Saturday, 23 May 2015, 08:30

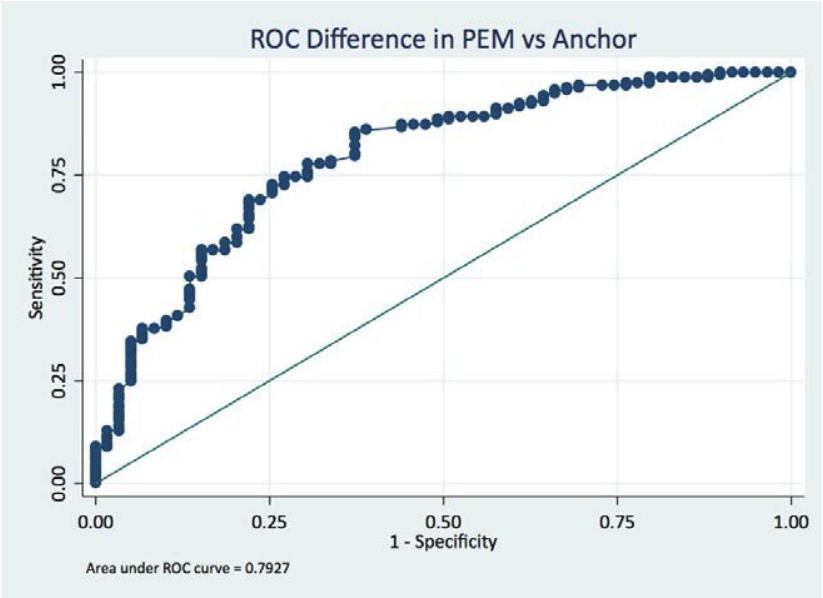
MCID for the Patient Evaluation Measure as a Patient Rated Outcome Measure for Dupuytren Contracture

Joseph Dias, Leela Sayeed, Bhaskar Bhowal; Academic Team of Musculoskeletal Surgery (ATOMS), University Hospitals of Leicester, LE5 4PW, UK.

Using multiple methods (ROC, Distribution, Social Comparison Approach) we investigated the MCID of PEM in 446 patients surveyed 3 years after their first visit. 27% were women and the mean age was 67 years.

The PEM was collected throughout treatment. The mean initial PEM was 42 (SD 21), the final PEM was 29.9 (SD24) and the improvement in PEM was 12 points. PEM reflected deformity (Pearson's Correlation 0.4) and correlated highly (0.79) with the 7-interval anchor question asking how the hand was, compared to before. Responses ranged from "delighted" to "terrible" with 4 representing "no change". Using ROC (AUC 0.79) and Youden's Index 3 points improvement in PEM classifies if patients will consider that they have improved clinically with a sensitivity of 0.85 and specificity of 0.63. This is similar to the figure of 2.8 obtained using the Social Comparison method. Common methods using statistical distribution gave varying and inconsistent values.

The PEM improved by 9.1 points over 3 years in the 103 patients who did not have surgery and by 13 points in the 343 patients who had surgery. 15.4% of untreated patients worsened which was the same proportion (15%) finding that they were worse after surgery. For our population of Dupuytren contracture patients we have established that the MCID of PEM is 3 points.



Saturday, 23 May 2015, 08:36

Predictors of Satisfaction with Hand Function In Patients With Dupuytren's Disease

Chao Zhou, Michiel Zuidam, Xander Smit, Harm Slijper, Reinier Feitz, Steven Hovius, Ruud Selles; Erasmus MC, Rotterdam; Xpert Clinic, Hilversum, The Netherlands.

Hypothesis: Understanding the factors that influence satisfaction with hand function in patients with Dupuytren's disease can offer unique insights into what patients perceive as successful outcomes. This prompted a study that examined which patient characteristics and postoperative outcomes predicted satisfaction with hand function in the first year after partial fasciectomy.

Methods: In this multicenter study, 236 patients treated with partial fasciectomy completed the Michigan Hand Questionnaire (MHQ) preoperatively and at varying time points in the first year after surgery. From the most recently completed questionnaire, we derived satisfaction subscores, ranging from 0 (completely dissatisfied) to 100 (completely satisfied). These scores were used to classify patients into a satisfied and dissatisfied category according to a previously published satisfaction assessment approach. Baseline characteristics and outcomes assessed at the first follow-up visit (including joint contracture and MHQ scores) were considered as possible predictors. Uni- and multivariable regression models were used to identify independent predictors of satisfaction. Receiver-operating curves assessed the ability of the model to distinguish satisfied from dissatisfied patients.

Results: At an average of 10 months (range, 6-12 months) after surgery, 65% (N=153) of patients were considered satisfied with their hand function. Univariable analysis indicated that satisfied patients were more likely to be males, have milder baseline PIP joint contractures and better self-reported hand function, and had less residual joint contracture and better self-reported hand function postoperatively.

In multivariable analysis accounting for baseline hand function ($p=0.02$), postoperative residual joint of contracture (<0.01) and hand appearance (<0.01) remained as independent predictors, contributing to a predictive model with good discriminative ability.

Conclusion: Satisfaction with hand function was predominantly associated with the degree of residual joint contracture and self-reported hand appearance after surgery. Our study shows that the way patients perceive their hand aesthetically may be relevant for some patients with Dupuytren's contractures. Moreover, these findings provide reassurance for the legitimacy of patient satisfaction with hand function as a proxy for quality of care.

Saturday, 23 May 2015, 08:42

URAMS as a PROM for Dupuytren Contracture Patients

Joseph Dias, Leela Sayeed, Aamer Ullah; Academic Team of Musculoskeletal Surgery ATOMS, University Hospitals of Leicester, LE5 5PW, UK.

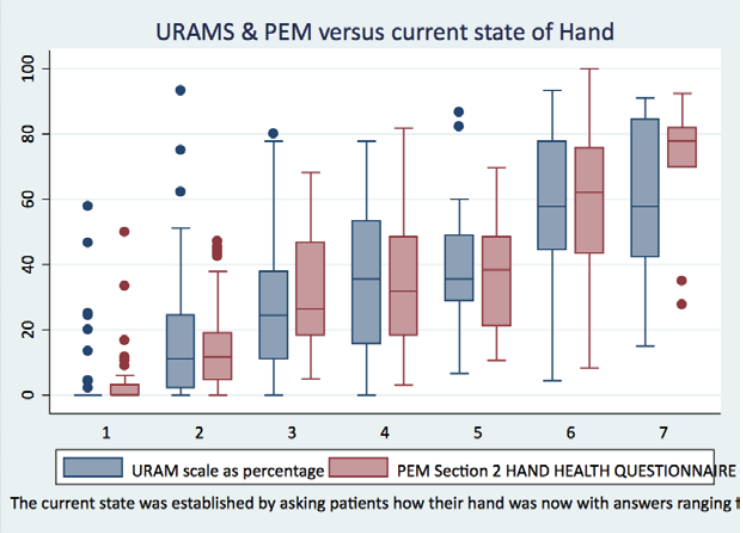
We investigated whether the URAM scale was useful as a PROM for routine monitoring of patients with Dupuytren's contracture.

