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Technique

The use of ADCON-T/N after repair of zone II flexor tendons

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Summary

This double-blinded randomised clinical trial investigated whether application of ADCON-T/N to zone II tendon repairs improved their outcome. Fifty-nine patients were randomised into control or ADCON-T/N treated groups and all followed an early mobilisation regime following tendon repair. Tendon rupture rates were comparable between the control and ADCON-T/N treated patients. At six months follow-up, the ADCON-T/N treated group had better proximal interphalangeal motion. © 2001 Éditions scientifiques et médicales Elsevier SAS

ADCON-T/N / flexor tendon

Résumé – L'utilisation de l'adcon-t/n lors de la réparation des tendons fléchisseurs en zone 2.

Cette étude en double aveugle a pour but de vérifier si l'utilisation de l'adcon-t/n améliore les résultats lors de la réparation des tendons fléchisseurs en zone 2. Cinquante neuf patients ont participé à l'étude (groupe témoin et groupe avec l'adcon-t/n). Tous ont fait l'objet d'une mobilisation précoce après la suture de tendon. Les taux de rupture étaient comparables entre le groupe témoin et le groupe traité avec l'adcon-t/n. A six mois, le groupe ayant reçu l'adcon-t/n avait une meilleure mobilité de l'IPP. © 2001 Éditions scientifiques et médicales Elsevier SAS

adcon-t/n / tendon fléchisseur

The formation of adhesions around a tendon repair reduces the tendon's ability to glide, and thus limits active finger motion. ADCON-T/N (Gliatech Inc.) is a carbohydrate polymer gel discovered as a result of research into glial cells, which acts as a barrier to the migration of fibroblasts and inhibits scar and adhesion formation after tendon and nerve surgery. It is bioabsorbable over a period of approximately four weeks and can be applied directly to organs and tissues following surgery (Gliatech Inc. product literature).

Ahmad et al. [1], and then DeMedinaceli et al. [2], demonstrated the efficacy of ADCON-T/N in inhibiting peritendinous adhesions in a rabbit model. Raffoul et al. [3] subsequently evaluated its use after tenolysis and reported that it improved the final range of movement an did not cause any adverse side effects. Others (Peterson et al. [4]; Palatinsky et al. [5]) have demonstrated that ADCON-T/N prevents extraneural scarring after nerve injury in rodents and does not inhibit nerve regeneration.

While there is proven benefit to the use of ADCON-T/N after tenolysis. It is not known whether it improves the outcome after repair of divided tendons. As some consider that adhesion formation around repaired tendons is an essential part of the repair process, concern has been raised that ADCON-T/N may increase the postoperative tendon rupture rate. We have performed double-blind randomised study to assess the use of ADCON-T/N after zone II flexor tendon repair.

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PATIENTS AND METHODS

All patients who were admitted to Morriston Hospital, Swansea, between 1997–1999 with zone II flexor tendon injuries (either or both FDS and FDP tendons), without any concomitant bone, joint or vascular compromise were considered for the study. This study had the approval of local ethical committee. Digital nerve injury was not a contraindication to inclusion, but patients who were very old (more than 80 years old) or very young (less than 12 years old), or were unable to comply with the postoperative hand therapy were excluded. After obtaining informed consent, the study patients were randomised into control and ADCON-T/N treated groups. Their age, hand type, hand dominance and concurrent medical history were obtained and the pre- and postoperative management was the same for all patients.

The tendon repairs were done in a standard fashion, with a modified Kessler core stitch (4/0 PDS) and an epitendinous continuous stitch (6/0 prolene). A small amount of ADCON-T/N was applied to the repaired tendon of the treated group (2 mL): the technique of application did not require any special training and there was no bias towards any particular surgeon when the outcome of surgery was evaluated. ADCON-T/N was simply smeared on the repaired tendon, with no particular attention paid to prevent it entering the repair. The surgeons were aware of the fact that ADCON-T/N was applied to the repaired tendon, as no placebo was used in the control group. However, this fact was not known to the hand therapists who subsequently assessed the patients.

