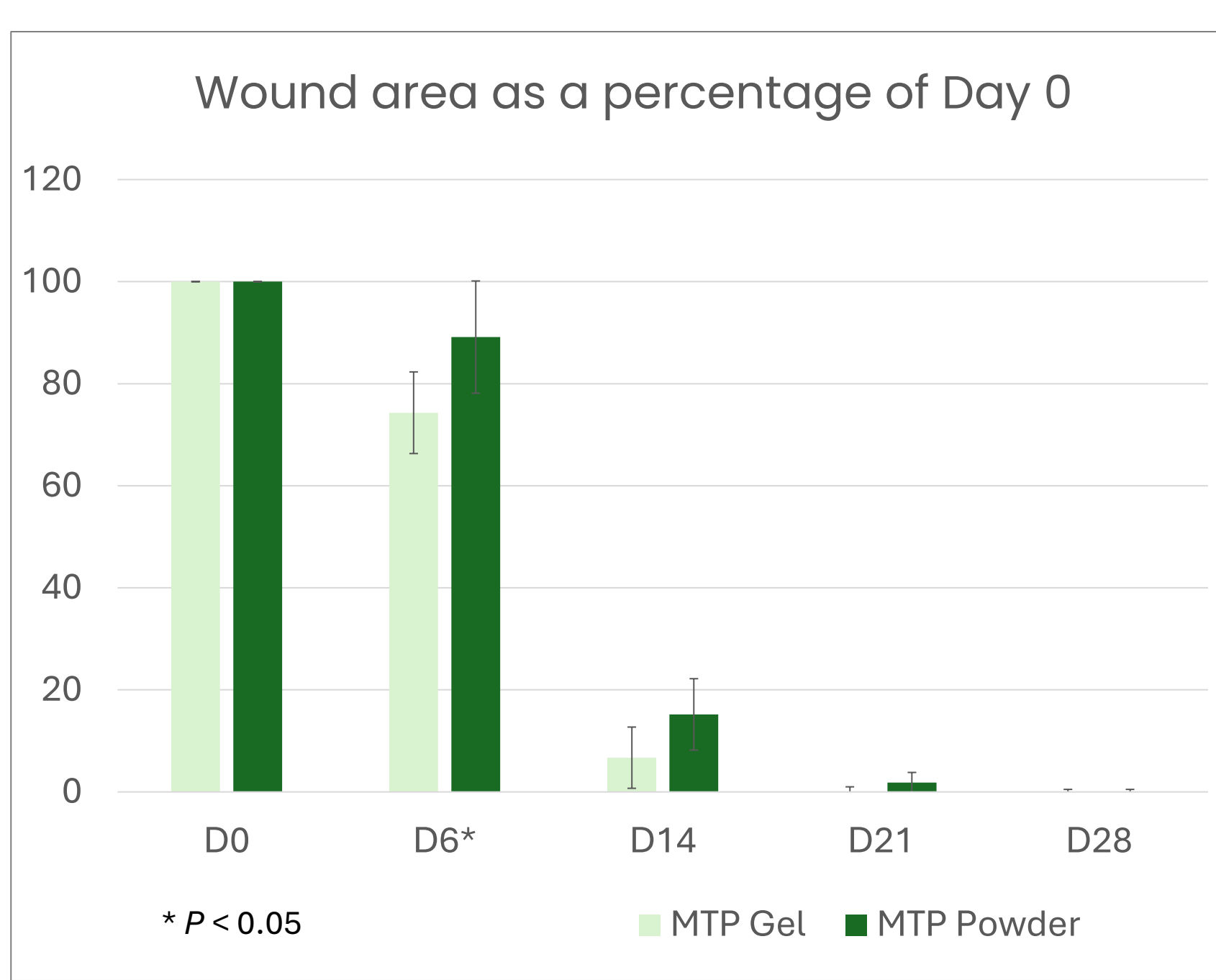
MTP Powder, Day 28. The bracket indicates the width of the wound bed.

Figure 2



MTP Gel, Day 28. Close-up image of residual MTP Gel noted in the wounds at 28 days. Black arrow heads point to fragments of gel present within the cytoplasm of multinucleated giant cells. The black asterisk notes a small, predominantly resorbed fragment of gel infiltrated by lymphocytes and macrophages.

Figure 3



MTP TECHNOLOGY – A NOVEL PLATFORM FOR WOUND HEALING

The Multi-Tissue Platform (MTP) is a versatile, naturally-derived medical technology made from decellularized lung & spleen extracellular matrix.