We asked 1074 consecutive patients with Dupuytren's contracture seen in our hand unit to complete a patient evaluation measure, an URAMS and to provide feedback on the ability of URAMS to represent the disability they perceived of their hand. All patients had completed a PEM when first seen in clinic. There were 804 male and 270 female (25%) patient with a mean age of 64 years. 457 had no surgery while 617 had surgery to correct contracture. Of these 490 responded. 402 of 490 responses form the basis of this abstract. The mean interval between the initial clinic visit and final response was 33.5 months.

The mean PEM at follow up was 24 (SD 23) and the mean URAMS was 10 (SD 11). URAMS had a high correlation 0.78 with PEM and reflected the degree of contracture of the worst affected finger (Pearsons Correlation 0.44). We asked patients if the URAMS captured what was important to them. 25.7% found that the URAMS did not properly represent the condition of the hand.

Using the anchor method the MCID for change for URAMS in our population was 2.8 between patients who had slight improvement and 3.6 between those who had slight worsening and no change at 3 years.

URAMS reflects contracture and disability but may not completely capture the state of the hand after intervention for Dupuytren contracture and so if used should be combined with generic Hand outcome measures such as the PEM, or MHQ of the general Upper limb measure DASH.



Saturday, 23 May 2015, 09:03

Tips and Pearls for Percutaneous Needle Fasciotomy and Collagenase - A Ten Year Personal Experience

Gary M. Pess; Central Jersey Hand Surgery, 2 Industrial Way West Eatontown, NJ, USA; Drexel University Medical School, Philadelphia, PA, USA.

The utilization of percutaneous needle fasciotomy (PNF) and Collagenase, for the treatment of Dupuytren Contracture (DC), has not been universally accepted in the USA or worldwide. Some of the reasons given by non-users include: high recurrence rate, lack of long-term results, fear of causing nerve and tendon damage and potential complications. Some physicians will use PNF and collagenase for metacarpophalangeal joint contractures, but claim that it is too dangerous to utilize for proximal interphalangeal joint contractures.

I began utilizing minimally invasive treatments for Dupuytren Contracture in 2004. Since that time, I have personally performed over 6,000 PNF procedures and over 600 collagenase injections. For my patients with DC, I utilize these techniques almost exclusively, rarely if ever performing fasciectomy. I have had the opportunity to perform successful PNF after previous PNF, collagenase, open fasciectomy and dermofasciectomy. I have also injected collagenase after previous collagenase, PNF, open fasciectomy and dermofasciectomy.

This presentation is a based on a ten-year experience. The goal is to simplify the two techniques and devise a step-by-step plan that can be used to safely achieve the best possible result, lowest recurrence rate and minimize complications. Tips, tricks and pearls of wisdom I have accumulated over the last ten years will be discussed.

The fear of performing PNF and collagenase can be minimized through education and subsequent personal experience. A physician will then be able to offer their patients two minimally invasive alternatives for treatment of their DC.

Saturday, 23 May 2015, 09:09

Percutaneous Needle Fasciotomy for secondary or higher recurrence in Dupuytren's disease

Margot Vlot, Paul Werker; University Medical Center Groningen, Hanzeplein 1, 9713 GZ Groningen, The Netherlands.

Hypothesis: Percutaneous needle fasciotomy (PNF) has been shown to be an effective treatment for primary contractures and first recurrences in Dupuytren's disease[1, 2, 3]. The aim of this study was to find out if PNF was an effective treatment option for secondary, tertiary and quaternary recurrent Dupuytren's disease. Indication for this was a Total Passive Extension Deficit (TPED) of at least 30°.

Methods: This was a retrospective medical file study on patients who underwent secondary (or higher) treatment for DD using PNF. Patients treated in between 2007 and 2014 were identified using operation codes for PNF. Inclusion criteria for this study were: third, fourth or fifth treatment of the same ray. The primary outcome measurement was the reduction of TPED as a result of third, fourth or fifth treatment at 4-6 weeks postoperatively. Time to subsequent recurrence was also noted, as well as mean time to more aggressive treatment.

Results: 8 patients underwent PNF three times, 4 patients four times and 3 patients five times. TPED reduction after a third, fourth and fifth treatment was respectively 71.4%, 63.3% and 25.7%. Tertiary and quaternary treatment was just as effective as primary and secondary treatment.[2, 3] Treatment was significantly less effective at PIP than at MCP level, irrespective of treatment number. After a third treatment with PNF, 4 out of 11 patients (36%) returned with recurrent disease after a mean of 24 months. The others did not return with a recurrence after a mean of 20.3 months. Three out of these four patients underwent PNF again, one chose limited fasciectomy. One of the three returned with a fourth recurrence 7 months post-PNF and underwent limited fasciectomy. By means of PNF, a more aggressive treatment was postponed with an overall average of 32 months.

Summary:

- This study showed that the effectiveness of PNF for secondary and tertiary recurrences was similar to that for primary disease and primary recurrences.
- Subsequent treatment after treatment for secondary recurrences was necessary in approximately 30% of cases.
- By means of PNF, limited fasciectomy in total was postponed for 32 months

[1] Pess GM, Pess RM, Pess RA. Results of needle aponeurotomy for Dupuytren contracture in over 1,000 fingers. J Hand Surg Am. 2012 Apr;37(4):651-6.

[2] van Rijssen AL, ter Linden H, Werker PM. Five-year results of a randomized clinical trial on treatment in Dupuytren's disease: percutaneous needle fasciotomy versus limited fasciectomy. Plast Reconstr Surg. 2012 Feb;129(2):469-77.

[3] van Rijssen AL, Werker PM. Percutaneous needle fasciotomy for recurrent Dupuytren disease. J Hand Surg Am. 2012 Sep;37(9):1820-3.

Saturday, 23 May 2015, 09:15

Extensive Percutaneous Aponeurotomy and Lipofilling versus Limited Fasciectomy in Patients with Primary Dupuytren's Contracture; a Randomized Controlled Trial

Steven Hovius, Hester J. Kan, Ruud W. Selles, Christianne A. van Nieuwenhoven, Chao Zhou, Roger K. Khouri; Erasmus MC, Rotterdam, The Netherlands; Miami Hand Center, Miami, USA.

Hypothesis: As an alternative for the standard percutaneous release, we recently introduced a new extensive percutaneous aponeurotomy with lipofilling (PALF) and found that contracture was significantly improved and that most patients returned to normal use of the hand within 2 to 4 weeks. In this single-blind multicenter randomized trial, we compare the effectiveness of PALF with limited fasciectomy (LF), evaluating contracture correction and convalescence as the primary outcome measures.

Methods: patients with a primary Dupuytren's contracture of at least 20° (MP joint) or 30° (PIP joint) were randomly assigned to the LF group or the PALF group. Patients were measured at baseline and at two weeks, three weeks, six months and one year post-operatively. Primary outcome measures of the trial were contracture correction and convalescence and groups were compared using a mixed models approach.

