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Original Research

Dynavisc as an Adhesion Barrier in Finger Phalangeal Plate Fixation—a Prospective Case Series of 8 Patients

Johanna von Kieseritzky, MD, PhD, [*,†] Jenny Rosengren, MSc, [†] Marianne Arner, MD, PhD [*,†]

[*] Department of Clinical science and Education, Karolinska Institutet, Södersjukhuset, Stockholm, Sweden
[†] Department of Hand Surgery, Karolinska Institutet, Södersjukhuset, Stockholm, Sweden

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Purpose: Adhesion problems are common after plate fixation of finger phalanges and often lead to stiffness and reoperations with plate removal and tenolysis. The aim of this prospective case series was to study the effect of the adhesion barrier gel Dynavisc on total active motion (TAM), postoperative pain, and grip strength after plate fixation of phalangeal fractures. Total active motion at 3 months after surgery was the primary outcome.
Methods: Eight patients with a fracture of the proximal phalanx underwent surgery with open reduction and plate fixation. The adhesion barrier Dynavisc was applied between plate and extensor tendon and between tendon and skin. Results in terms of pain, grip strength, and TAM at 2 weeks, 3 months, and 1 year after surgery were collected. Results on TAM were classified according to Page and Stern.
Results: After 3 months, only 2 patients had a result classified as excellent. After 1 year, 3 patients fulfilled the criteria for an excellent result. There were no adverse events. Patients with long-standing postoperative pain had a worse outcome on TAM.
Conclusions: The antiadhesive effect of Dynavisc in this prospective case series was unconvincing. Only 2 patients had an excellent result on TAM at 3 months. Because the gel is resorbed within 30 days after application, it is questionable whether the gel had a role in improvement that occurred later in the postoperative course. Larger, randomized studies would be required to show any anti-adherent effect of Dynavisc definitively in finger fracture surgery.
Type of study/level of evidence: Therapeutic IV.

Finger stiffness resulting from adhesion formation after plate fixation in the phalanges is a well-recognized problem.[1–7] Different kinds of adhesion barriers have been tested in hand surgery, both in fracture treatment and in tendon repair. The lactoferrin derivative PXL01 (Gliatech, Cleveland, OH),[8] denaturized cellulose,[9] mannose 6-phosphate,[10] Adcon-T/N,[11] hyaluronic acid,[12] polytetrafluoroethylene diffuse membrane,[13] collagen,[14] alginate,[15] amniotic fluid,[16] flexible, inert silicone elastomer sheeting,[17] amnioplastin,[18] and cellophane[19] are some examples of materials used. So far, the results have been unconvincing and none of these materials are currently widely used in a clinical setting. In fracture treatment, plate design and a surgical approach have also been suggested as means of avoiding adhesions. However, neither a low profile plate design[4] nor a lateral plate application has resulted in less postoperative adhesions.[20]

Dynavisc is a Conformité Européene—marked gel designed to prevent adhesion formation after surgery by acting as a barrier to surrounding tissues and by reducing inflammation. The chemical component methylcellulose is the physical barrier separating and coating tissues, and polyethylene oxide prevents inflammatory processes by inhibiting protein deposition and thrombus formation.[21] The chemical composition with the polyethylene oxide and the gel formulation in Dynavisc differs from the methyl cellulose previously tested in fracture surgery by Kappos and coworkers.[9] In that study, a net of methylcellulose only was placed between plate and extensor tendon. According to the manufacturer of Dynavisc, the product is resorbed by the body within 30 days through hydrolysis. Dynavisc has been reported to have a positive effect when used in revision surgery of recurrent carpal tunnel syndrome[22] and to prevent peritendinous adhesions after tenolysis in rabbits (Riccio M, unpublished data). The same formulation, in

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Corresponding author: Johanna von Kieseritzky, MD, PhD, Department of Hand Surgery, Hiss C Plan 7, Sjukhusbacken 10, 118 83 Stockholm, Sweden.
E-mail address: Johanna.vonkieseritzky@sll.se (J. von Kieseritzky).

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a product called Oxiplex (FzioMed, Inc., San Luis Obispo, CA), was reported to prevent adhesion formation in spinal root surgery and gynecological procedures.[23,24]

The aim of this study was to determine the effect of the adhesion barrier gel Dynavisc on range of motion (ROM) and postoperative pain after plate fixation of phalangeal fractures.