- FDA-cleared in 2 forms for use in wound management (MTP Powder* and MTP Gel**).
- Used in hospitals across the US for trauma, burns, surgical, and non-healing wounds.
- Thousands of advanced and non-healing wounds treated since 2018 with no adverse events.
- Indicated for use in a variety of wound healing procedures including post-laser surgery, surgical wounds, donor sites/grfts, partial and full-thickness chronic vascular and diabetic wounds, second degree burns, and tunneled/undermined wounds.

This study compared healing rates, biocompatibility, and safety of MTP Gel and Powder in a swine full-thickness wound model. An illustrative human clinical case is also presented.



SWINE WOUND HEALING STUDY RESULTS

- MTP Gel wounds were statistically smaller ($p < 0.5$) than MTP Powder wounds on Day 6 but were similar thereafter.
- Erythema, edema, and extent of granulation were comparable at all time points.
- Histopathology demonstrated that healing in both groups followed normal wound healing patterns (increased maturation of granulation tissue, decreased epidermal hyperplasia, and complete re-epithelialization) (Figure 1 & Figure 2).
- Morphometric measurement of the granulation tissue thickness showed MTP Powder wounds had slightly thicker granulation tissue than MTP Gel wounds at both time points.
- MTP Gel wounds had smaller wound surface lengths than the MTP Powder wounds at both 6 and 28 days and had a higher percent re-epithelialization on Day 6 (Figure 3, Table 1).

Table 1. Wound parameters at 6 and 28 days.

Morphometry Data								
Parameter	Time Point	Treatment	n	M	± SD	Min	Max	Med
Mean Granulation Tissue Thickness (mm)	Day 6	Powder	14	4.2616	0.9598	2.9343	6.2212	4.0698
		Gel	15	3.5115	0.6992	2.2023	4.7614	3.6155
	Day 28	Powder	15	3.7522	0.6442	2.5673	4.9297	3.7793
		Gel	15	3.1734	0.6481	1.8601	4.3582	3.2328
Total Re-Epithelialization Length (mm)	Day 6	Powder	15	3.5040	0.5158	1.9699	4.1390	3.4529
		Gel	15	3.5679	0.8643	2.3712	5.1503	3.6458
	Day 28	Powder	15	10.1376	3.6412	4.7911	16.1573	10.8669
		Gel	15	9.0820	2.5891	3.9698	12.9979	9.4148
Total Wound Surface Length Sum (mm)	Day 6	Powder	15	21.2213	2.6000	18.3766	27.2671	20.9375
		Gel	15	18.8179	2.4681	14.8231	23.9777	18.8248
	Day 28	Powder	15	10.1376	3.6412	4.7911	16.1573	10.8669
		Gel	15	9.0820	2.5891	3.9698	12.9979	9.4148
Percent Re-Epithelialization	Day 6	Powder	15	16.76%	3.22%	8.84%	21.21%	17.43%
		Gel	15	19.15%	4.78%	11.74%	26.41%	18.67%
	Day 28	Powder	15	100.00%	0.00%	100.00%	100.00%	100.00%
		Gel	15	100.00%	0.00%	100.00%	100.00%	100.00%

n = Sample Size; M = Mean; SD = Standard Deviation; Min = Minimum; Max = Maximum; Med = Median

HUMAN CLINICAL USE



A 65-yo female diabetic was hit by a car while riding a bike. She was discharged to rehab with EX-Fix and NPWT and instructions to follow up in 1 week. Due to transport issues, she didn't return for follow-up for six weeks. Patient presented with necrosis over the exposed tendon.



Debridement was followed with application of 250 mg MTP Powder in the clinic and continued NPWT.



One week follow-up showed new tissue growth covering the tendon. More MTP Powder was applied and at the next follow up one week later the tendon was completely covered. The patient received an STSG 2 weeks later.

CONCLUSIONS

The MTP Technology can be formulated into a variety of products for different applications. The difference in early healing rates suggests that solubilization of MTP into Gel form may contain matrix components that are more available for use by the body than in Powder form. However, both products induce comparable wound healing and may therefore each play a valuable role in advanced wound care depending on the type and location of the wound.

* XCelliStem® Wound Powder, StemSys (a wholly owned subsidiary of FetTech) Ft Lauderdale, FL

** ReyaGel®, ReyaMed (a wholly owned subsidiary of FetTech) Ft Lauderdale, FL