Results: Eighty patients with 88 treated hands were included in this study and randomized to PALF or LF treatment. We found that in both groups a strong contracture correction was obtained. However, comparing groups, the overall interaction effect between time and group was not statistically significant (p=0.35), indicating a similar contracture change in both groups over time. In addition, we found that patients in the PALF group returned significantly earlier to their normal daily activity (median of nine days in the PALF group compared to a median of 19 days in the LF group (p=0.001)) but found no significant differences in recurrence rate and hand function between groups. Satisfaction was significantly better in the LF group for overall treatment outcome, contracture correcting, and whether the treatment expectations were met; all other satisfaction-related questions were similar between 2 groups. The overall complication rate was not significantly different among the groups (p = 0.402).

Summary: In this study, we found that PALF and LF lead to similar outcomes in terms of contracture correction, recurrence rate and hand function. PALF leads to earlier return to normal daily activity whereas LF leads to more patient satisfaction on some of the satisfaction items.

Saturday, 23 May 2015, 09:37

Controversies 4:

How to treat severe PIP contractures: minimally invasive or surgically?

Chair: Joseph Dias

Minimally invasive methods: Clayton Peimer

Surgical correction: Caroline Leclercq

Saturday, 23 May 2015, 10:45

Lecture: Treatment of Dupuytren Disease: Where are we now?

David Elliott, Spire Wellesley Hospital, South End, United Kingdom.

Saturday, 23 May 2015, 11:05

Steroid injection and needle aponeurotomy for Dupuytren disease: long-term follow-up of a randomized controlled trial

Paul Binhammer, Catherine McMillan; Sunnybrook Health Sciences Centre, 2075 Bayview Avenue, Toronto, Ontario M4N 3M5, Canada.

Purpose: To compare long-term outcomes and re-treatment rates for patients with Dupuytren disease who underwent needle aponeurotomy (NA) combined with a series of triamcinolone acetonide injections (NATI group), or underwent NA alone (NA group) as part of a prior randomized controlled trial.

Hypothesis: Participants in the NATI group will experience less joint contracture and a delay to re-treatment relative to the NA group.

Methods: During this follow-up study, 44 of 47 participants in the original study were examined as needed between 6 and 53 months from their initial procedure. Those who had not been reassessed by 18 months were asked to return for follow-up. The total active extension deficit (TAED) of previously treated joints was measured. Average TAED was compared between groups 7-12, 13-24, 25-36, and 37-48 months following treatment. Timing of re-treatment (if performed) was recorded.

Results: Forty-four participants returned for assessment an average of 4.8 times over 53 months. Mean TAED was significantly less in NATI subjects at 6 months and between 13 and 24 months (Figure 1). Sixty-two percent of NA group subjects and 30% of NATI group subjects returned for a second treatment on the same digit(s) (re-treatment). This difference was not significant. Mean time to re-treatment and mean TAED immediately prior to re-treatment did not differ significantly between groups. Kaplan-Meier survival estimates demonstrate a significantly higher percentage of NA group subjects expected to return for re-treatment by 24, but not by 36 months (Figure 2). Younger age, more than one joint treated at the initial NA, and higher follow-up TAED were significantly associated with earlier re-treatment.

Summary: The use of serial triamcinolone injections combined with NA was associated with significantly lower TAED for up to 24 months. A trend toward later re-treatment was also observed in the NATI group. A large prospective long-term study including TAED, re-treatment, and patient-reported outcomes would accurately characterize quantify the potential benefits of combining triamcinolone injections with NA for treatment of Dupuytren disease.

Figure 1.

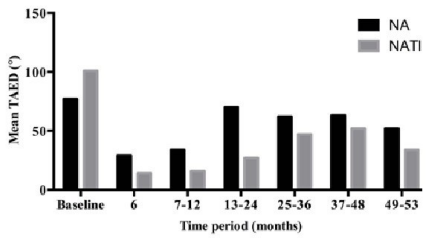
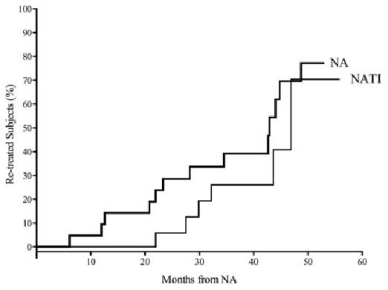


Figure 2.



Saturday, 23 May 2015, 11:11

Minimally invasive treatment of Dupuytren: Collagenase vs. PNF

Eva-Maria Baur, Zimmermann, Müller; University Clinic of Plastic, Reconstructive and Aesthetic Surgery, Innsbruck, Austria.

At the university clinic of plastic, reconstructive and aesthetic surgery of Innsbruck we are looking for the results after two minimally invasive treatments for Dupuytren disease.

With the upcoming possible treatment with collagenase the “old fashioned” therapy with percutaneous needle fasciotomy (PNF) becomes a big revival.

The purpose of the non-randomized prospective study was to look for differences after 12, 18 and 24 months regarding the two possible treatments.

In our clinic we propose and perform both treatments, the decision is taken together with the patient. Since more than 2 years we follow-up the patients regarding the results after 3 weeks, 3, 6, 12, 18, 24 months; regarding function, scars, and recurrence (worsening of contracture in comparison to 3 weeks postop at least for 20°).

Patients treated with

> Xiapex : 12 months postop. – 25 patients; 18 months postop. - 16 patients; 24 months postop. - 13 patients
>
> PNF: 12 months postop. - 30 patients; 18 months postop. - 19 patients; 24 months postop. - 18 patients

Post “operative” treatment is night-splinting for 6 weeks at least.

We report our results of both groups. We cannot find a real difference between both groups. But the follow-up is only 24 months for the moment. We report also the pros and cons of the two different treatment options.

Saturday, 23 May 2015, 11:17

Collagenase Clostridium Histolyticum versus Partial Fasciectomy for Dupuytren's contracture: Early Outcomes From A Multicenter Propensity-Score Matched Study

Chao Zhou, Steven Hovius, Harm Slijper, Reinier Feitz, Christianne van Nieuwenhoven, Hanneke Pieters, Ruud Selles; Erasmus MC, Rotterdam; Xpert Clinic, Hilversum, The Netherlands.

Introduction: Collagenase Clostridium Histolyticum (CCH) offers an alternative to Partial Fasciectomy (PF) in the treatment of Dupuytren's disease. The few available studies comparing both techniques reported similar results but may have been subjective to treatment selection bias. Propensity score matching is a statistical approach to account for the pretreatment factors considered in treatment selection, and was applied to evaluate CCH versus PF in terms of early outcomes.

Methods: We evaluated all patients who were treated with CCH or PF for Dupuytren's contractures affecting metacarpophalangeal (MP) and/or proximal interphalangeal (PIP) joints between 2011 and 2014 by 15 surgeons from multiple practice sites. We compared the degree of residual joint contracture (active extension deficit), Michigan Hand Questionnaire (MHQ) sub-scores, and adverse events at follow-up visits occurring between 6 and 12 weeks after surgery or the last injection with the use of propensity-score matching.

