

Long-term outcome after all-inside meniscal repair using the RapidLoc system

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Abstract

Purpose The purpose of the present study was to evaluate the outcome at a minimum of 7 years following meniscal repair using the RapidLoc (suture anchor) system. It was hypothesized that most patients would have an intact meniscus, as has been reported in several short- and medium-term studies.

Methods In the time period from 2002 to 2007, all patients with a vertical longitudinal tear of the meniscus that was judged to be repairable were treated with rasping of the tear area and nearby parameniscal synovium and fixation of the torn part with the use of RapidLoc implants. Using a surgeon-administered form, baseline information about the arthroscopic findings and procedures performed was recorded (at the time of surgery). A median 10-year (range 7–12 years) follow-up was conducted in 2014–2015, and surgical procedures to the knee following the (index) meniscal repair were registered. Treatment failure was defined as a new surgical procedure to the same meniscus.

Results At the time of follow-up, 39 out of 82 patients (48 %) had undergone further surgery to the repaired meniscus (failures). Nine of these occurred within the first 6 months after surgery, 21 within the first 12 months and 26 within the first 24 months. Thus, the failure rate was 11 % at 6 months, 23 % at 12 months and 28 % at 2 years.

One-third ($N = 13$) of the failures occurred 2 years or later after the (index) meniscal repair.

Conclusions Long-term results of meniscal repair using the RapidLoc implants were found to be poor with a high failure rate. In a large proportion of the cases, re-rupture appeared several years after the index surgery, and a commonly used follow-up period of 2 years would therefore fail to detect them. In the day-by-day clinical work, of interest to orthopaedic surgeons is that meniscal repair using an all-inside technique similar to the one used by the authors may not solve the problem in the long run.

Level of evidence IV.

Keywords Knee · Arthroscopy · Meniscus · Bucket-handle tear · Meniscal repair

Introduction

Meniscal lesions are commonly found during knee arthroscopies. In a series of 1000 arthroscopies, Hjelle et al. [16] demonstrated meniscal lesions in 57 % of patients, whereas an incidence of 74 % was found in a more recent study by Solheim et al. [34]. Vertical longitudinal tears—or bucket-handle tears—are more seldom occurring and are usually caused by a trauma, typically a combination of compressing and twisting forces. While the effect of surgery in degenerative meniscal lesions has been questioned in recent years [32], most authors recommend repair of traumatic longitudinal tears, especially in young patients. Since loss of meniscal tissue predisposes to osteoarthritis [10, 30], preserving meniscal tissue (by repairing rather than resecting) should consequently reduce the tendency for degenerative changes and disability [17, 42]. Arthroscopic techniques for meniscal repair evolved in the 1980s, offering

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better visualization of the interior of the joint, shorter rehabilitation period and lower morbidity [8, 18]. The inside-out repairs were associated with a non-negligible incidence of neurovascular injuries [33] propagating outside-in techniques [9, 39] and—later, the now most commonly used—all-inside techniques [22].

In 2002, we started using an all-inside technique with the RapidLoc implant for meniscal repair [31]. Earlier studies on the same technique have reported high proportions of successful outcome, with failure rates ranging from 6 to 13 % at a minimum follow-up of 18–24 months [3, 5, 20, 28]. Several of these studies have, however, included patients undergoing concomitant anterior cruciate ligament (ACL) reconstruction. It has been established that the healing rate in meniscal repair is higher when a concomitant ACL reconstruction is performed [4, 7, 15]. Further, as noted in a recent review by Nepple et al. [24], it has been found that meniscal repair may fail after several years and that a conventional 2-year follow-up evaluation might underestimate the total failure rate. Thus, the purpose of the present study was to examine the long-term failure rate at a minimum 7-year (median 10 years) follow-up after an all-inside meniscal repair using RapidLoc in stable knees without a concomitant ACL reconstruction being performed. It was hypothesized that the long-term failure rate would be similar to that of the short- and medium-term studies (with concomitant ACL repair). To the best of our knowledge, the present study is the first to report the long-term failure rate of the RapidLoc implant.

Materials and methods

From late 2002 to late 2007, our prime surgical procedure in repairable vertical longitudinal (bucket-handle) tear of menisci was an arthroscopic all-inside technique using the RapidLoc repair system. All meniscal repairs included in this study were performed by the same consultant surgeon—a qualified specialist in orthopaedic surgery with more than 15 years of surgical experience. Before introducing the technique at our institution, the surgeon had been trained by representatives of the company providing the implant and had performed about 10 surgeries with the implant at a university hospital.

