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The Development and Initial Testing of an Arthroscopic Needle-Knife Surgical Device (ANKSD) Prototype

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Research Article

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ABSTRACT

Purpose

It is common practice during arthroscopy to use a needle prior to a cutting knife to help target the correct entry point. This avoids damaging healthy structures and reduces healing time and scarring. However, once the knife itself is introduced, the risk of iatrogenic damage increases, potentially increasing the risk of post-operative complications like wound and joint infections, and ultimate cartilage damage. To develop a safer surgical instrument that is both cost-effective and environmentally-friendly, we designed and performed preliminary (pilot) testing on an Arthroscopic Needle-Knife Surgical Device (ANKSD) prototype.

Methods

An ANKSD prototype was developed using a 14-gauge 1.75-inch hypodermic needle, 10 cc syringe, and modeled handle. We then tested the device on 99 knees, using the ANKSD for the lateral portal and a

standard knife for the medial portal; and compared the two sides in terms of time to suture removal, presence of discharge or incomplete healing, and post-operative complications. A preliminary assessment of cost savings was performed. Results: Overall, all but one of 198 portals healed well without discharge; that one portal had been created with the ANKSD, but the discharge resolved and wound healed on oral antibiotics taken at home within 6 days. No other complications resulted at either portal. A comparison of the two portals revealed no statistically-significant differences in outcomes, but use of the ANKSD was less time-consuming and cheaper, and had the additional advantage, relative to the standard blade, of allowing for both the injection and aspiration of fluids.

Conclusion

The prototype ANKSD we have developed, using a 14-gauge hypodermic needle attached to a 10 cc syringe, appears to be a safe, effective and cost-effective alternative to a standard surgical cutting knife during knee arthroscopy. Further *in-vivo* testing is warranted.

INTRODUCTION

Arthroscopy of the knee is among the most common orthopaedic procedures performed, ranking first in some countries like the United States 1. It is utilized in a variety of settings and for a variety of injuries, as well as disease conditions like osteoarthritis [1-3]. Though serious complications generally are rare, they can be catastrophic, including deep venous thromboses 1, 2, sometimes fatal pulmonary emboli 2, 3, septic arthritis 4, 5, and damage to adjacent vessels and nerves 6-8. Concern over the potential for damage to surrounding neurovascular structures is typically reduced by means of using a simple needle to enter the joint space, prior to introducing the arthroscope or utilizing a surgical knife, since the risk of neurovascular damage from a needle is considered exceedingly low [4].

Over the past 20 years, the concept of using a needle as a knife has gained increasing support, but virtually only for gastrointestinal procedures [5]. Though initially and primarily used for procedures involving the biliary tree and pancreas, like Endoscopic Retrograde Cholangio Pancreatography (ERCP), sphincterotomies, papillotomies, and the drainage of pancreatic pseudocysts 9-17 , it has more recently gained acceptance in procedures involving virtually all other parts of the gastrointestinal tract 18-21 , as well as the urethra 22 . More recently still, its use to dissect the arachnoid membrane during microneurosurgery has been reported 23, 24.

However, reports of its use in orthopedic procedures are limited to a few brief papers published in Chinese language journals 25-27. For the purposes of potentially deriving both a safer and less-expensive alternative to traditional arthroscopy using a surgical scalpel, we designed an Arthroscopy Needle-Knife Surgical Device (ANKSD) and present our results comparing it to a traditional surgical blade in 99 consecutive knee arthroscopy procedures at a university hospital in Brazil [6]. The main objectives of this pilot study were (1) to see if there is any difference in the use of the ANKSD versus surgical blade in terms of the procedure itself and post-operative period; and (2) to identify potential advantages and disadvantages of using a needle knife [7].