Results: An analysis of 132 matched patients who were treated with CCH (N=66) or PF (N=66) showed that while the degree of residual contracture at follow-up for affected MP joints was similar among the treatment groups (13° vs. 6°, P=0.095), affected PIP joints had worse residual contracture in the CCH group compared with those in the PF group (25° vs. 15°, P=0.010). CCH patients experienced fewer serious adverse events and reported larger improvements in the MHQ subdomains of satisfaction with hand function, activities in daily life and work performance than did PF patients.

Summary: In this study, we found that CCH was similar to PF in reducing MP joint contractures, while affected PIP joints had worse residual contracture. However, CCH offered a more rapid recovery of hand function than did PF, and was associated with fewer serious adverse events.

Saturday, 23 May 2015, 11:35

Actual Indications of Continuous Extension Technique (tec) for Severe Dupuytren's Disease

Jane Messina, Antonino Messina, Gaetano Pini; Orthopaedic Institute, Milan, Italy; Clinica Fornace di Sessant, Turin, Italy.

Hypothesis: The treatment of Dupuytren's Disease has evolved in the last years and has become widely spread. Treatment of more and more early stages has been performed by surgical approach or by use of collagenase. Nevertheless still some cases presenting at a severe stage or severe/ multiple recurrence are seen in specialised Hand Surgery Centres. Amputation of the digits is still performed by some surgeons and this should be avoided. The continuous extension technique is an external fixation system that can be used in severe uni-multidigital cases of DD as an alternative to amputation.

Materials and Methods: TEC device is an external fixator able to extend the retracted finger or fingers up to the initial stage of the disease. After its positioning the extension is perfomed by the patient himself for 3 weeks. At the end of the treatment the device is removed and a simple aponevrectomy is performed.

We have been treating 130 patients, 86 were reviewed with a mean follow-up of 4 years (8months-10 years).

Results: Excellent and good results were obtained in 85% of cases, fair in 15%, no poor result. All fingers survived to amputation, 16% of stiffness was reported and 18% of recurrence or extension (8% recurrence and 10% extension) of the disease.

Summary: Nowadays indications to use this technique are rare as patient is sent early to the surgeon. But in some cases where there is a severe contracture of one or several digits, when surgery is risky the treatment is indicated as an alternative to a proposed amputation or if a multiple operation plan is needed (as severe recurrences with suspect vasculo-neural damage, skin loss, stiffness, risk of necrosis, severe contracture with difficult surgical access).

This procedure is simple and can be use also for any retracted finger as an alternative to amputation (DD or burns), the gradual extension leads to tissue regeneration as demonstrated by histological studies (as in Ilizarov method), is atraumatic for the patient and the subsequent aponevrectomy is an easy procedure to be performed.

Saturday, 23 May 2015, 11:41

Preliminary soft-tissue distraction versus checkrein ligament release after fasciectomy in the treatment of Dupuytren proximal interphalangeal joint contractures.

Anthony Smith, **Atanu Biswas**; Division of Plastic Surgery, Mayo Clinic Arizona, 5777 E. Mayo Blvd., Phoenix, AZ, 85253, USA.

Hypothesis: Preliminary soft-tissue traction produces improved outcomes when compared to checkrein ligament release after fasciectomy for severe Dupuytren PIP joint contractures.

Methods: Thirty patients (37 digits) were studied after either checkrein ligament release and fasciectomy or preliminary soft tissue distraction employing the Digit Widget(Hand Biomechanics Lab). Seventeen patients (20 digits) underwent checkrein ligament release(mean contracture, 55.9 degrees); six of these 20 were reoperations> Thirteen patients(17 digits) underwent preliminary distraction followed by operative release(mean contracture, 67.6 degrees); 10 of 17 were reoperations.

Results: The 20 digits treated with fasciectomy plus checkrein ligament release had an average extension improvement of 31.4 degrees (range, -4 to 70 degrees). Digits treated with preliminary soft-tissue distraction followed by operative release had an average extension improvement of 53.4 degrees (range, 30 to 75 degrees) ($p<0.001$ versus ligament release). Initial contractures of 60 degrees or less treated by checkrein ligament release (n=12) or soft-tissue distraction (n=7) improved by means of 28.8 and 47.7 degrees, respectively (p=0.48). Contractures greater than 60 degrees treated by checkrein ligament release (n=8) or soft-tissue distraction improved by means of 35.3 and 57.3 degrees, respectively (p=0.02).

Summary:

- Checkrein ligament release for treatment of proximal interphalangeal joint Dupuytren contractures does not address the shortened digital arteries or deficient skin.
- The Digit Widget (Hand Biomechanics Lab) uses soft-tissue distraction to overcome these issues.
- Our study compares checkrein ligament release after fasciectomy versus preliminary soft-tissue distraction, followed by operative release, for treatment of PIP joint Dupuytren contractures.
- Soft-tissue distraction followed by operative release showed greater correction than Dupuytren fasciectomy plus checkrein ligament release.

Saturday, 23 May 2015, 11:55

The Palmodigital Spiralling Sheath

Rinze Lykele Zwanenburg, A.T. Malsagova, P.M.N. Werker; University Medical Center Groningen, Hanzeplein 1, 9700 RB, Groningen, The Netherlands.

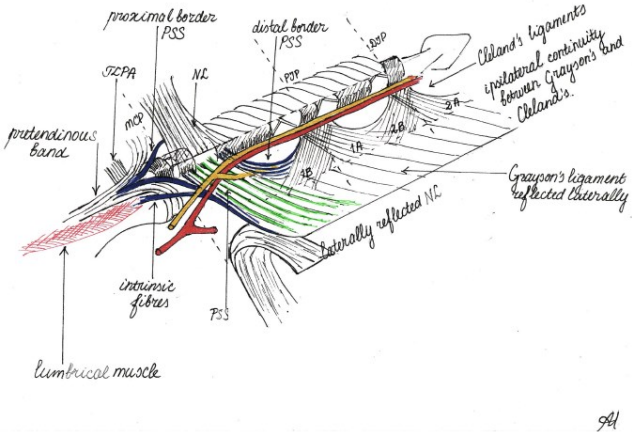
Hypothesis: Understanding the normal microanatomy of the fascial structures in the hand is essential to get insights in the development and progression of Dupuytren's disease. The literature is unequivocal especially about the transition of the palmar fascia into the digital fascia. The aim of this study is to elucidate the microanatomy of the palmodigital junction in relation to the palmar and digital fascia.

Method: We performed a dissection study and included 26 cadaveric digits, 13 middle and 13 ring fingers from 13 fresh frozen cadaveric hands. A longitudinal midline incision was used on the volar aspect of the hand, running from the midpalm to the tip of the finger. The characteristics of the palmodigital fascia and their interrelations with palmar and digital structures were observed. Measurements about origin, insertion length and width were taken.