Patients and Methods

We planned for a randomized controlled trial to find out whether the use of this adhesion barrier between plate and extensor tendon in plate fixation of finger phalanges would improve mobility in the operated fingers. The extent of such a study, both in cost and duration, motivated a prior test of the product in this prospective case series.

Patients aged 18 to 70 years who presented with a finger fracture of the proximal phalanx suitable for plate fixation were offered to participate in the study. Exclusion criteria were fractures of the thumb, open fractures, intra-articular fractures, other injuries distal to the wrist, chronic joint diseases, conditions that could influence fracture healing, or the ability to participate in hand rehabilitation.

All operations were performed using a dorsal approach in which the fracture or osteotomy was fixated with a mini plate (Compact Hand 1.5, Synthes, New Brunswick, NJ [n = 7] or Stryker VariAx, Kalamazoo, MI [n = 1]). After plate fixation, the 1-mL content of the prefilled syringe of Dynavisc gel was distributed between plate and extensor tendon and between tendon and skin. Active mobilization exercises were started 1 to 4 days after surgery. The postoperative rehabilitation was conducted by a single experienced hand therapist and included full-range joint motion exercises with a minimum of 5 repetitions every other hour. Six patients started directly with 10 repetitions; one patient started with 5 repetitions, reaching 10 repetitions at 9 days after surgery; and one patient had to manage all of her training by herself owing to traveling, starting directly with 5 repetitions and increasing to 10 repetitions when tolerated. The need for a protective orthosis was decided by the surgeon. Six patients used a static orthosis in the position of safety between training sessions and at night during the first 2 to 4 weeks; one patient had an orthosis only at night and for riskier activities, and one patient only wore a buddy strap in activities entailing a risk for too much load.

Active ROM in metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints summarized as total active motion (TAM) was the primary outcome and was measured with a standard goniometer at 2 weeks, 3 months, and 1 year after surgery and classified according to Page and Stern[2] (Table 1). Proximal interphalangeal joint extension lag was also documented because this a common residual condition after proximal phalangeal fractures.[4] Median values and interquartile range (IQR) were used. Pain at rest and during motion was the secondary outcome and was reported at baseline, 2 weeks, 3 months, and 1 year on a physical visual analog scale from 0 to 100, in which patients could move and place a plastic knob on an unmarked line indicating pain.[26] Grip strength was measured at 3 months and 1 year after surgery with a Jamar dynamometer (Saehan Medical, Changwon, South Korea).[25] All measurements were performed by one of the authors (J.R.), an experienced physiotherapist.

Table 1
Classification of results according to Page and Stern[2]

Result	TAM
Excellent	> 240°
Good	220° to 239°
Fair	180° to 219°
Poor	< 179°

Ethics

Ethical approval was granted by the regional ethics committee in Stockholm, Sweden (numbers 2015/846-31/2 and 2016/1953-32). All patients provided signed consent to participate in the study.

Results

Eight consecutive patients (5 men and 3 women), mean age 45 years, were included from April 2016 to June 2017, all with complete follow-up at 1 year. One patient was simultaneously treated for bilateral distal radius fractures with plate fixation (Table 2). There were no wound healing problems and no infections in any patients. All fractures healed without complications. One plate removal was performed at 5.5 months after surgery owing to volar screw penetration. However, there was no major improvement of TAM after surgery in this patient (Table 2).

After 3 months, 2 patients had excellent, one had good, one had fair, and 4 had poor results (Table 2).[2]

At 1 year, the results had improved: 3 had excellent, one had good, and 4 had fair results (Table 2).

At 2 weeks, median TAM was 133° (IQR = 88°); at 3 months it was 203° (IQR = 58°); and at 1 year, it was 217° (IQR = 55°). At 3 months, a minor proximal interphalangeal extension lag was found in 7 patients (median 20°; IQR = 15). This had decreased marginally to 18° (IQR = 9) at 1 year (Fig. 1).

Median pain at rest was 7 at baseline (IQR = 15) on a visual analog scale and on 50 at motion (IQR = 28). At 3 months, pain at rest had decreased to 0 (IQR = 0), and pain at motion to 9 (IQR = 25). At 1 year, median pain at motion had decreased further to 4 (IQR = 17). The 4 patients with a poor result 3 months after surgery and fair results at 1 year had longer-lasting pain at motion than did the other patients. At 3 months, median pain at motion for this subgroup was 29.5 (IQR = 33), and at 1 year, 19 (IQR = 15) (Table 2).