The study included patients with a characteristic history of injury of the knee and resulting pain in the joint space, and a confirmatory physical examination that included palpable tenderness at the joint space that was reproduced with the McMurray test. All patients had a pre-operative MRI positive for meniscal injury. Repair was performed in vertical longitudinal (bucket-handle) tears of length 10 mm or greater—that could be reduced—in the red-red or red-white meniscal zones located in the posterior two-thirds

of the menisci. Exclusion criteria were concomitant ACL reconstruction, cartilage repair, other procedures not related to the meniscal repair or the finding of (other) significant pathology (such as osteoarthritis, avascular necrosis, osteochondritis dissecans or rheumatoid arthritis). At each surgery, a form was completed, which included peroperative findings such as localization and extent of the meniscal tear, number of implants used and placement of these (indicated on a drawing) [16].

Failure was defined as repeat surgery with a new procedure to the same meniscus. To evaluate this, we examined all patients' medical records and contacted all patients and performed a standardized telephone interview at median 10 years (range 7–12 years) after the prime meniscal repair. If a new surgical procedure had been performed at another institution, the institution was contacted (with the patient's consent) to learn the nature of the repeat surgery.

Surgical technique

The surgery was performed in an outpatient surgery unit under combined general anaesthesia (total intravenous anaesthesia) and local anaesthesia subcutaneously at the portals. The meniscal tear was assessed for stability and reparability. If the patient was found to have a repairable tear, the tear area and nearby synovium were debrided by a rasp to generate capillary bleeding and enhance healing. The tear was reduced and fixed by an all-inside technique using exclusively the RapidLoc meniscal repair system (Depuy-Mitek, Rayham, MA, USA). The system incorporates a 4.5-mm-wide and 0.25-mm-thick PLLA (which was later changed to PSD) top hat (to hold the torn part in place), Panacryl long-term absorbable suture with a pre-tied, self-sliding, integrated knot (over the top hat) and a 5 × 2.5 mm backstop anchor placed extracapsularly (Fig. 1). A knot pusher was used to seat the knot



Fig. 1 Arthroscopic close-up view of the 4.5-mm-wide and 0.25-mm-thick PLLA (which was later changed to PSD) top hat and Panacryl long-term absorbable suture with a pre-tied, self-sliding, integrated knot (over the top hat). In the opposite end of the suture is a 5 × 2.5 mm backstop anchor placed extracapsularly

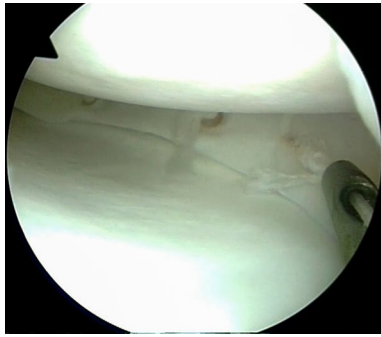


Fig. 2 The third implant is being seated in the bucket-handle (of a tear of the posterior half of the medial meniscus of the right knee) with the use of a knot pusher

(and top hat) to gain adequate compression across the tear site. Depending on the length and stability of the tear, 1–4 implants were used (Fig. 2).

Rehabilitation

The patients were instructed in the use of crutches and maintained foot-touch weight-bearing for 4 weeks and then partial weight-bearing for the following 2 weeks. Thereafter, full weight-bearing was gradually introduced. Flexion of the knee beyond 90° was not allowed during the first 6 weeks. A knee brace was not used. All patients were referred to a physiotherapist. Initial exercises included stretching, straight-leg rises and passive motion, progressing gradually through active closed chain exercises including stationary bicycling to dynamic weight training. Squatting was not allowed during the first 3 months after surgery. After 3 months, a gradual return to unrestricted activities was encouraged as desired and tolerated. Full contact sports was discouraged for the first 4–6 months. The Ethical Committee at Teres Bergen reviewed and approved the study (TB ID 2014-1216). All patients gave their informed consent prior to their inclusion in the study.

Statistical analysis

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) on a personal computer. As measures of central location and spread of data, mean and standard deviation (SD) or median and range were calculated. The primary outcome measure was failure, which was defined as a repeat surgical procedure in the same knee and same meniscus (resection or new repair) due to returning (or persisting) pain and disability [38]. The Kaplan–Meier method was used for the construction of a survival functions plot for the event

“failure”. Chi-squared test was used for the comparison of incidence of failure in subgroups of patients with different characteristics. A P value <0.05 was considered statistically significant.