Results: At the palmodigital junction we found a complex fascial structure that has not yet been properly described. This structure forms a spiral around the neurovascular bundle at the palmodigital junction and therefore we call it the palmodigital spiralling sheath. This sheath is formed out of three parts; the most proximal fibres originate from the pretendinous band that dives underneath the NV-bundle and is fed by fibres that originate from the intrinsic muscle fascia. These fibres insert into the dorsal aspect of the natatory ligament. The intermediate fibres originate from the flexor tendon sheath over the A1 pulley and continue as Grayson's fibres. The distal border fibres originate from the flexor tendon sheath just distal to the proximal border of the A2 pulley and arch into Clelands PIP-P ligament which attaches to the flexor tendon sheath at the proximal interphalangeal joint. The palmodigital spiralling sheath forms the most proximal part of a spiralling structure that encases the neurovascular bundle.

Summary:

- This study has provided new insights in the microanatomy at the palmodigital fascias of the hand.
- The palmodigital spiralling sheath is an important linkage between the palmar and digital fascia. It is an intertwining continuum of fibres instead of separate structures.
- We believe that any part of this continuum has the potential of becoming part of a pathological cord.
- These new insights bring us closer to understanding the development of Dupuytren's pathological cords.



Session 6: Comparative Studies / Recurrence

Saturday, 23 May 2015, 12:01

Clusters in short term disease course in participants with primary Dupuytren Disease

Rosanne Lanting, Edwin R. van den Heuvel, Paul M.N. Werker; University Medical Center Groningen, Department of Plastic Surgery and Department of Epidemiology, Hanzeplein 1, 9700 RB Groningen, The Netherlands.

Hypothesis: The course of Dupuytren disease (DD) is thought to be progressive, however, the speed and pattern of development of the disease differs between patients, and knowledge about the short term disease course is incomplete.

Methods: The course of DD was prospectively objectified at intervals of 3-6 months in 247 participants with primary DD by measuring surface area of nodules and cords, and total passive extension deficit (TPED) if a contracture was present. The association between surface area and Tubiana stage was tested with generalized estimating equations (GEE). Changes over time in surface area and TPED were studied with a linear mixed model for each ray separately. Latent class models were used to cluster change profiles, and we studied whether well-known typical risk factors for DD had an effect on short term change by testing a difference in these risk factors for the observed clusters.

Results: A high association was found between surface area and Tubiana stage (OR 3.24; 95% CI 2.55-4.13). On average, in one year the surface area increased with 0.22 cm2 and TPED with 5.5 degrees; however, the variance between participants was large. Regarding change in surface area and TPED different clusters were observed; progression of disease was seen, but also stability and even regression (Figure 1 and 2). Study cases with a smaller surface area at baseline were more likely to exhibit regression. No other typical factors could be linked to disease course.

Summary: This study shows that DD is not always progressive, and that up to 75% of cases has a different short-term disease course. This should be taken into account when evaluating the effects of treatment for early-phase DD, and in the design of future studies.

Saturday, 23 May 2015, 12:15

Recurrence after Treatment for Dupuytren's Disease; A consensus-based definition

Ruud Selles, Hester J. Kan, Frank W. Verrijp, Steven E.R. Hovius, Christianne A. van Nieuwenhoven, Dupuytren Delphi Group; Erasmus MC, 3000 CA Rotterdam, The Netherlands.

Hypothesis: Many different definitions of recurrence have been described in the literature. In a systematic review, we have shown that applying these different definitions on a single dataset resulted in recurrence rates ranging 2% to 86%. As this shows that it is not possible to compare recurrence rates reported in clinical outcome studies and randomized controlled trials, in this study, we aimed to achieve consensus on a universal and easily to apply definition for recurrence of DD after treatment.

Methods: We invited 43 experts in Dupuytren research and treatment from 10 countries to participate this Delphi study. Every round, experts were asked to fill in a questionnaire. After each round, we analyzed the answers and the experts received a feedback report. We defined that consensus was reached when at least 70% of the experts agreed on a topic.

Results: After four consensus rounds, experts agreed a consensus definition of recurrence of DD, namely as "an increase in joint contracture in any treated joint of at least 20 degrees at one year post-treatment compared to six weeks post-treatment". In addition, consensus was to advise to repeated yearly measurements and to report recurrence for all treated joints individually.

Summary: After four Delphi rounds with an international expert group, we were able to construct a uniform definition for recurrence of DD after treatment. The definition is easy to apply and can be combined with other descriptors of Dupuytren's recurrence, for example focusing on the presence of palpably nodules and cords. We suggest that this definition should be the minimally-reported recurrence outcome in future clinical outcome studies and clinical trials. Using this definition will allow better comparison of recurrence rates between different studies.

Dupuytren Delphi Group: Peter C. Amadio (Mayo Clinic, USA); Ilse Degreef (University Hospitals of Leuven, Belgium); Keith Denkler (University of California, USA); Joseph Dias (University hospitals of Leicester NHS Trust, UK); Charles Eaton (Dupuytren Foundation, USA); Charles A. Goldfarb (Washington University School of Medicine, USA); Vincent Hentz (Stanford University, USA); Raymund E Horch (Friedrich Alexander University Erlangen-Nuernberg, Germany); Lawrence Hurst (SUNY Stony Brook, USA); Christina Jerosch-Herold, (University of East Anglia, UK); Roger K. Khouri (Miami Hand Center, USA); Donald Lalonde (Dalhousi University, Canada); Christina Leclercq (Institut de la Main, France); Duncan Angus McGrouther (University of Manchester, UK); Jagdeep Nanchahal (University of Oxford, UK) Phillipe Pelissier(CHU Bordeaux, France); Michael Tonkin (University of Sydney Medical School; Australia); Paul M.N. Werker (University Medical Center Groningen, The Netherlands); Stephan Wilbrand (Uppsala University Hospital, Sweden); Andrzej Zyluk (Pomeranian Medical University, Poland).

Session 6: Comparative Studies / Recurrence

Saturday, 23 May 2015, 12:21

Recurrence after Dupuytren's disease: the time factor.

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Rates of recurrence in Dupuytren's Disease are highly variable from study to study in the literature. Several factors account for these differences, including the type of treatment, and the definition of recurrence. The main goal of this study was to study the importance of another aspect which has not received much attention so far: the time factor in recurrence.

The authors studied a consecutive cohort of of 225 patients treated surgically by a single surgeon over a 17 years period and followed clinically for an average of 3.1 years (range 15 days, 18 years) . All the parameters relevant to the disease were considered (e.g. age at onset, family history, ectopic lesions, habitus, concurrent pathologies…) and Tubiana's scoring system was used to assess the degree of contracture. Surgical treatment consisted of regional fasciectomy in 82% patients, dermofasciectomy in 11.8%, and needle fasciectomy in 6.8%. All patients were reevaluated clinically for this study, with a focus on recurrence, which was defined as reappearance of Dupuytren's tissue in an area previously cleared of the disease, regardless of the degree of recurring contracture. Kaplan-Meier regression analysis was utilized to assess time to recurrence. It takes into account the number of "survivors", i.e. the patients free of recurrence at the time of last follow-up. Proportional hazards model was applied to assess the influence of the "risk factors" (age at onset, bilaterality, family history of Dupuytren's disease, ectopic lesions) as well as other factors (gender, tobacco, alcohol, severity score, type of surgery, PIP joint release, peroperative extension, complications) on the occurrence of recurrences.