Early active mobilisation regime was used for all patients [6]. Neither the hand therapists nor the patient knew whether ADCON-T/N had been used. Postoperative assessments were made at six weeks, three and six months. A modification of Strickland's evaluation system was used. Range of active motion at both the proximal and distal interphalangeal joints and the nail to palm distance were assessed on each occasion and grip strength was measured at three and six months. Comparisons were made with the contralateral uninjured side and the deficits in range of movement and grip strength were expressed as a percentage of the normal side. The deficits in range of movement and grip strength was then compared between the control and treated groups using the paired 't' test.

RESULTS

Fifty-nine patients were recruited in the study, with a total of seventy injured fingers. When two fingers in one hand were injured, both fingers were treated with or without ADCON-T/N, and each finger was used as an independent variable. Demographic data on patients in the control and treated groups were similar *(table I)*. The number of fingers assessed at each follow up time is listed in *table II*, together with the distribution of the tendon injuries. The distribution of tendon injury in both groups of patients was comparable. Follow-up in some patients had proved to be difficult as they refused to attend follow up clinics, and most of them did not have fixed address. Numerous reminder letters to attend

Table I. Dermographic data on patients in the study.

	Control	*ADCON*
Total number of patients	31	28
Total number of injured fingers	35	35
Male/female	24/7	18/10
Mean age at injury	31	30
Dominant hand injured (no. fingers)	11	9
Tendon rupture	8	7
Average delay in repair (days)	1.0	0.6

Table II. Assessment recorded – number of fingers assessed.

	Control			*ADCON-T/N treated*		
Tendons injured	*FDP*	*FDP + FDS*	*Total*	*FDP*	*FDP + FDS*	*Total*
Six weeks	5	15	20	6	13	19
Three months	5	10	15	5	11	16
Six months	3	7	10	4	10	14

Table III. Results in treatment and control groups.

		Control			*ADCON-T/N treated*		
Assessment interval		*6 weeks*	*3 months*	*6 months*	*6 weeks*	*3 months*	*6 months*
PIPJ deficit (% of normal)	Mean	0.47	0.69	0.65	0.50	0.72	0.84
	Range	0.21–0.75	0.39–0.95	0.24–0.96	0.18–0.71	0.31–0.69	0.68–0.97
	SD	0.19	0.16	0.23	0.17	0.18	0.11
DIPJ deficit (% of normal)	Mean	0.41	0.53	0.58	0.41	0.45	0.59
	Range	0–1.08	0.11–0.97	0.17–0.92	0–1.05	0–0.92	0.05–1.2
	SD	0.34	0.26	0.29	2.67	0.28	0.38
Power grip deficit (% of normal)	Mean		0.78	0.78		0.61	0.78
	Range		0.41–1.21	0.39–1		0.24–0.78	0.49–0.97
	SD		0.26	0.24		0.16	0.17
Pinch grip deficit (% of normal)	Mean		0.75	0.83		0.56	0.87
	Range		0.48–1	0.50–1.48		0.36–0.83	0.70–0.96
	SD		0.15	0.32		0.17	0.10
Nail to palm distance (cm)	Mean	2.12	1.67	1.38	2.42	1.74	1.62
	Range	0.2–5.75	0.25–3.60	0.2–2.5	0–4.9	0–3.8	0–2.9
	SD	1.49	0.83	0.70	1.3	1.27	1.19
PIPJ movement (degrees)	Mean	49.86	72.07	79.70	53.95	73.72	89.55
	Range	17–78	31–100	22–109	15–80	30–108	65–107
	SD	19.23	20.25	24.09	20.07	20.47	12.34
DIPJ movement (degrees)	Mean	34.81	44.93	60.9	30.58	35.94	50.64
	Range	0–78	9–91	12–94	0–82	0–85	10–86
	SD	25.73	24.64	28.31	24.30	25.35	26.26

SD = standard deviation.

follow-ups were also ignored by these patients. Travelling expenses were offered to those who live far from the hospital.

There were a total of fifteen re-ruptures of tendons, eight in the control group and seven in the ADCON treated group. Most of these were patient dependent and due to various reasons, such as lifting with splint off, falling over, forced extension and fighting. Ruptured tendons were excluded from the study altogether and were not included after re-repair. Tendon rupture occurred at an average of 23 days after repair in the control group, and at an average of 33 days in the ADCON treated group. This difference was not statistically significant (student 't' test, $p > 0.05$).

