

## CHAPTER 4

### Results

Ten dogs were used in this study; eight dogs served as a treatment group given 10 mg deslorelin-containing implants and two dogs served as a control group given placebo implants. One dog (Dog6) in the treatment group died at week 16 because of *E.canis* infestation. Results of the treatment group included eight treated dogs were carried out until week 16. From week 16 to week 48, there were only seven treated dogs.

#### 1. Body weight

Dogs used in this study weighed between 10-20 kg (mean  $\pm$  SD;  $15.2 \pm 2.5$  kg) at the time of pretreatment and  $15.2 \pm 2.4$  kg over the period after implantation.

#### 2. Site of implantation

There was no an inflammatory reaction observed at the site of implantation at two-week observation period or at any time of study in both groups.

#### 3. Semen characteristics

One week before implantation, semen collections were performed in both groups. The sperm-rich fractions were obtained to evaluate semen quality. Semen characteristics varied among dogs and were summarized in table 2.

Table 2. Characteristics of semen before deslorelin implantation (n=10 dogs)

Characteristics	Mean $\pm$ SD
volume (ml)	2 $\pm$ 0.5
total number of spermatozoa ( $\times 10^6$ )	566.2 $\pm$ 257.4
motility (%)	75.5 $\pm$ 10
pH	6.6 $\pm$ 0.5

All dogs showed normal signs of ejaculation at the time of semen collection throughout the study. In the control dogs, semen characteristics were in normal range, and no significant changes were observed during the observation.

Marked changes in semen characteristics were shown in the treated dogs. The volume of sperm-rich fraction and total number of spermatozoa per ejaculation were considerably reduced within 5.2 weeks (mean percentage decrease, 71.6%) and within 6 weeks (mean percentage decrease, 87.1%) after deslorelin implantation, respectively (Figure 1).

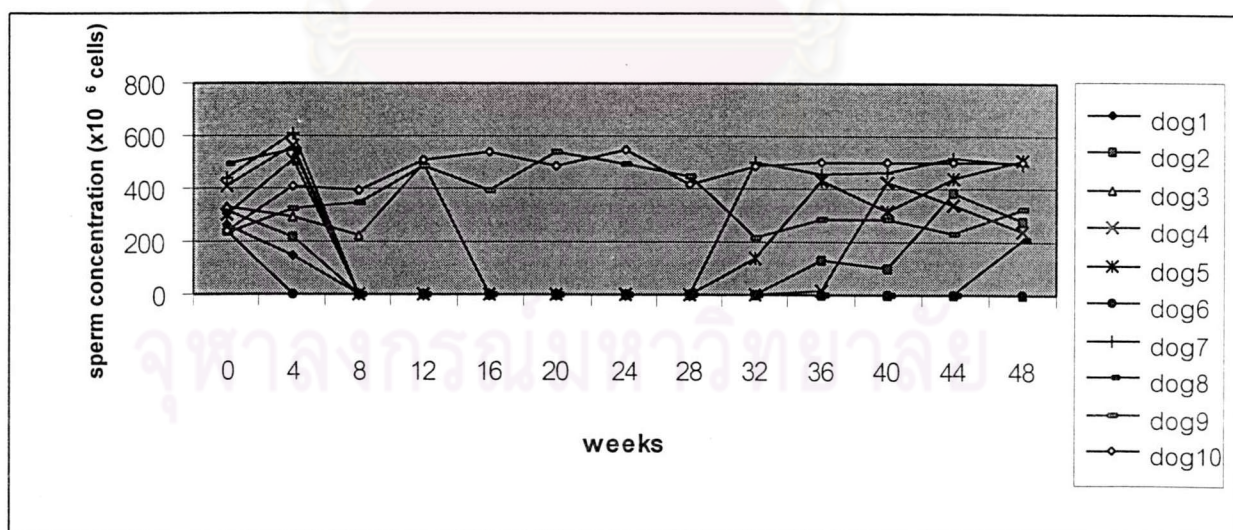


Figure 1. Change in sperm concentration in both groups before (week 0) and after implantation with deslorelin-containing or placebo implants (week 2-48). Dog 1-8 were the treatment group and dog 9-10 were the control group.