According to our definition, 43 recurrences (19.1%,) were identified. Time to recurrence was 0.4 to 13.6 years (median 2.0). The Kaplan-Meier plot showed a specific non-linear curve of time to recurrence, with a sharp and quasi-linear increase of recurrences from 6 months till 2,6 years follow –up, then a much slower rate but which continues to increase, up to 13.6 years follow-up (Figure 1). Bivariance analysis showed a significant relationship between recurrence and age at onset, age at surgery, ectopic lesions (strongest with knuckle pads), alcohol intake and needle fasciectomy.

Although recurrence is more frequent in the first two postoperative years, it can occur at any time after Dupuytren's treatment (up to 13.6 years in our series). This time factor must therefore be taken into account when assessing the recurrence rate in a group of patients. The Kaplan-Meier calculation is a helpful tool, by providing an accurate representation of recurrence at any given follow-up time for any given group of patients. It allows to compare recurrence in different groups of patients treated with different techniques, and with different times to follow-up, provided there is a common definition of recurrence.

Saturday, 23 May 2015, 12:27

Is Recurrence of Dupuytren's Disease Prevented by Full-thickness Grafting Surgery?

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Dupuytren's disease knows a high variability in clinical presentation and behaviour. In advanced stages, finger contractures occur, most frequent in the ulnar 4th and 5th digit and the deformity leads to an increase of disability. Numerous surgical techniques are available to correct the disabling finger contractures in Dupuytren's disease. However recurrence rates of these contractures varying from 2% to 63% have been reported. Bulstrode et al even suggested that recurrence of the contractures is imminent if only the patient lives long enough. But is this true? And can we consider the degree of diathesis as very important in predicting recurrence and extension of Dupuytren disease after surgical management?

Hypothesis: We investigated the hypothesis that recurrence after fasciectomy and full-thickness skin grafting for correction of Dupuytren contractures is non-existent.

Method: In this hospital-based, retrospective, cohort study, we reviewed 47 patients after fasciectomy and full-thickness skin grafting for Dupuytren disease after a follow-up ranging from 3 years to 16 years. Extension and recurrence beneath the skin graft were evaluated. We discriminated the origin of recurrence, true or false recurrence, and/or extension of the disease via clinical examination. Recurrence was defined as the development of new Dupuytren disease lesions including the smallest palpable nodule in the same area where surgery had been performed. False recurrence can consist of non-developing scar contracture, joint contracture, and extrinsic tendon imbalance and is caused by surgical complications. We determined extension as the appearance of lesions outside the operated area where previously no disease had been detected. The age of onset, gender and factors considered to influence the outcome due to a certain fibrosis diathesis such as bilateral disease, family history, the presence of diabetes, smoking and alcohol intake, were noted.

Results: The recurrence rate underneath the skin grafts was 0%, which confirms the early findings of Hueston. However, the disease extended in 83% of the cases. 38% of the patients had a high-risk score of Abe, higher than 4, meaning a high risk for recurrence of Dupuytren's disease. The mean Abe score was 4.5. We analysed that the mean Abe score of the group patients without presentation of extension of the disease amounted 3.4. The group patients with extension had a mean Abe score of 4.7. The group of patients with extension of the disease had a significantly higher mean Abe score, confirming that the degree of fibrosis diathesis influences extension of Dupuytren disease, even after surgical management.

Summary: This study brings evidence to certainly consider the use of the full-thickness skin grafting for Dupuytren disease control, as to avoid severe recurrent disease and the need for complex revision surgery.

Session 6: Comparative Studies / Recurrence

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Lecture: Radiotherapy for Early Stage Dupuytren and Ledderhose Disease

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Background: Radiotherapy (RT) has been used for early stage primary and recurrent palmar and plantar fibromatosis (Dupuytren Disease, DD and Ledderhose disease, LD). The use of ionizing radiation to influence the hyperproliferative tissues in the early stages are not well known or controversially discussed among surgeons, although clinical studies and results have a long standing tradition in radiation medicine. The radiobiological rationale for the application of RT is strong with direct impact on proliferating fibroblasts and /or myofibroblasts. Clinical RT practice started inthe early 60es and 70es of the last century, but prospective studies and long-term data are required to justify the role in the interdisciplinary setting.

Herein we summarize our clinical experience and outcome date over a period of almost 18 years.

Methods:

Dupuytren Disease: From 1997 to 2009, 612 patients were referred to our clinic. 594 patients (356 M; 238 F) were followed for 5–17 (mean 11) years, 18 patients (3%) were lost in FU. With bilateral affliction (n = 268), a total of 880 hands (sites) were evaluated. Tubiana stage was 575 hands (65%) with stage N (nodules/cords, no extension deficit), 158 (18%) stage N/I (≤ 10° deficit), 126 (14%) stage I (11–45° deficit), and 21 (2%) with stage II (46–90° deficit). After clinical assessment and informed consent, 101 patients (with 141 hands) decided for “watchful waiting”; 511 patients (739 hands) were randomized for RT: Group A (258 patients / 374 hands) received 30 Gy (2 series of 5 × 3 Gy, 12 weeks break); Group B (253 patients / 365 hands) received 21 Gy in one series within 2 weeks. Relevant patient and disease parameters were equally distributed between control and the two RT groups. Primary endpoints were objective clinical progression and necessity of surgery. Secondary endpoints were side effects and objective parameters (number and size of nodules, cords) and patient’s satisfaction.

Ledderhose Disease: From 1997 to 2009, 158 patients (91 M, 67 F; mean age 49, range 9–81 years) with LD were referred to our clinic. A total of 222 feet were affected (84 bilateral, 29 R, 25 L). After clinical assessment and informed consent, 91 patients decided to receive RT for 136 feet, while the other 67 patients served as control group. All sites had clear signs of progression. Ledderhose Classification revealed 31 feet with stage N/1, 55 stage 2, 35 stage 3 and 15 stage 4. Thirty-five feet (26%) had prior surgery. RT was applied in two series of 5 x 3 Gy repeated after 12 weeks up to 30 Gy; three patients (5 feet) received only one series. Primary endpoints were prevention of progression and avoidance of surgery. Secondary endpoints were size and number of nodules or cords and symptom relief (pain), function improvement and patient’s satisfaction. Side effects were scored using CTC and LENT scales.