MATERIALS AND METHODS

Before data collection commenced, the study protocol was approved by the university ethics board for research on human subjects, and all subjects provided their signed consent prior to being enrolled in the study [8]. Subjects were recruited over the 16 months from November 2010 through February 2012. To be eligible, an individual had to be at least 18 years of age and undergoing either unilateral or bilateral knee arthroscopy procedures for repair of either an anterior cruciate or medial meniscus tear. Patients were excluded if they had already known septic arthritis, inflammatory arthritis or any other systemic condition that would alter the arthroscopy procedure or impair wound healing [9]. Patients who underwent bilateral knee arthroscopies had each knee evaluated and analyzed separately. Instruments the initial ANKSD prototype was an 18-gauge, 1½ inch needle attached to a 10 cc syringe. As will be noted later in the Results section, after the first few cases, several problems were noted with this needle. It was too malleable, the bevel was small, the cutting area was small, and there was no handle or shield protective needle cover. Because of this, it was decided to upgrade in size to the same needle used as a catheter for peripheral intravenous therapy, which is 14-gauge x1.75 inches, for all further medial incisions. This needle was found to be easier to use and more accurate while performing the portal incision [10]. From this, the final ANKSD was designed with a 14-gauge by 1.75 inch needle that is elliptic and not rounded; this unique design has several advantages, particularly increased needle stiffness, bevel, and cutting surface area. With the attached syringe, it is possible to aspirate and inject while cutting [11]. For ease of handling, a handle was attached for gripping, and a protective needle cover was developed 28. The surgical blade used to create the lateral arthroscopy port was a disposable #11 blade attached to a disposable knife handles [12].

Arthroscopic procedure

Each arthroscopy procedure was performed by the same surgical team following usual surgical practices, except that our newly-designed ANSKD prototype (described above) was used exclusively for the lateral portal, whereas a standard surgical knife (also described above) was used for the medial portal, following the introduction of an 18-gauge needle to localize the joint space [13]. Patients were first placed under sedation and given spinal anesthesia. Esmarch and pneumatic tourniquets were used after an intravenous antibiotic infusion of 1.5 g cefuroxime. Aseptic and antiseptic technique was used, including chlorhexidine 4% and drape placement over the previously-marked knee, which was flexed to 100 degrees [14]. The lateral portal needle was inserted into the midpoint of the soft spot in the transverse line passing through the inferior pole of the patella. With an 18-gauge needle, the skin was severed longitudinally, an equidistant 0.5 cm above and below needle placement. The subcutaneous tissues and knee capsule then were incised using the 18-gauge needle by performing several small strokes. Once created, the incision was dilated using a small artery (mosquito) forceps in all directions. A 5 mm arthroscopic canula and trocar or obturator set then were introduced into the lateral portal and a normal saline infusion begun. For the medial port, an 18-gauge needle was introduced medially guided by video augmentation. After insertion into the joint space, the 18-gauge needle was removed and a number 11 cutting knife (disposable blade and handle) was used to sever the skin, subcutaneous tissues and capsule. As for the lateral port, the medial incision was dilated with a small artery (mosquito) forceps in all directions. Subsequent to this, the arthroscopic procedure was performed to address the patient's pathology using standard treatment. Ultimately, both portals were closed with number 4-0 mononylon mattress stitches, in accordance with Donati [15-17]. Opsite dressings with pads were used, followed by a simple bandage. All patients underwent standard post-operative follow-up in the Surgery clinic, at which time their arthroscopy port incisions were inspected by the attending surgeon for drainage and closure and, when appropriate, their sutures removed [18-21]. Statistical analysis: Since some patients underwent bilateral

arthroscopies and others underwent repeat arthroscopies over the 16 months of recruitment, rather than analyzing cases per subject, they were analyzed per procedure (i.e., per knee). Since this was a pilot study, analysis was limited to descriptive analysis (including means and standard deviations) and Pearson χ^2 analysis to compare the lateral and medial portals (ANKSD *vs*. standard knife) in terms of the percentage with discharge and percentage with total healing. More specifically, the two portals were compared statistically with respect to the following outcomes: (a) days to suture removal; (b) presence/absence of complete healing at the time of the final post-operative assessment in clinic; and (c) presence/absence of any discharge from either portal at any time during the course of follow-up. All quantitative analyses were performed in the statistical program SPSS version 20.0, with all inferential analyses two-tailed and $p<0.05$ set as the threshold for statistical significance [22-25]. Qualitatively, any issues with the ANKSD prototype were noted, and specifically if its use affected the ease or time of the arthroscopy procedure. For cost analysis, since the procedures were identical except for the use versus non-use of the #11 surgical blades, and all surgeons utilized needles to access the joint through both portals, the only difference in cost was the price of one surgical blade per procedure, which was determined by accessing the manufacturer's website order page.