At 3 months, median grip strength was 25.5 kg (IQR = 19.4 kg) compared with 38.3 kg (IQR = 25 kg) in the uninjured hand. At 1 year, median grip strength had increased to 26.2 kg (IQR = 22.2 kg) compared with 37.7 kg in the uninjured hand (IQR = 25.6 kg).

Discussion

In this prospective case series, only 2 of 8 patients had reached an excellent result of TAM after 3 months. At 1 year, 3 were considered excellent and 1 was considered good, meaning that 4 patients exceeded a TAM of 220° or greater. These results were better than those reported by Page and Stern,[2] in which only 4 of 37 phalangeal fractures (11%) reached TAM of 220° or greater. However, because Page and Stern included open and intra-articular fractures and the follow-up of 6 months was shorter, it is difficult to perform comparisons. The same pattern is seen in the study of Pun et al,[1] in which only 26% of the plate-fixated fractures reached a ROM of 210° or greater. The studies by Page and Stern and Pun et al were conducted during the 1990s; hence, plates used were older and perhaps more prominent. In the study by Brei-Thoma et al[4] from 2015, which used newer thin plates more comparable to those used in the current study, an average TAM of 213° was measured. This is slightly better than our result with a mean of 202° and a median of 203°, which suggests that Dynavisc had had little impact on results. Furthermore, that 4 of 8 patients in the current study had only fair results despite the use of Dynavisc shows that employing an adhesion barrier of this kind does not seem to solve the problem of stiff fingers after plate fixation of the proximal phalanx.

Table 2
Individual Patient Data and Results for TAM and Pain

Case Data					3 Mo						1 Y					
Patient	Sex	Age	Finger	Fracture Type	Finger TAM (°)	Proximal Interphalangeal Extension Lag (°)	TAM Classification According to Page and Stern[2]	Pain at Rest	Pain at Motion	Grip Strength (kg)	Finger TAM (°)	Proximal Interphalangeal Extension Lag (°)	TAM-Classification According to Page and Stern[2]	Pain at Rest	Pain at Motion	Grip Strength (kg)
1	M	30	Little	Proximal transverse	220	10	Good	0	0	36	238	12	Good	0	0	28.6
2*	F	34	Middle	Diaphyseal transverse	257	10	Excellent	0	0	14.3	273	12	Excellent	0	0	23.7
3	M	39	Middle	Comminute	215	20	Fair	0	0	32	255	20	Excellent	0	0	39.3
4	M	57	Index	Proximal transverse	145	20	Poor	0	73	5.3	190	15	Fair	0	45	16.3
5	F	60	Little	Proximal transverse	160	40	Poor	4	20	11.6	185	30	Fair	2	8	18.6
6	M	32	Little	Spiral	255	0	Excellent	0	18	52.6	240	0	Excellent	0	0	54.3
7†	M	52	Ring	Diaphyseal transverse	175	25	Poor	0	0	22	180	25	Fair	0	23	19
8	F	58	Little	Proximal oblique	190	25	Poor	0	39	29	195	20	Fair	0	15	46.3

* Patient was treated for bilateral distal radius fractures simultaneously.
† Patient was reoperated on after 5.5 months with extraction of the plate.

Page and Stern[2] measured ROM before additional surgery as the final outcome. Only one patient in the current study needed additional surgery with plate removal; in this patient, TAM was classified as fair both before and after plate removal, and TAM improved by only 5°. The lack of improvement of TAM after plate removal corresponds well with the results of Page and Stern, in which 13 of 82 patients (16%) had additional surgery, but only 3 of those had improved ROM afterward.

In our study, 4 patients had a poor outcome at 3 months. These were also the patients who had reported the highest scores on pain both at rest and at motion throughout the rehabilitation period. This raises the issue of the importance of adequate treatment of pain during postoperative rehabilitation. Better pain management might have further improved the results of these patients in our study. Additional information on the importance of adequate pain medication before performing all exercises might have proved beneficial. However, the significance of this finding would have to be examined in a larger cohort before any conclusions were made. The origin of pain in these patients is unknown. One could speculate that adhesions could aggravate pain during rehabilitation exercises, but this does not explain the perceived pain at rest in these patients.

The recovery pattern matched that of Miller et al[27] until 3 months. In our study, there was further improvement in joint motion between 3 months and 1 year, but because Dynavisc is said to be resorbed within 30 days, it is unlikely that the improvement in TAM several months later resulted from the use of the barrier gel. It is more reasonable to think that intensive and persistent physiotherapy was the key to improvement rather than the use of Dynavisc.

