FECHNICAL REPORT

INJEX[™] and Dupuytren Treatment

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A thickening of the connective tissue of the palmar fascia is called Dupuytren's Disease (Dupuytren's Contracture or Palmar Fibromatosis). Starting at the palmar aponeurosis, strong cords run deep to the periost and the surface to the connective tissue layers of the skin. Flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint - hyperextension in the distal interphalangeal joint in the final stage - are typical symptoms of the disease. The hand's ability to function is severely limited.

Described as early as 1831 by the French surgeon Baron Guillaume Dupuytren, the disease's cause is still unknown. Genetic predisposition seems to play an important part. For every third person affected, a family member is also affected. Men are affected 6 to 9 times more than women. The disease is common among Caucasians, and becomes more frequent the closer one gets to Northern Europe. Although the disease is benign and never results in a malign degeneration, patients are impaired in their manual activities (e.g. during personal hygiene, when writing, getting dressed or shaking hands), which decreases their quality of life.

- The disease progresses in different stages:
- Stage 1: nodules and cords in the palm of the hand
- Stage 2: flexion contracture in the metacarpophalangeal point
- Stage 3: flexion contracture in the metacarpophalangeal joint and the proximal interphalangeal joint
- Stage 4: severe flexion contracture in the metacarpophalangeal and proximal interphalangeal joints with a hyperextension in the distal interphalangeal joint

Dupuytren's Disease progresses slowly and can go into periods of temporary arrest during any one of its stages. Traditional therapies (physical treatment etc.) bring little relief and are only applied during Stage 1.

Local injection (very painful) of Cortisone softens the cords and brings on the side affects typical of Cortisone, but does not cause the disease to regress. The best indicators for surgery are cord development in its beginning stages with flexion contracture in one finger (Stage 2) or the continuing spread of the disease to the palm. One cannot and should not expect surgical treatment to completely cure the disease, which frequently recurs in the surgically treated area (15 - 20% of the cases), making a further surgical intervention inevitable.

> The painless, non- traumatic and infection-free injection technology of the INJEX[™] system lends itself perfectly to this type of procedure.

Casuistic I: Patient L. P. (F), born in 1914

About 10 years ago, this patient underwent a subtotal fasciectomy left (ring finger). The scar areas are a hindrance and are cosmetically ugly. For these reasons, the patient refuses to undergo surgery on her right hand, which shows a pronounced flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint of the right finger (Stage 3). The proximal interphalangeal joint is chronically inflamed, is



painful when pressure is applied, and shows joint play.

Needle injections in the palmar aponeurosis are turned down.

On August 15, 2000 the first needle-free injections (4 x) are performed with the **INJEX**TM system. A mixture of Procaine and Traumeel is drawn up into a disposable ampoule and applied at six different points along the contracture cords. The injection volume selected was lower than 0.1 ml. The needle-free injections with the **INJEX**TM system were well tolerated and virtually painless. A further 5 needle-free injections with the **INJEX**TM system were performed between August 16 -18, August 21-23 and on August 29 respectively.

During the treatment, the entire palm became suppler and the tension the patient felt was clearly reduced. According to the patient, overall movability improved. Small, insignificant blood tumours developed at only two of the injection points.

The patient was so enthusiastic that the painful joint was added to the list of application points on August 31, 2000. Further needle-free injections with the **INJEX**TM were performed on 08/31/00 and 09/01/00 as well as between 09/04 and 09/08/00 and on 09/14/00. At this point in time, it was possible to measure the results, which were more than successful in the eyes of the patient. The ring finger had reduced in size from its previous 6.5 cm to 5.8 cm and hardly hurt anymore. When laid flat on a surface, the stretched out hand had a height of 2.4 cm compared to its previous 3.2 cm.

This state has been maintained since October 2000 by continuing the **INJEX**TM treatment in a 10-day rhythm. The patient is very happy with the results, and notices both a subjective and objective improvement of the use of her hand when performing her daily activities.

Casuistic 2: Patient G. S. (M), born in 1946

In 1980, the patient developed gouty nodules in the palm of his right hand. In October 2000, the patient arrived with Dupuytren's Disease Stage 3 (flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint) in the middle finger of his right hand. The left hand was also affected - Stage I (nodules and cords in the palm). The patient wanted to avoid having surgery for as long as possible. The patient, a right-handed teacher, found it very difficult to perform some of his professional activities (he uses a pen and a computer).

There was a pronounced flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint of the right middle finger. Needle injections in the palmar aponeurosis were turned down after a few very painful tries.

On October 25, 2000 the first needle-free injections are performed with the **INJEX**TM system. A mixture of Procaine, Traumeel and Graphites is drawn up into a disposable ampoule and applied at six different points along the contracture cords. The injection volume selected was between 0.1 ml and 0.15 ml. The needle-free injections with the **INJEX**TM system were well tolerated and virtually painless.

Further needle-free injections were performed on 10/26/00, 10/27/00, 10/30/00, 10/31/00, 11/06/00, 11/08/00, 11/09/00, 11/10/00, 11/13/00 and 11/15/00 with up to 10 needle-free applications. The left hand was treated at the same time with 2 to 3 needle-free injections.

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During the treatment the entire palm became suppler and the tension that the patient felt was clearly reduced. The numb and swollen feeling in the morning improved considerably after the 4th, 5th and 6th injections.

Further needle-free injections with the **INJEX**TM system were performed on 11/17/00, 11/20/00, 11/27/00, 11/30/00, 12/06/00, 12/14/00 and 12/20/00. At this point in time, it was possible to measure the results, which were more than successful in the eyes of the patient.

This state has been maintained since January 2001 by continuing the $INJEX^{TM}$ treatment on a weekly basis.

The patient is very happy with the results, and notices both a subjective and objective improvement of the use of his hand when performing his daily activities. An external evaluation of the treatment's success could be made during the teaching staff's new year's welcome due. When shaking hands, colleagues either refrained from making the usual annual comments or they commented on the positive improvement.

For the first time, the **INJEX**TM system makes it possible to apply medication in the palm virtually without pain. For the therapist, this presents a new way to treat Dupuytren's Disease.



Patient G. S.

Flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint with a hyperextension in the distal interphalangeal joint of the ring finger. State on 01/30/01 after a 3-month treatment Improvement by ca. 20 - 25 angular degrees.

Patient G. S. Still recognisable, the considerably reduced cord development in the palm with flexion contracture in the ring finger. State on 01/30/01 after a 3-month treatment







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Patient L. P. (F) Clearly recognisable, the cord development in the palm with flexion contracture in the ring finger. State on 08/15/00 at the beginning of the treatment





- CORRER OF

Patient L. P. (F) Still slight cord development, but ability to almost completely stretch the ring finger. State on 01/30/01 after a 5-month treatment

Patient L. P. (F) Flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint of the ring finger. State on 08/15/00 at the beginning of the treatment.





Patient L. P. (F) Flexion contracture in the metacarpophalangeal joint and proximal interphalangeal joint of the ring finger. State on 01/30/01 after a 5-month treatment



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