RESULTS

Over the study recruitment period, a total of 99 knee arthroscopy procedures were performed following the study protocol, in 64 different patients. Six patients (12 knees) underwent bilateral procedures, and there were 23 repeat procedures [26]. The vast majority were simple arthroscopies for medial meniscal repair, versus 16 complex arthroscopies for anterior cruciate ligament repair. Of the 99 procedures, 56 were performed on females versus 43 in males. The mean age of subjects at the time of surgery was 42.0 years. Procedures were evenly split between the right and left knee (Table 1).

Table 1. Demographics and clinical characteristics of 99 knee arthroscopies.

Number of knees operated on	99
Number of different subjects	64
Number of bilateral arthroplasties	12
Number of repeat arthroplasties	23
Number of simple arthroscopies	83
Number of complex arthroscopies	16
Number of males (by procedure)	43
Number of females (by procedure)	56
Mean age (years)	42
Standard deviation	11.3
Minimum age	19
Maximum age	64
Number of right knees	50
Number of left knees	49

In all 99 cases, sutures were removed from the medial and lateral portal incisions on the same day, the mean time to suture removal being 7.3 days (range 5 to 13 days). Subjects were followed for an average of 8.2 days post-operatively (range 5 to 14 days), at which time all 99 medial portal incisions (standard knife) were completely healed versus 98 of 99 (99.0%) of lateral portal incisions (ANKSD, χ^2=1.005, p=0.316).Similarly, discharge was noted from no medial versus only one (1.0%) lateral portal incision (χ^2=1.005, p=0.316). No other complications were noted. After the first several cases, the only difficulties noted using the needle-knife that it was a bit too flexible, and that the bevel and cutting surfaces were so small that cutting was slightly tedious. For this reason, a decision was made to increase the needle size to 14-gauge x1.75 inch, thereby increasing its firmness and the bevel and cutting surface length, and thereby the ease of cutting [27]. From that point on, no further difficulties were noted. Of particular note was the increased ease of not having to withdraw the needle and replace it with a surgical blade, thereby seeming to reduce the duration of the procedure (though time was not formally measured). In terms of cost, one disposable knife set with a single handle and a #11 blade was found to cost $12.99 for the handle and roughly $0.27 US per blade when purchased in a box of 100 ($26.99 for the box), for a total unit cost of $13.26 US. Since needles and syringes already were used by all the surgeons, there was no additional cost of the needle-knife device (Table 2).

Table 2. Outcomes of 99 knee arthroscopies.

Number of knees operated on	99	
Days to suture removal		
Mean	7.3	
Standard deviation	1.2	
Minimum 5	5	
Maximum	13	
Days to final post-operative assessment		
Mean	8.2	
Standard deviation	1	
Minimum	5	
Maximum	14	
ANKSD with discharge 1.0% p	0.316	p=0.316
Standard blade with discharge 0.0%	0.00%	
ANKSD with total healing 99.0% p	0.316	P=0.316
Standard blade with total healing 100.0%	100.00%	

