



BIO
PAD™

A Clinical Perspective of BIOPAD



Purity of BIOPAD™

The preservation of the native structure of the collagen protein in BIOPAD has been verified through electron microscopy and electrophoresis.

The electrophoresis of the protein confirms that BIOPAD is unaltered structurally.

Purity and nativity of BIOPAD was also confirmed by the determination of water-soluble peptides, hydrolyzed collagen products originated by extraction, lyophilization and sterilization processes. Such tests were conducted in comparison with Purity Standard Collagens (SIGMA 129F8130, SIGMA 128F81451 and CALBIOCHEM 014491). The statistical evaluation performed with Student's "t" test confirmed that groups of tested values were statistically significant.

The collagen protein being denatured may also be "damaged" by manufacturing processes. Such "damage" may be measured by means of enzymatic hydrolysis of bacterial collagenases. Long term evaluation (24 hours) of the BIOPAD's integrity proves comparable to the Purity Standard Collagen, as illustrated by the kinetics graph to the right.

The BIOPAD collagen dressing has the highest collagen content on the market.

The BIOPAD structure provides more real native collagen to "feed" elastase and active MMP's, speeding-up the fibroblast depletion of autologous collagen.

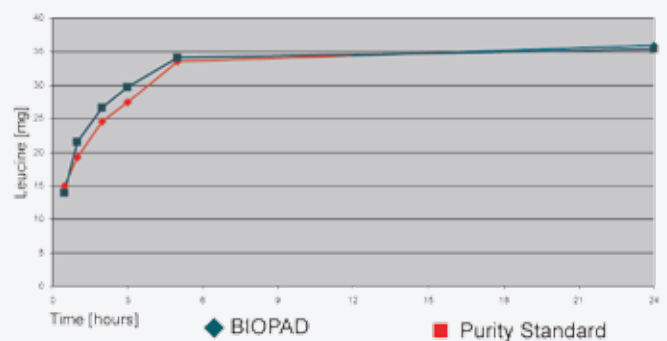
BIOPAD Purity

BIOPAD Lot No.	% of water-soluble peptides
2389	10.60
2689	12.00
3389	9.00
3889	11.00
4089	7.00
4389	8.00
Mean±S.D.	9.60 ± 1.90

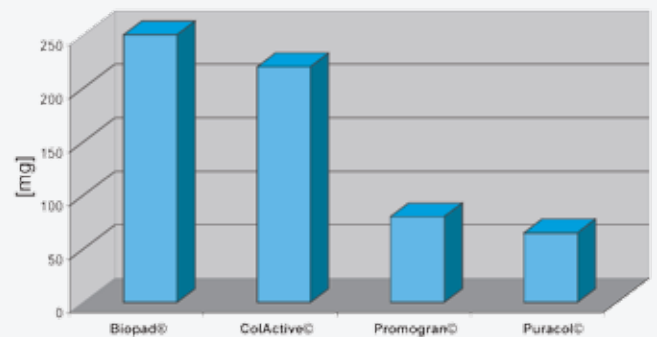
Reference Product Purity Standard

Standard Lot No.	% of water-soluble peptides
S-129F8130	10.40
S-128F81451	6.60
C-014491	7.80
Mean ± S.D.	8.30 ± 1.94

Kinetics of Enzymatic Hydrolysis with Bacterial Collagenase



Actual Collagen Content (mg)



BIOPAD's Role in the Tissue Repair Processes of Wounds (Animal Model)