Results

A total of 82 patients fulfilled the requirements for inclusion in the study. By examining medical records and making standardized telephone interviews, we were able to identify the status concerning any repeat surgery (after the index meniscal repair) in all patients. Thus, 82 patients (100 %), 66 male and 20 female, with a median age of 33 years (range 14–57) at the time of surgery were included in the study. The right knee was affected in 53 patients (65 %). The medial meniscus was affected in 64 patients (78 %). A median of 2 (range 1–4) RapidLoc implants was used. All tears were situated within the posterior two-thirds of the menisci and in the red–red or red–white zone. In 38 patients (46 %), the tear was 15 mm or less in length and the length of the remaining tears was 16–35 mm. Ten patients had undergone an ACL reconstruction prior to the meniscal repair (no concomitant ACL reconstructions were included). The Lachman and pivot shift tests were negative at the time of the meniscal repair in all patients.

Failure—defined as a repeat surgery of the previously repaired meniscus—occurred in 39 patients (48 %) during the follow-up period. Nine failures occurred within 6 months after surgery, 21 within 12 months and 26 within 24 months after surgery (Fig. 3). One-third ($N = 13$) of the failures occurred after 2 years (after the index meniscal repair). Thus, the failure rate was 11 % at 6 months, 26 % at 12 months and 32 % at 2 years.

In patients with repeat surgery, the following procedures had been performed; resection of a re-torn bucket-handle ($N = 27$), partial resection of partly healed meniscus ($N = 8$) and new all-inside repair (with RapidLoc implants) of unhealed vertical longitudinal tear ($N = 4$). In two of the latter patients, a new re-reoperation was done at a later time; this time, a resection of the bucket-handle was performed. At the repeat surgery, no patient had a resection larger than the original tear; in eight patients, the partial healing led to a smaller resection.

The failure rate was 53 % in men and 32 % in women (n.s.); 51 % in patients aged 30 years or less ($N = 35$) and 45 % in older patients (n.s.); 55 % in left knees and 43 % in right knees (n.s.); 49 % in medial meniscus tears and 44 % in lateral meniscus tears (n.s.); 40 % in previously ACL reconstructed knees and 49 % in knees with intact ACL (n.s.); and 48 % in short tears (15 mm or less) and 47 % in longer tears (n.s.).

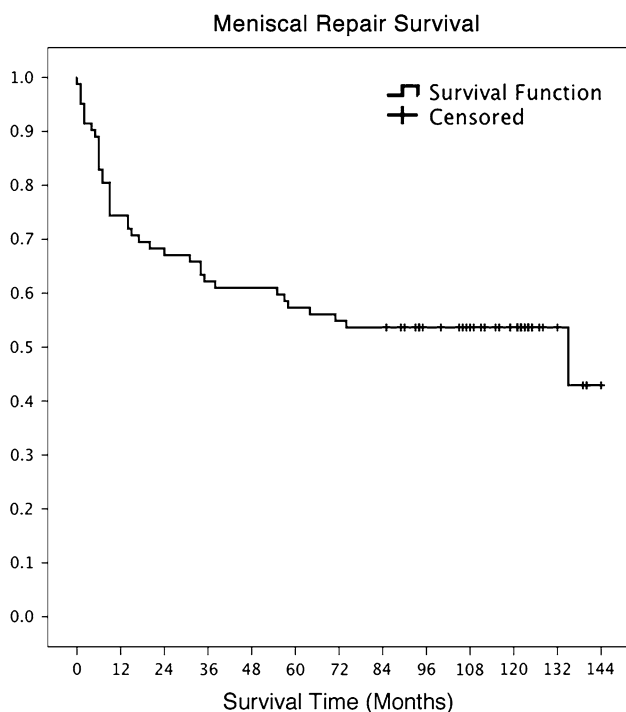


Fig. 3 Kaplan–Meier survival functions plot for the event “failure” ($N = 39$)—a repeat surgery of the same meniscus (most often a partial meniscectomy)

Discussion

The most important finding of the current study was that failures continued to appear through most of the follow-up period, increasing from 11 % at 6 months to 48 % at the minimum 7-year follow-up. For this study, failure—the occurrence of a repeat surgical procedure in the same knee and same meniscus (as in the index meniscal repair procedure)—was used as the outcome measure. Failure is a commonly used prime outcome measure in studies on both open and arthroscopic meniscal repair [24] including various all-inside techniques [3, 5, 20, 21, 28, 36].

In four patients, a new all-inside repair (with RapidLoc implants) was performed at the repeat arthroscopy. In two of these patients, a new re-reoperation was done at a later time; this time, a resection was performed. In the rest of the patients, a resection was done at the repeat meniscal procedure; in eight patients, part of the bucket-handle tear was healed and the resulting resection was smaller than the original tear. In the rest of the patients, the re-tear (or non-healed tear) was identical to the original tear. In no patients, the re-tear was larger than the original tear. These findings are in concordance with those of Pujol et al. [26] who evaluated outcomes after meniscal repairs in 295 patients.