DISCUSSION

The concept of using a needle for fine cutting is not new the term needle-knife first appeared in the medical literature in 1952 29. However, it was not until the late 1980's and early 1990's that needle-knife techniques started to be adopted widely, and this was virtually always for procedures relating to the pancreas, in particular sphincterotomies and the resection of bile duct papillomas 14,30. More recently, though it continues to be used extensively for biliary tree related procedures like Endoscopic Retrograde Cholangiopancreatography (ERCP) 11 , pancreatic sphincterotomies 10,17 and biliary papillotomies 14,30,31, the range of gastrointestinal disorders for

which a needle-knife is used has expanded dramatically to include the release of oesophageal stenosis 18 , biopsy of gastrointestinal tumours virtually anywhere along the GI tract's length 19,21 and repair of leaking surgical anastomoses following resections of GI tract segments 20 [28]. In several instances, a needle-knife has been compared with traditional surgical blades in this setting and found to yield comparable if not enhanced results, at lower cost, and with no additional risk 12,15,17,21,25,30. In two recently-published papers, simple 18-gauge 24 and 25-gauge 23 needles have been used to cut through the arachnoid during micro-neurosurgical procedures, again with good results. In Mexico City, Nathal reported more than 350 cases in which an 18-gauge needle was used instead of a standard arachnoid knife, all without incident 24. In this setting, the disparity in cost between the non-disposal arachnoid knives, which are made from stainless steel, titanium, or diamond-tipped materials and, hence, very expensive, can be quite stark [29]. And, though such blades are labelled 'non-disposable', repeated use and repeated cleaning causes the blades to become dull, so they do need to be replaced on a frequent basis. In this setting, three advantages of using simple hypodermic needles for cutting are (1) that they are disposable by nature, and hence always maximally sharp; (2) their cost is minimal; and (3) they are readily available. The same can be said of arthroscopy procedures, especially in countries or other settings where the cost of thirteen plus dollars per procedure is not so insignificant, and where sterilization procedures may not be as reliable as in more technologically-advanced settings [30]. In our series, the only difference between 99 portals created with a simple needle and syringe and 99 created using a standard surgical knife was a single case of minimal drainage and delayed wound closure, which required a short course of antibiotics at home and prolonged total healing by roughly 6 days. In exchange, the cost savings over 99 procedures would have been roughly $1300.

We found, however, that using a larger bore needle (gauge 14 instead of 18½) was preferable because the thinner needle was overly flexible. Comparing the smaller and larger bore needle is akin to comparing Gigli wire bone saws *vs*. a pneumatic power oscillating bone saw, in that the latter required fewer strokes to create the right size incision [31].

CONCLUSION

This paper is the first published assessment of needle-knife use for an orthopaedic procedure outside the Chinese language literature. Our results are a clear indication that further research on this potentially-useful surgical alternative is warranted. Clearly, our study has limitations, including the lack of randomization; the use of both treatments on each knee (as opposed to patients receiving exclusively one approach or the other); the absence of long-term follow-up and outcomes like ultimate pain level and function; our failure to compare outcomes of interest like the actual procedural time needed for arthroscopy using the ANKSD versus standard knife, since operating room time is a sizeable, though often overlooked determinant of treatment cost; and a more detailed economic analysis that includes the cost of antibiotics and other medications with one approach versus the other.

Another advantage not yet mentioned of a needle over a blade is that the former can be mutli-purpose, not just cutting, but also available for the infusion of fluid into or aspiration of fluid out of the joint. In injured knees, both functions can be of value, as dried blood or other debris is rinsed away and then aspirated out of the joint to aid in visibility and facilitate repair.