The ejaculates ceased completely at week  $7.5 \pm 3.4$  (mean  $\pm$  SD; n=8) or at week 6 (mode; n=8), ranging from 4-16 weeks. The number of treated dogs at week the ejaculates were unobtainable was one dog at week 4, four dogs at week 6, two dogs at week 8 and one dog (Dog3) at week 16 (n=8). If the results for treated Dog 3 are excluded (see discussion), the ejaculates ceased completely at week  $6.3 \pm 1.4$  (mean  $\pm$  SD; n=7) which was more rapid than the value including this dog. Mean  $\pm$  SD period ejaculates were unobtainable was  $28.6 \pm 6.7$  weeks (range, 22-38 weeks; n=7). When ejaculates became obtainable after long-term cessation, total number of spermatozoa per ejaculation was significantly decreased comparing to those prior to treatment. There was no difference in sperm motility at any week of observation before ejaculates completely ceased, but sperm motility showed great variation at the first week ejaculates appeared again comparing to those before treatment. When ejaculates were obtainable, there was no marked change in pH of semen throughout this study.



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#### 4. Serum testosterone concentrations

Mean  $\pm$  SD pretreatment serum testosterone concentrations were  $2.5 \pm 2.5$  ng/ml (range, 0.6 to 6.5 ng/ml;  $n=8$ ) in the treated dogs and  $2.0 \pm 0.4$  ng/ml (range, 1.7 to 2.3 ng/ml;  $n=2$ ) in the control dogs. Values were not significantly different between groups. In the treatment-group dogs, mean serum testosterone concentrations were significantly decreased (mean percentage decrease, 94.7%) from week 8 to week 24 ( $P<0.05$ ), and returned to the pretreatment value by week 40. Excluding Dog3 in the treatment group, mean serum testosterone concentrations was significantly decreased (mean percentage decrease, 94.2%) from week 6 to week 24 ( $P<0.05$ ). Following implantation, mean serum testosterone level declined precipitously and reached 0.3 ng/ml, which is under basal level in normal dogs, by week 8, and were then maintained at less than 0.2 ng/ml (mean  $\pm$  SD;  $0.1 \pm 0.1$  ng/ml) for a 16-week period (Figure 2).

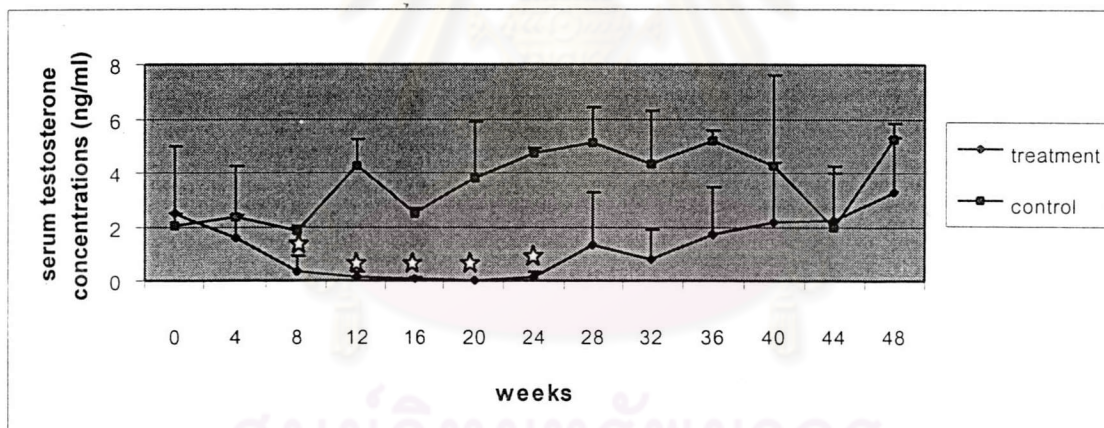


Figure 2. Changes in mean serum testosterone concentrations ( $\pm$  SD) in the treatment-group and the control-group dogs before (week 0) and after implantation with deslorelin-containing or placebo implants (week 2-48). A star symbol indicated significant difference within treatment group ( $P<0.05$ ).