Results:

Dupuytren Disease: Acute toxicity was low (25% CTC 1°; 2% CTC 2°; late effects included dry skin in 14% (LENT 1); no ulcers or secondary cancer occurred in long-term FU. 139 (19%) sites showed remission of nodules, cords or T-stage; 390 (53%) remained stable and 210 (28%) progressed and of those 129 (17%) required surgery. In the control group (n = 141) disease progression occurred in 93 (66%), hand surgery was required in 68 (48%) hands as compared to Group A (30Gy, n = 374) with

19% progression and 8% surgery and Group B (21Gy, n = 365) with 26% progression and 14% surgery ($p < 0.0001$). Number of nodules and cords decreased in both RT groups as compared to the control group ($p < 0.01$). T-stage progressed in the control group significantly more often as compared to both RT-groups ($p < 0.01$). Overall 54 (7%) relapses occurred inside, 128 (17%) outside the RT field. Salvage surgery after RT was possible w/o complications. Uni- and multivariate prognostic factors for progression were smoking (trend), symptom duration prior to RT, T-stage, extension deficit, and digital involvement (all $p < 0.05$). The most important factor was use of RT (Group A better than B) as compared to control without RT.

Ledderhose Disease: In 11/2014, all 91 patients (136 feet) were evaluated (mean FU of 9.5 (range 5 – 17) years). 56 feet (41%) remained stable, 59 (43%) regressed with nodules, cords or symptoms; at last FU, 33 (24%) feet had complete freedom of nodules, cords, and symptoms, 26 feet had partial remission (> 50% regression). Symptoms and dysfunctions improved in 114 (84%) feet. Patients' satisfaction improved by 3.0 points in 78 (86%) patients. 12 (13%) patients (19 (14%) feet) progressed and of those 9 (10%) pts (15 (11%) feet) had salvage surgery, which was possible and with only two patients (3 sites) requiring a longer healing period. Acute side effects (21% CTC 1°, 5% CTC 2°) occurred in 36 (26%) feet, chronic sequelae (LENT 1°: dryness or fibrosis of skin) in 22 (16%) feet. Of the 67 untreated patients (134 feet, control group (no-RT) 43 (64%) developed progression in long-term FU, and of those 27 had RT and 10 foot surgery. Multivariate analysis found previous surgery, recurrent LD, nicotine abuse, advanced and symptomatic disease as poor prognostic parameters.

Conclusions :

Ionizing radiation has a unique activity on proliferating fibroblasts and myofibroblasts, Thus, its clinical application is justified and most useful in the early stages of both DD and LD with active cells in the proliferative stage. As compared to surgical outcome data, the two RT series have a systematic clinical assessment with long-term data beyond 10 years. Two compare these data with surgical series the follow-up has to be shortened to 5 years FU. After this period, few patients developed progressive DD and LD following primary RT, whereas all untreated patients, or their affected hands or feet respectively, developed progression in almost 50%. Thus, although no cure is available for DD and LD so far, the use of RT appears to be still the "best care" for primary early stage DD and LD. Future clinical research will address the potential role of postoperative RT after hand surgery in high risk situations.

Saturday, 23 May 2015, 14:10

A Systematic Review of Non-Surgical Treatments for Early Dupuytren's Disease

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Hypothesis: There is no approved treatment for early Dupuytren's disease (DD) that would prevent progression of flexion deformities requiring subsequent treatment with invasive procedures. We systematically reviewed the literature to determine the role and efficacy of non-surgical treatments for early DD with the aim of providing an evidence base for the management of these patients.

Method: We systematically searched databases (Ovid Medline, Ovid EMBASE) from their inception using an inclusive search strategy to capture all relevant publications of studies, letters and conference abstracts published in English. Titles and abstract were screened using predefined criteria to identify studies reporting outcomes specifically relating to the treatment of early disease. In the absence of a definition of early disease, studies were included if early DD was described clinically, with digital contractures not exceeding 30 degrees, Tubiana grades N, N/1 and 1, and which reported identifiable early DD data. Studies were excluded if data for early DD patients could not be extracted for analysis. The remaining studies were independently reviewed by 2 authors.

Results: Sixteen studies met the inclusion criteria, covering drug therapies (9), physical therapies (4) and radiotherapy (3). The heterogeneity of the studies and variability in the techniques used to analyse and report the data prevented statistical evaluation and, therefore, narrative descriptions of the data are presented. Many publications reported data collected retrospectively using outcome measures that were variable in quality and often subjective.

Drug therapies included topical application, systemic administration or local injection. The use of topical, oral and intramuscular steroids and oral vitamin E, reported by mostly small retrospective studies or case studies, showed varying results. Intralesional steroid injection was reported as leading to improvement in nodule consistency, although disease reactivation 1 to 3 years after the last injection was reported in 50% of patients. Physical therapies investigating the use of ultrasound, splinting and friction massage were the most robustly assessed, using objective measures but the studies were under powered, providing insufficient evidence of efficacy. Three studies reported data for radiotherapy treatment for early disease suggested up to 80% of improvement. However, whilst the results were based on clinical assessment of the quantity, size and consistency of nodules and cords, the data were presented simply as improved, no change or worsened. Early disease was inconsistently defined between studies and toxicity was only reported by one study.

Summary: Intralesional steroid injections and radiotherapy resulted in improvements, although only subjective outcome measures were used. Based on our systematic review, we recommend that:

- A clear definition of early disease is agreed
- Treatment outcomes are measured using objective, reproducible methods
- Safety is reported and described in all studies.
- A consensus on the definition of disease recurrence is required.

Saturday, 23 May 2015, 14:16

The Patient's View and Needs – An International Survey: Ledderhose Disease

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Hypothesis: Potentially there might be a discrepancy between the actual expectations and views of patients and what their doctors believe to be the patients' view. An overall overview of preferences and guidelines for individual assessment are required.

Method: To get a better understanding how patients view their treatments options, what their preferences are an international survey of patients was conducted. Patients were recruited from Dupuytren forums of the International Dupuytren Society, the British Ledderhose Disease Blog, the German Dupuytren-Gesellschaft (using an equivalent German questionnaire and providing an example of country specific responses), the US Dupuytren Foundation, and from a British survey of patients having had fasciectomy.

The survey was conducted using an online questionnaire and, for the British fasciectomy patients, an interview. Patients were free to fill out the whole questionnaire or parts of it. The questionnaire addressed both, Dupuytren and Ledderhose disease.

Results: The survey is still ongoing. So far well over 2,000 patients have responded. Participants were predominantly from the USA, the UK, and Germany. Final results will be reported in Groningen.

This abstract addresses responses regarding Ledderhose disease. Dupuytren's results are presented in a separate paper. Preliminary results show that some aspects assumed to be the same as Dupuytren's are not, such as a higher incidence in men and age of onset. Surveying the treatment options showed that the options most readily available, surgery, orthotics and steroid injections, are from a patients view amongst the least effective options, with radiotherapy and cryotherapy scoring highly but being much less available, e.g. on the NHS.

Analysis of the associated risk factors showed that there was often an earlier onset for patients with one or more of these present. Finally, from a patients view it was felt that what they want is a wider understanding of the choices in the medical community and better publications on the effectiveness of all the treatments so that they are able to make an informed decision with their doctor.

Summary: Ledderhose and Dupuytren's are not the same and this survey shows that not only do the patents have a different demographic but the favoured treatment options are those that have limited or no use for Dupuytren's and globally have more restrictive availability.