Patients in the ADCON-T/N treated group regained 87 percent of full active proximal interphalangeal joint motion, while control patients regained only 68 percent of full motion. This difference is statistically significant ('t' test, $p = 0.005$), but there is no statistically significant difference for the ranges of motion of the distal interphalangeal joint, or hand grip or pinch strength. There was no statistically significant difference between the results at six weeks and three months *(table III)*.

DISCUSSION

This study concludes that ADCON-T/N may improve the range of motion at the proximal interphalangeal joint, though not the distal interphalangeal joint, after repair of zone II flexor tendons. The lack of benefit at the distal interphalangeal joint may be explained by our failure to take into account whether both flexor tendons or only the flexor digitorum profundus tendon was injured. However, such

distinction was not possible in this small study, especially as patient compliance was often poor, resulting in high rate of tendon rupture and loss to follow up.

ADCON-T/N works by inhibiting migration of fibroblasts and hence the formation of scar tissue. While its effect in improving the surgical outcome in tenolysis is undisputed in several studies [1–5], its use in flexor tendon surgery is new. There are two theories on tendon healing: firstly, the extrinsic mechanism, which states that tendon healing is dependent entirely on cells migrating into the repair area from outside the tendon, and secondly the intrinsic mechanism, which states that tendons are capable of participating in repairing process independent of surrounding adhesions. The first theory has since been challenged by in vivo and in vitro studies, and therefore the fear of applying a substance that inhibits fibroblast migration into tendon repair sites leading to failure of tendon healing is unfounded, as demonstrated in this study. The tendon rupture rate after repair was found to be the same in both the control and ADCON-T/N treated group. It is more likely that ADCON-T/N inhibits the peritendinous fibrosis that impairs tendon gliding, resulting in better surgical outcome in the treated group.

While the use of ADCON-T/N was shown to be technically easy and without complications, there was a question of whether it would stay where it was intended at the repaired tendon with post-operative elevation and active mobilisation. Post-operative bleeding may also dilute the effect of ADCON-T/N. There was also concern that ADCON-T/N that seeped through onto the skin wound may retard wound healing, but this did not seem to be a problem in this study.

Although the benefit of using ADCON-T/N in routine primary repair of zone II flexor tendons is not great, as seen in this study, its use in repairing re-rupture tendons or other difficult repairs where early mobilisation is detrimental to the repair, may be helpful. This area of use, as other situations where scar formation is detrimental to surgical outcomes, should be explored.

In summary, the results of this study suggest that ADCON-T/N may be useful after repair of zone II flexor tendons. However, a larger study with a longer and more complete follow-up is needed to confirm our findings.

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REFERENCES

1 Ahmed S, Hingson M, Maer K, Touhaliski D, Coker III G. Inhibition of peritendinous adhesions by Adcon-T/N intenolysis. Presented to the 2nd Congress of the Federation of the European Societies for Surgery of the hand, Dublin, 1994.

2 DeMedinaceli L, Merle M, Dautel G. Effect of locally applied Adcon-T/N on experimental adhesion of flexor tendons. Presented to the 6th Congress of the International Federation of Societies for surgery of the hand, Helsinki, 1995.

3 Palatinsky EA, Maier KH, Touhalisky DK, Mock JL, Hingson MT, Coker GT. ADCON-T/N reduces in vivo perineural adhesions in a rat sciatic nerve reoperation model. J Hand Surg (Br) 1997; 22: 331-5.

4 Peterson J, Russell L, Andrus K, MacKinnon M, Silver J, Kliot M. Reduction of extraneural scarring by ADCON-T/N after surgical intervention. Neurosurgery 1996; 38: 976-83.

5 Raffoul W, Egloff DV. A novel bioreabsorbable barrier gel (Adcon-T/N) for the inhibition of post-operative peritendinous adhesions; a clinical study of tenolysis procedures of the hand. Poster presentation and discussion at the 20th World Congress of the Societe Internationale de Chirurgie Orthopedique et de Traumatologie (SICOT), 1996.

6 Small JO, Brennen MD, Colville J. Early active mobilisation following flexor tendon repair in zone 2. J Hand Surg 1989; 14B: 383-91.