### 5. Scrotal circumference measurements

Mean  $\pm$  SD pretreatment scrotal circumference measurements were  $14.8 \pm 2.7$  cm (range, 11 to 19 cm;  $n=8$ ) in the treatment-group dogs and  $15.2 \pm 1.0$  (range, 14.5 to 16 cm;  $n=2$ ) in the control-group dogs. Values were not significantly different between groups. For treated dogs, mean scrotal circumference was significantly decreased (mean percentage decrease, 22.7%) from week 6 to week 32 ( $P<0.05$ ). In the control dogs, mean scrotal circumference measurements did not significantly change during the 48-week period (Figure 3).

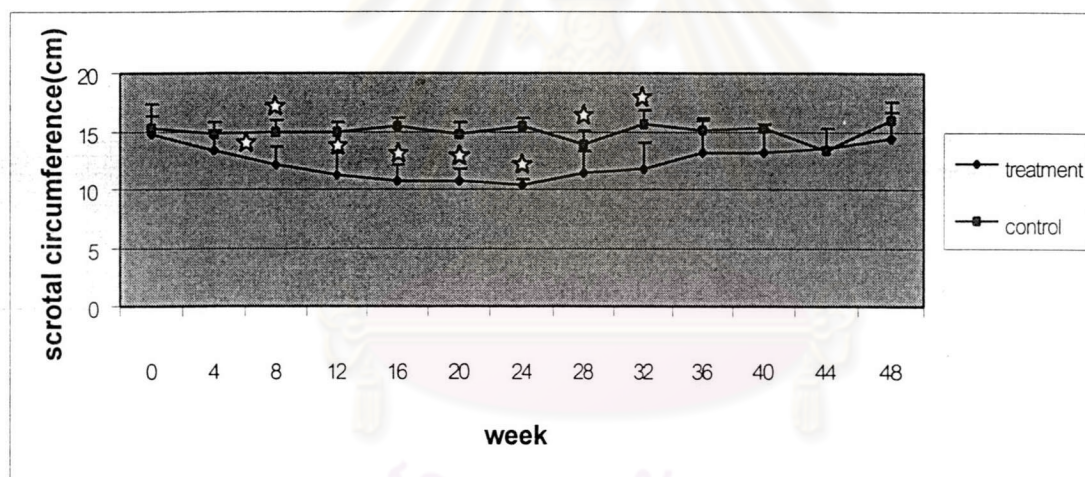


Figure 3. Changes in mean scrotal circumference measurements ( $\pm$  SD) in the treatment-group and the control-group dogs before (week 0) and after implantation with deslorelin-containing or placebo implants (week 2-48). A star symbol indicated significant difference within treatment group ( $P<0.05$ ).

## 6. Total testicular volume

Mean  $\pm$  SD pretreatment total testicular volume was  $16.6 \pm 4.5 \text{ cm}^3$  (range, 9.7 to  $25.0 \text{ cm}^3$ ;  $n=8$ ) in the treatment-group dogs and  $16.0 \pm 1 \text{ cm}^3$  (range, 15.3 to  $16.7 \text{ cm}^3$ ;  $n=2$ ) in the control-group dogs. Values were not significantly different between groups. In the treatment-group dogs, mean total testicular volume was significantly decreased (mean percentage decrease, 38.5%) from week 6 to week 40 ( $P<0.05$ ). In the control dogs, mean total testicular volume did not significantly change during the 48-week period (Figure 4).