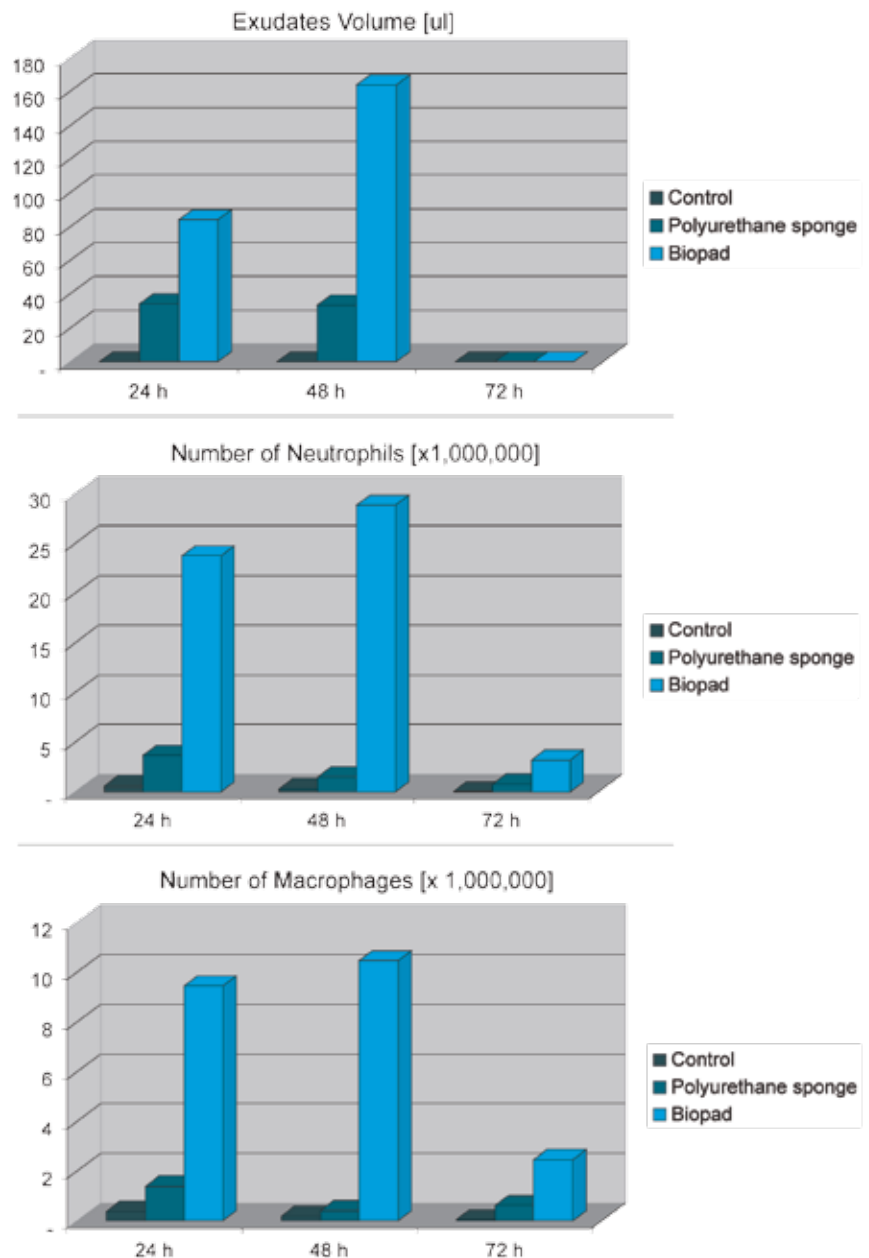
The most important and appropriate application of collagen is to wound healing. We tested the efficacy of BIOPAD* on wounds using an animal model where a surface wound was induced to obtain a "pocket" where BIOPAD and reference product (polyurethane sponge) were packed in. The animal control group had wounds excised. Three (3) groups of 18 were created and 6 wound measurements were taken at 24, 48 & 72 hour intervals in order to evaluate the wound healing process.

The evaluation criteria were the following:

1. Exudate volume present in the wounds
2. Number of granulocytes (in the exudate, plus those collected from washing the "pocket")
3. Number of macrophages (in the exudate, plus those collected from washing the "pocket")

The results shown demonstrate that BIOPAD exerts a substantial and beneficial chemotactic effect on the macrophages and neutrophils which are important in wound healing. The increase in the number of macrophages and neutrophils were shown to be statistically significant ($p < 0.01$) as compared to the control group.

Cell migration, towards and in the induced wound, was faster with the BIOPAD than in the control group.



*(native type I collagen derived from hinder equine tendon)

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