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Use of Acellular Dermal Matrix in Dupuytren Disease

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Hypothesis: Recurrence following surgical treatment of Dupuytren disease remains a common problem. We hypothesize that the use of acellular dermal matrix is associated with decreased recurrence rates in Dupuytren disease.

Method: We performed a retrospective cohort study of 43 patients undergoing open fasciectomy for Dupuytren disease from years 2005 through 2012 performed by a single surgeon at our academic institution. Standard fasciectomies of the affected palmar and digital fascia were performed via Brunner incision on all patients. Patients in the experimental group had a sheet of acellular dermal matrix (Alloderm, LifeCell, Bridgewater, NJ) sutured into the surgical bed prior to closure, whereas patients in the control group were not closed with acellular dermal matrix. Patients were then evaluated at follow-up for disease recurrence, defined as presence of Dupuytren's tissue in an area previously operated on, with a contracture greater than that recorded following the surgical fasciectomy.

Results: Among our cohort of 43 patients, 23 (53.5%) were treated with acellular dermal matrix while 20 (46.5%) were not. The median age of our cohort was 66.5 years (range 54 to 91 years). The median follow-up was 1.8 years. During this follow-up period, recurrence of contracture was observed in 1 of 23 patients in the experimental group, compared to 5 of 20 in the control group ($P = 0.045$). No differences in the incidence of minor wound complications were observed.

Summary:

- We observed lower recurrence rates in the cohort of patients who were treated with placement of acellular dermal matrix into the wound bed following open fasciectomy for Dupuytren disease
- Our novel technique has implications for future surgical treatment strategies to reduce recurrence rates in Dupuytren disease.

Saturday, 23 May 2015, 14:38

Tension versus compression on Dupuytren

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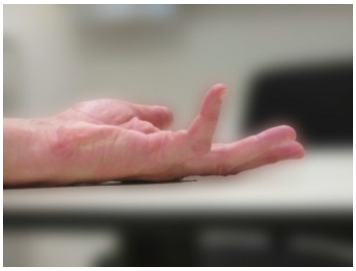
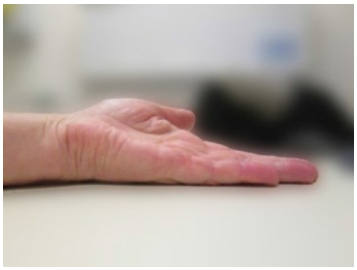
Hypothesis: Post-surgical outcomes in patients with Dupuytren's disease are unpredictable and can be inconsistent. A non-operative treatment as splinting is controversial, but is a low-invasive treatment of a widespread disease that influence myofibroblasts of the noduli.

Method: A randomized controlled trial was approved by the (REMOVED FOR ANONYMITY). Thirty patients with measurable flexion contractures of the metacarpophalangeal (MCP), proximal and/or distal interphalangeal (PIP and/or DIP) joint were identified for this study. Both primary diseases as recurrences after surgery were included. Patients were randomized in 2 groups of 15 patients. One group had a standardized tension splint (Levame), the other group a new designed silicon compression splint with silicon bed and Velcro strips. Patients were instructed to wear the splint 20 hours a day during 3 months. Data were collected at first consultation and after 3 months wearing the splint. Primary outcomes active extension deficit (AED) of each joint and total active extension (TAE) of the digit. Secondary outcome was patient satisfaction. VAS-score (Visual Analog Scale) of function and aesthetics (0 to 10 points) were demanded commencing the splint regime and afterwards. An analysis of covariance (ANCOVA) with the baseline value as covariate, has been used to compare the outcome (Active extension, total active extension, VAS functional, VAS esthetical) between both groups after 3 months.

Results: Flexion contractures of all patients reduced at least 5 degrees. The mean change in TAE was 32.36° (median 30, SD 15.03, range 5 – 60°) in case of the tension splint and 46.47° (median 40, SD 30.56, range 15 – 115°) in the compression group (Fig 2). After 3 months, there was a significant reduction of TAE wearing both the tension ($p<0.001$) as the compression splint ($p<0.001$). Although more reduction of total active extension deficit in the compression group, there was no significant difference between the compression and the tension splint at 3 months ($p=0.39$). VAS-scale of aesthetics and functionality was significantly increased in both treatment groups ($p<0.01$) The functional VAS-scale after 3 months was 11% higher in the compression group compared to the tension group ($p=0.03$, 95% CI: 1.01-1.21).

Summary: Tension and compression splints can be used as non-operative treatment of Dupuytren's disease in both early proliferative untreated hands as aggressive post-surgery recurrence disease. Compression splints appear to be more efficient and better tolerated. Nevertheless, adjustment of splint design and research about long term results are necessary.





Saturday, 23 May 2015, 14:54

Lecture: Diagnosis and treatment of Peyronie's disease A.D. 2015

Mels Frank van Driel, University Medical Center Groningen, The Netherlands.

History: Acquired penile curvature is secondary to Peyronie's disease (PD). Although he was not the first who described it, this disease was given its name to the French physician François Gigot de la Peyronie.

Pathophysiology and epidemiology: Just as Dupuytren's disease (DD) PD is a poorly understood connective tissue disorder. PD is most commonly attributed to repetitive microvascular trauma during intercourse in combination with a genetically predisposition. PD starts with an acute inflammatory process, characterized by increased proliferation of the tunical fibroblasts, some of which differentiate into myofibroblasts with excessive deposition of collagen, the persistence of fibrin, and elastin fragmentation. A prolonged inflammatory response may result in the remodeling of connective tissue into a dense fibrotic plaque. Plaque formation can result in penile curvature, which, if severe, may prevent vaginal intromission. Prevalence rates of 0.4–9% have been published.

Co-morbidities: The most commonly associated co morbidities is erectile dysfunction (ED). DD is more common in patients with PD, affecting around twenty percent of our case series. Although much more difficult to investigate, around four percent of the patients with DD report PD (?).

Diagnosis: Diagnosis is based on the medical and sexual history, which in general are sufficient to establish the diagnosis. Physical examination includes assessment of nodules ant the length of the stretched penis. Curvature is best documented by a self-photograph at home or in office after a pharmacologically induced erection. In case of concomitant ED color duplex ultrasound of the cavernous arties is mandatory.

Non-surgical therapy: Pharmacotherapy includes oral potassium para-aminobenzoate, intralesional treatment with verapamil, clostridial collagenase or interferon, topical verapamil gel, and iontophoresis with verapamil and dexamethasone. They can be efficacious in some patients, but up till now none of these options carry a grade A recommendation. Steroids, vitamin E, and tamoxifen cannot be recommended. Penile traction or vacuum pump devices may be used to reduce or to prevent further penile deformity.

Surgery: Surgery is indicated when Peyronie's disease is stable for at least one year. Tunical shortening procedures are the first treatment options. Non-shortening procedures are preferred in severe curvatures or in complex hourglass deformities. The risk of de novo ED or exacerbation of the ED is greater for non-shortening procedures. Penile prosthesis implantation is recommended in patients with ED not responding to PDE5 inhibitors or intracavernous injection pharmacotherapy.