Four clinical studies investigating the failure rate after all-inside meniscal repair using the RapidLoc implant were identified [3, 5, 20, 28]. The short to medium report failure rate reported in these studies ranged from 7 [20] to 13 % [3]. Combined, the studies reported 19 failures in 196 patients (10 %) [3, 5, 20, 28]. The minimum follow-up time ranged from 18 [3] to 24 months [28]. The number of patients (with a RapidLoc system repair) evaluated ranged from 30 to 46 in three of the studies [3, 5, 28], whereas 88 RapidLoc patients were included in Kalliakmanis study [20]. In three of the studies, all patients underwent a concomitant ACL reconstruction [5, 20, 28], whereas 23 out of 32 patients (72 %) in the Barber study had a concomitant ACL reconstruction [3].

Both the shorter follow-up period and the inclusion of patients with concomitant ACL reconstruction may explain the lower failure rate in the previous studies on RapidLoc [3, 5, 20, 28]. It has been shown that cases of meniscal repair performed in conjunction with an ACL reconstruction have a decreased failure rate [4, 7, 15]—possibly related to more release of factors promoting healing (including marrow elements from the drill holes)—and a slower rehabilitation programme that also protects the meniscal repair [4, 7, 15, 31, 40, 41]. In the present study, no cases of concomitant meniscal repair and ACL reconstruction were performed. It could be hypothesized that RapidLoc being a weaker implant (and being gradually resorbed), e.g. compared to traditional suture repair [14, 23], is more dependent on the healing boost by a concomitant ACL reconstruction than that of a stronger and non-absorbable implant.

Even a biomechanically stronger meniscal repair, using non-absorbable outside-in sutures [13], results in non-healing or only partial healing (that may not be symptomatic) in about 30 % [2, 15, 29, 35] or at an even higher rate [7], especially in isolated repairs (without concomitant ACL reconstruction) [7, 37]. Still, it seems that the development of techniques and implants has focused more on speed (shorter time spent in the operation theatre) and convenience for the surgeon rather than focusing on improvement in the (complete) healing rate [12]. Partial healing may be more common than we believe (because we seldom look), and it seems reasonable to postulate that even if a partially healed meniscus is non-symptomatic over the short term, it may be prone to re-tear (due to the *locus minoris resistentiae*), resulting in symptoms and possibly new meniscal procedures (failure) in the long run. In concordance with such a postulate, several authors have advocated long-term studies [3, 6, 24].

While it is possible that the poor long-term outcome of the present study is due to some inherent hapless property of the RapidLoc implant, it is equally possible that a similar failure rate will be found in other implants used

for isolated all-inside repairs, if followed up for a similar period of time. In support for such a view—the negative effect of increasing follow-up time—is the fact that whereas Albrecht-Olsen et al. [1] found 18 % non-healed or only partly healed menisci at re-arthroscopy 3–4 months after the repair with resorbable meniscus arrows, the failure rate (using the same implant) in the medium- and long term has been reported to be 30 % at the 2-year follow-up [19] and 41 % at a mean 4.7-year follow-up [11]. In opposition to the findings in meniscus arrows (and the present study), Pujol et al. [27], using Fast-Fix implants with or without supplementary mattress sutures, did not find deterioration in outcome with time.

In the day-by-day clinical work, of interest to orthopaedic surgeons is that meniscal repair using an all-inside technique similar to the one used by the authors may not solve the problem in the long run. It is tempting to question whether biomechanical testing—and perhaps a few short-term clinical studies—constitutes sufficient documentation for the introduction of new devices (such as that evaluated in the current study) intended for implantation (during arthroscopic surgery). The RapidLoc implant has recently been replaced by a new implant without the top hat (Omnispan, DePuySynthes, Raynham, MA, USA), and new modifications may very well be made before any long-term studies get to be published.

The strengths of our study include the high number of patients, a 100 % follow-up rate, a uniform surgical technique, evaluation of a relatively homogenous patient group (i.e. no concomitant ACL reconstructions included) and, most importantly, a long follow-up time. The important limitations of our study are the lack of a control group, no functional evaluation, no evaluation of the healing in the patients that was not submitted to a second-look arthroscopy (e.g. by MR arthrography [25]) and no evaluation of secondary osteoarthritis.

Conclusion

Long-term results of meniscal repair using the RapidLoc implants were found to be poor, with a failure rate approaching 50 %. In a large proportion of the cases, the re-tear appeared several years after the index surgery, and a commonly used follow-up period of 2 years would therefore fail to detect these.

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