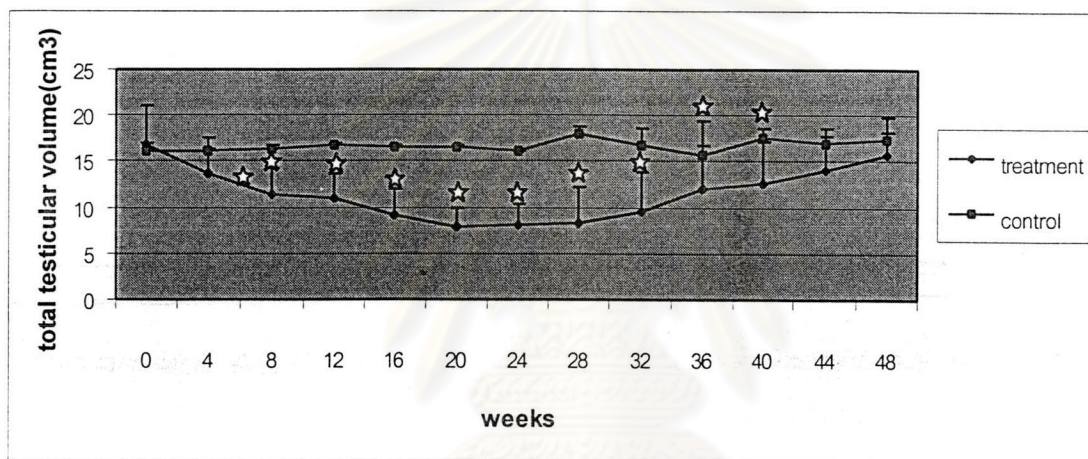


Figure 4. Changes in mean total testicular volume ( $\pm$  SD) in the treatment-group and the control-group dogs before (week 0) and after implantation with deslorelin-containing or placebo implants (week 2-48). A star symbol indicated significant difference within treatment group ( $P<0.05$ ).

### 7. Prostatic volume

Mean  $\pm$  SD pretreatment prostatic volume was  $9.3 \pm 3.6 \text{ cm}^3$  (range, 5.0 to  $15.7 \text{ cm}^3$ ;  $n=8$ ) in the treatment-group dogs and  $9.9 \pm 0.5 \text{ cm}^3$  (range, 9.5 to  $10.3 \text{ cm}^3$ ;  $n=2$ ) in the control-group dogs. Values were not significantly different between groups. In the treatment-group dogs, mean prostatic volume was significantly decreased (mean percentage decrease, 50.2%) from week 6 to week 44 ( $P<0.05$ ). The maximal regression ( $P\leq 0.0001$ ) was shown from week 8 to week 32 (mean percentage decrease, 57.6%). The prostate returned to approximately pretreatment prostatic volume by week 48. In the control dogs, mean prostatic volume did not significantly change during the 48-week period (Figure 5).

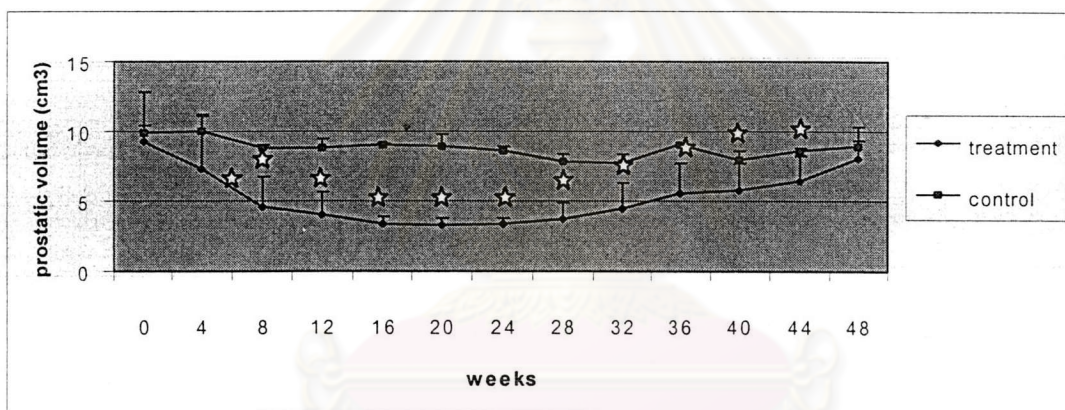


Figure 5. Changes in mean prostatic volume ( $\pm$  SD) in the treatment-group and the control-group dogs before (week 0) and after implantation with deslorelin-containing or placebo implants (week 2-48). A star symbol indicated significant difference within treatment group ( $P<0.05$ ).

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