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REFERENCES

1. Kim TK, et al. Neurovascularcomplications of knee arthroscopy. Am J Sports Med. 2012; 30:619-629.
2. Iliha OA, et al. Deep venous thrombosis after kneearthroscopy: a meta-analysis. Arthroscopy. 2005; 21:727-730.
3. Reigstad O, et al. Complications in knee arthroscopy. Knee Surg Sports Traumatol Arthrosc. 2006; 14:473-477.
4. Marmor S, et al. Joint infection after kneearthroscopy: medicolegal aspects. Orthop Traumatol Surg Res 2009;95:278-283.
5. Wind WM, et al. Infection following knee arthroscopy. Arthroscopy. 2001; 17:878-883.
6. Krivic A, et al. Lesion of thecommon peroneal nerve during arthroscopy. Arthroscopy. 2003;19: 1015-1018.
7. Hussein R, et al. Management of knee arthroscopy portals. Knee. 2001; 8:329-331.
8. Peicha G, et al. Transsection of the peroneal nerve complicating knee arthroscopy: casereport and cadaver study. Arthroscopy. 1998; 14:221-223.
9. Azar RR, et al. Wire-guided pancreatic pseudocyst drainage by using a modified needleknife and therapeutic echoendoscope. Gastrointest Endosc. 2006;63:688-692.
10. Buscaglia JM, et al. Pancreatic sphincterotomy: technique,indications, and complications. World J Gastroenterol 2007;13:4064-4071.
11. Gullichsen R, et al. Needle-knife assistedERCP. Surg Endosc. 2005; 19:1243-1245.
12. Katsinelos P, et al. Needle-knife papillotomy:a safe and effective technique in experienced hands. Hepatogastroenterology. 2004; 51:349-352.
13. Lim JU, et al. Early Use of Needle-Knife Fistulotomy IsSafe in Situations Where Difficult Biliary Cannulation Is Expected. Dig Dis Sci. 2012.
14. Rabenstein T, et al. Benefits andrisks of needle-knife papillotomy. Gastrointest Endosc. 1997;46:207-211.
15. Siegel JH, et al. The needle knife: a valuable tool indiagnostic and therapeutic ERCP. Gastrointest Endosc 1989; 35:499-503.
16. Tham TC, et al. Needle-knife sphincterotomy and post-ERCPpancreatitis: time to lower the threshold for the needle? Gastrointest Endosc. 2010; 71:272-274.
17. Varadarajulu S, et al. Randomized trial comparing needle-knifeand pull-sphincterotome techniques for pancreatic sphincterotomy in high-riskpatients. Gastrointest Endosc 2006; 64:716-722.
18. Canhoto M, et al. Needle-knife incisional treatment of refractory esophagic caustic stenosis. Endoscopy 2011; 43:UCTN:E386.
19. de la Serna-Higuera C, et al. EUS-guided single-incision needle-knife biopsy: description and results of a new method for tissue sampling of subepithelial GI tumors. Gastrointest Endosc 2011; 74:672-676.

20. Zhou JI, et al. Endoscopic Needle Knife Therapy for Anastomotic Leakage Following Anterior Resection for Rectal Cancer. Colorectal Dis. 2011.

21. Zhou PH, et al. Advantages of endoscopic sub mucosal dissection with needle-knife over endoscopic mucosal resection for small rectal carcinoid tumors: a retrospective study. Surg Endosc 2010; 24:2607-2612.

22. Fritsche HM, et al. Water-jet-aided transurethral dissection of urothelial carcinoma: a prospective clinical study. J Endourol2011; 25:1599-1603.

23. Leach PA, et al. A 25-gauge needle used as an arachnoid knife in micro neurosurgery. Br J Neurosurg 2004; 18:506.

24. Nathal E. Arachnoid knife from a hypodermic needle Technical note. Surg Neurol 2007; 68:541-543.

25. Lu D, et al. Small needle-knife for the treatment of heel pain according to its classification. Zhongguo GuShang 2010; 23:616-619.

26. Zeng GG, et al. Effects of needle knife relaxingtherapy on tension of local soft tissue and pain of osteoarthritis of knee. Zhongguo Zhen Jiu. 2008; 28:244-247.

27. Zhao XH, et al. Close lysis with needle knife for thetreatment of gluteus contracture. Zhongguo Gu Shang 2009; 22:517-518.

28. Arthroscopic Needle-Knife Surgical Device (ANKSD). 2011.

29. Ot'lan RG. Needle-knife in tissue therapy, preliminary communication. Vestn Oftalmol. 1952; 31:44.

30. Dowsett JF, et al. Needle knife papillotomy: howsafe and how effective? Gut. 1990; 31:905-908. [Crossref] [Pubmed]

31. Baillie J. Needle-knife papillotomy. Gastroenterol Hepatol (N Y) 2010;6:759-761.