A strength of our study is the prospective study design, the standardized and well-controlled rehabilitation program, conducted by a single experienced physiotherapist. We also had complete follow-up of all patients 1 year after surgery and used a standardized approach by testing the adhesion barrier on dorsal plate fixation for proximal phalangeal fractures. This model is more reliable than that of a tenolysis model in which the presence of adhesions and baseline ROM is more variable. The phalangeal fracture model is also clinically relevant considering the prevalent problems of adhesion formation after plate fixation.[9] The largest drawback of this study is the small sample size of 8 patients. The next step would be a larger randomized trial. Another potential drawback could be the variation in postoperative therapy intensity among patients. However, we do not believe this had an influence on results. In work on tenolysis of flexor tendons on rabbits (Riccio M, unpublished data), the Dynavisc-treated rabbits had better results than untreated rabbits, regarding not only adhesion formation but also regeneration of peritendinous structures and of the synovial sheath. One explanation for the difference from our results could be that we used Dynavisc on the extensor side where there is no synovial sheath. Also, comparison between species is difficult.

The results of this small study did not support the use of Dynavisc as an adhesion barrier. The results for TAM compare well with those of previous studies.[2,4] However, the anti-adhesive effect of Dynavisc should have been evident during the first month after surgery and we expected more impressive improvement in TAM during the first 30 days. Only 3 patients had an excellent result regarding TAM at 3 months. The fairly good results at 1 year in this study were more likely the result of continued physiotherapy. Four of 8 patients with the highest pain scores had a poor result at 3 months. This seems to indicate that Dynavisc had little influence on pain and inflammation properties. Larger, randomized trials would be required to reveal the potential effects of Dynavisc on adhesion formation and pain after surgery of the finger phalanges.

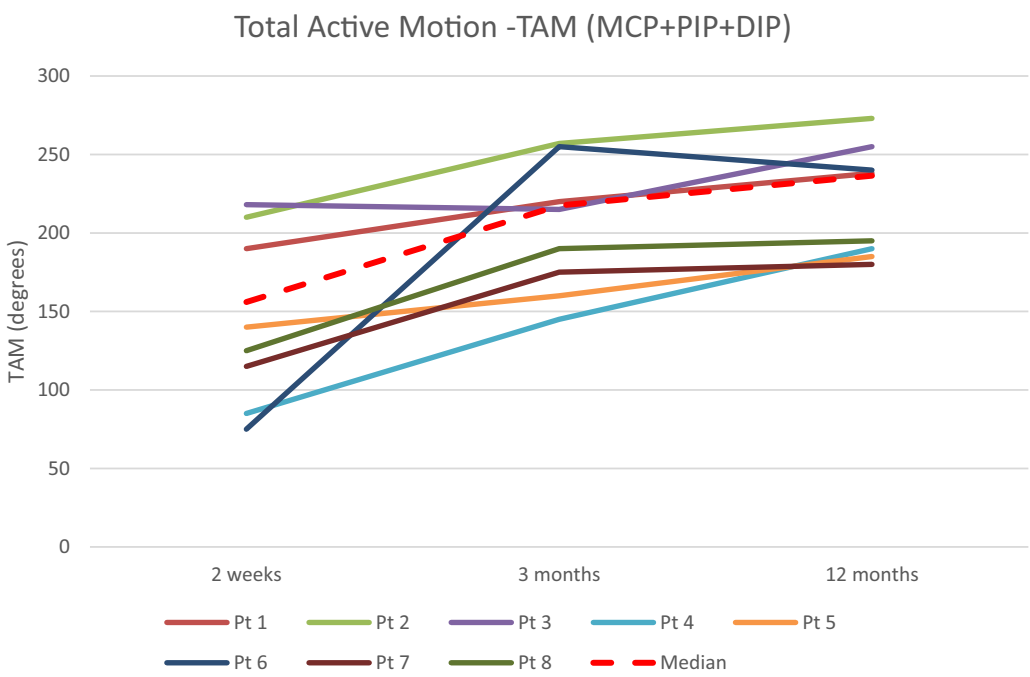

Figure 1. Progression of TAM for each patient at defined follow-up intervals. The interrupted red line shows median values of the 8 patients. The time scale is not linear. DIP, distal interphalangeal; MCP, metacarpophalangeal; PIP, proximal interphalangeal.

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